Annex I

List of nationally authorised medicinal products

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Austria	Hexal Pharma Gmbh	Ranic	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Austria	Hexal Pharma Gmbh	Ranic	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
Austria	1a Pharma Gmbh	Ranitidin 1a Pharma	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
Austria	Accord Healthcare B.V.	Ranitidin Accord	Ranitidine Hydrochloride 167.5mg Tablet	Film-coated tablet	Oral use
Austria	Accord Healthcare B.V.	Ranitidin Accord	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use
Austria	Teva B.V	Ranitidin Ratiopharm	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Austria	Teva B.V	Ranitidin Ratiopharm	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
Austria	Stada Arzneimittel Gmbh	Ranitidin Stada	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Austria	Stada Arzneimittel Gmbh	Ranitidin Stada	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Austria	Gebro Pharma Gmbh	Ulsal	Ranitidine Hydrochloride 167.4mg Tablet	Effervescent tablet	Oral use
Austria	Gebro Pharma Gmbh	Ulsal	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Austria	Gebro Pharma Gmbh	Ulsal	Ranitidine Hydrochloride 334.8mg Tablet	Effervescent tablet	Oral use
Austria	Gebro Pharma Gmbh	Ulsal	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Austria	Gebro Pharma Gmbh	Ulsal	Ranitidine Hydrochloride 56mg/2ml	Concentrate for solution for injection/infusion	Intravenous use
Austria	Glaxosmithkline Pharma Gmbh.	Zantac	Ranitidine 150mg Tablet	Effervescent tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Austria	Glaxosmithkline Pharma Gmbh.	Zantac	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Austria	Glaxosmithkline Pharma Gmbh.	Zantac	Ranitidine 300mg Tablet	Effervescent tablet	Oral use
Austria	Glaxosmithkline Pharma Gmbh.	Zantac	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Belgium	Eurogenerics N.V./S.A.	Acidine	Ranitidine 75mg Tablet	Effervescent tablet	Oral use
Belgium	Eurogenerics N.V./S.A.	Acidine	Ranitidine 75mg Tablet	Oral solution	Oral use
Belgium	Eurogenerics N.V./S.A.	Ranitidine Eg	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Belgium	Eurogenerics N.V./S.A.	Ranitidine Eg	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Belgium	Eurogenerics N.V./S.A.	Ranitidine Eg	Ranitidine 300mg Tablet	Effervescent tablet	Oral use
Belgium	Eurogenerics N.V./S.A.	Ranitidine Eg	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Belgium	Mylan Bvba/Sprl	Ranitidine Mylan	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Belgium	Mylan Bvba/Sprl	Ranitidine Mylan	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Belgium	Sandoz N.V.	Ranitidine Sandoz	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Belgium	Sandoz N.V.	Ranitidine Sandoz	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Belgium	Glaxosmithkline Pharmaceuticals Sa	Zantac	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Belgium	Glaxosmithkline Pharmaceuticals Sa	Zantac	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Belgium	Glaxosmithkline Pharmaceuticals Sa	Zantac	Ranitidine 150mg/10ml	Syrup	Oral use
Belgium	Glaxosmithkline Pharmaceuticals Sa	Zantac	Ranitidine 300mg Tablet	Effervescent tablet	Oral use
Belgium	Glaxosmithkline Pharmaceuticals Sa	Zantac	Ranitidine 50mg/2ml	Solution for injection	Intramuscular use and intravenous use
Bulgaria	Accord Healthcare Polska Sp. Z O.O.	Ранитидин Акорд	Ranitidine Hydrochloride 167.5mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Bulgaria	Accord Healthcare Polska Sp. Z O.O.	Ранитидин Акорд	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use
Bulgaria	Sopharma Ad	Ранитидин Софарма	Ranitidine 50mg/2ml	Solution for injection	Intramuscular use and intravenous use
Bulgaria	Sopharma Ad	Ранитидин Софарма	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Bulgaria	Sopharma Ad	Ранитидин Софарма	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Bulgaria	Tchaikapharma High Quality Medicines, Inc.	Ранитидин Чайкафарма	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Croatia	Belupo D.D.	Gastrobel	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Croatia	Pliva Hrvatska D.O.O.	Peptoran	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
Croatia	Pliva Hrvatska D.O.O.	Peptoran	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Croatia	Pliva Hrvatska D.O.O.	Peptoran Max	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Croatia	Sandoz D.O.O.	Ranital	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Croatia	Sandoz D.O.O.	Ranital	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Croatia	Sandoz D.O.O.	Ranital S	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Croatia	Sandoz D.O.O.	Ranitidin Sandoz	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Croatia	Jadran-Galenski Laboratorij D.D.	Ranix	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Croatia	Jadran-Galenski Laboratorij D.D.	Ranix	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Croatia	Farmal Dd.	Rantin	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Cyprus	Medochemie Ltd.	Arnetin	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Cyprus	Medochemie Ltd.	Arnetin	Ranitidine 50mg/2ml	Solution for injection/infusion	Intramuscular use and intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Cyprus	Elpen Pharmaceutical Co. Inc.	Lumaren	Ranitidine 50mg/2ml	Solution for injection	Intramuscular use and intravenous use
Cyprus	Elpen Pharmaceutical Co. Inc.	Lumaren	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Cyprus	Remedica Ltd	Raniplex	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Cyprus	Codal Synto Ltd	Ranisynt	Ranitidine 50mg/2ml	Solution for injection/infusion	Intramuscular use and intravenous use
Cyprus	Accord Healthcare S.L.U.	Ranitidine Accord	Ranitidine Hydrochloride 167.5mg Tablet	Film-coated tablet	Oral use
Cyprus	Accord Healthcare S.L.U.	Ranitidine Accord	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use
Cyprus	Rafarm Sa.	Verlost	Ranitidine 30mg/ml	Oral solution	Oral use
Cyprus	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Cyprus	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine 150mg Tablet	Tablet	Oral use
Cyprus	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine Hydrochloride 56mg/2ml	Solution for injection	Intramuscular use and intravenous use
Czech Republic	Pro.Med.Cs Praha A.S.	Ranisan	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Czech Republic	Pro.Med.Cs Praha A.S.	Ranisan	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
Czech Republic	Lek Pharmaceuticals D.D. Ljubljana	Ranital	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Czech Republic	Lek Pharmaceuticals D.D. Ljubljana	Ranital	Ranitidine 50mg/2ml	Solution for injection	Intramuscular use and intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Czech Republic	Aurovitas Pharma Polska Sp. Z O.O	Ranitidine Aurovitas	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Denmark	Orifarm Generics A/S	Acikure	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Denmark	Orifarm Generics A/S	Acikure	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Denmark	Sandoz A/S	Kuracid	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Denmark	Sandoz A/S	Kuracid	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Denmark	Mylan Ab	Ranitidin ”mylan”	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Denmark	Mylan Ab	Ranitidin ”mylan”	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Denmark	Glaxosmithkline Pharma A/S	Zantac	Ranitidine 25mg/ml	Concentrate for solution for infusion	Intramuscular use and intravenous use
Estonia	Medochemie Ltd.	Arnetin	Ranitidine 25mg/ml	Solution for injection/infusion	Intramuscular use and intravenous use
Estonia	Berlin-Chemie Ag	Raniberl	Ranitidine Hydrochloride 167mg Tablet	Film-coated tablet	Oral use
Estonia	Berlin-Chemie Ag	Raniberl	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use
Estonia	Pro.Med.Cs Praha A.S.	Ranisan	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Estonia	Pro.Med.Cs Praha A.S.	Ranisan	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
Estonia	Accord Healthcare B.V.	Ranitidine Accord	Ranitidine Hydrochloride 167.5mg Tablet	Film-coated tablet	Oral use
Estonia	Accord Healthcare B.V.	Ranitidine Accord	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use
Estonia	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine 25mg/ml	Concentrate for solution for injection/infusion	Intramuscular use and intravenous use
Finland	Meda Otc Ab	Inside	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Finland	Meda Otc Ab	Inside Brus	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Finland	Sandoz A/S	Ranisan	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Finland	Mylan Ab	Ranitidin Mylan	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Finland	Ratiopharm Gmbh	Ranixal	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
Finland	Ratiopharm Gmbh	Ranixal	Ranitidine Hydrochloride 168mg Tablet	Effervescent tablet	Oral use
Finland	Ratiopharm Gmbh	Ranixal	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
Finland	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Finland	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine 15mg/ml	Oral solution	Oral use
Finland	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Finland	Laboratoire Glaxosmithkline	Zantac	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
France	Laboratoire Glaxosmithkline	Azantac	Ranitidine Hydrochloride 168mg Tablet	Effervescent tablet	Oral use
France	Laboratoire Glaxosmithkline	Azantac	Ranitidine Hydrochloride 336mg Tablet	Effervescent tablet	Oral use
France	Laboratoire Glaxosmithkline	Azantac	Ranitidine Hydrochloride 56mg Ampoule	Solution for injection	Intravenous use
France	Laboratoires Saint-Germain	Ranitidine	Ranitidine Hydrochloride 300mg Tablet	Effervescent tablet	Oral use
France	Accord Healthcare France Sas	Ranitidine Accord	Ranitidine Hydrochloride 167.5mg Tablet	Film-coated tablet	Oral use
France	Accord Healthcare France Sas	Ranitidine Accord	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
France	Arrow Generiques	Ranitidine Arrow	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
France	Arrow Generiques	Ranitidine Arrow	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
France	Arrow Generiques	Ranitidine Arrow	Ranitidine 300mg Tablet	Effervescent tablet	Oral use
France	Arrow Generiques	Ranitidine Arrow	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
France	Arrow Generiques	Ranitidine Arrow	Ranitidine Hydrochloride 83.7mg Tablet	Effervescent tablet	Oral use
France	Biogaran	Ranitidine Biogaran	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
France	Biogaran	Ranitidine Biogaran	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
France	Laboratoires Saint-Germain	Ranitidine Biogaran	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
France	Eg Labo Laboratoires Eurogenerics	Ranitidine Eg	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
France	Eg Labo Laboratoires Eurogenerics	Ranitidine Eg	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
France	Eg Labo Laboratoires Eurogenerics	Ranitidine Eg	Ranitidine 300mg Tablet	Effervescent tablet	Oral use
France	Eg Labo Laboratoires Eurogenerics	Ranitidine Eg	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
France	Mylan S.A.S	Ranitidine Mylan	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
France	Mylan S.A.S	Ranitidine Mylan	Ranitidine 300mg Tablet	Effervescent tablet	Oral use
France	Mylan S.A.S	Ranitidine Mylan	Ranitidine 75mg Tablet	Effervescent tablet	Oral use
France	Mylan S.A.S	Ranitidine Mylan	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
France	Mylan S.A.S	Ranitidine Mylan	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
France	Zentiva France	Ranitidine Zentiva	Ranitidine Hydrochloride 167.4mg Tablet	Effervescent tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
France	Zentiva France	Ranitidine Zentiva	Ranitidine Hydrochloride 334.8mg Tablet	Effervescent tablet	Oral use
Germany	Juta Pharma Gmbh	Junizac	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use
Germany	Betapharm Arzneimittel Gmbh	Ranibeta	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Germany	Betapharm Arzneimittel Gmbh	Ranibeta	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Germany	Mylan Germany Gmbh	Ranidura T	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Germany	Mylan Germany Gmbh	Ranidura T	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Germany	Hexal Ag	Ranitic	Ranitidine 50mg/5ml	Solution for injection	Intravenous use
Germany	Hexal Ag	Ranitic	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
Germany	Hexal Ag	Ranitic	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Germany	Hexal Ag	Ranitic	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
Germany	1 A Pharma Gmbh	Ranitidin 1 A Pharma	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Germany	1 A Pharma Gmbh	Ranitidin 1 A Pharma	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Germany	1 A Pharma Gmbh	Ranitidin 1 A Pharma	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
Germany	Abz-Pharma Gmbh	Ranitidin Abz	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Germany	Abz-Pharma Gmbh	Ranitidin Abz	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Germany	Aliud Pharma Gmbh	Ranitidin Al	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Germany	Aliud Pharma Gmbh	Ranitidin Al	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Germany	Axcount Generika Gmbh	Ranitidin Axcount	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Germany	Axcount Generika Gmbh	Ranitidin Axcount	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Germany	Basics Gmbh	Ranitidin Basics	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Germany	Basics Gmbh	Ranitidin Basics	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Germany	Ratiopharm Gmbh	Ranitidin Ratiopharm	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Germany	Ratiopharm Gmbh	Ranitidin Ratiopharm	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Germany	Ratiopharm Gmbh	Ranitidin Ratiopharm	Ranitidine 50mg/5ml	Solution for injection	Intravenous use
Germany	Ratiopharm Gmbh	Ranitidin Ratiopharm	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Germany	Ratiopharm Gmbh	Ranitidin Ratiopharm	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
Germany	Hexal Ag	Ranitidin Sandoz	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Germany	Stadapharm Gmbh	Ranitidin Stada	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Germany	Stadapharm Gmbh	Ranitidin Stada	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Germany	Glaxosmithkline Gmbh & Co. Kg	Zantic	Ranitidine Hydrochloride 168mg Tablet	Effervescent tablet	Oral use
Greece	Minerva Pharmaceutical S.A	Alphadine	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Greece	Heremco	Aova	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Greece	Medicus A.E	B-Alcerin	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Greece	Medicus A.E	B-Alcerin	Ranitidine Hydrochloride 27.9mg/ml	Solution for injection	Intramuscular use and intravenous use
Greece	Medicus A.E	B-Alcerin	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Greece	Vivax Pharmaceuticals Ltd	Baroxal	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Greece	Vivax Pharmaceuticals Ltd	Baroxal	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Greece	Norma Hellas S.A.	Bindazac	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Greece	Norma Hellas S.A.	Bindazac	Ranitidine 25mg/ml	Solution for injection	Intramuscular use and intravenous use
Greece	Demo Abee	Epadoren	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Greece	Demo Abee	Epadoren	Ranitidine Hydrochloride 28mg/2ml	Solution for injection	Intramuscular use and intravenous use
Greece	Demo Abee	Epadoren	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Greece	Demo Abee	Epadoren	Ranitidine Hydrochloride 83.5mg/5ml	Syrup	Oral use
Greece	Vita Longa Pc	Galebiron	Ranitidine 30mg/Ml	Oral solution	Oral use
Greece	Sja Pharm Ltd	Lomadryl	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Greece	Sja Pharm Ltd	Lomadryl	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Greece	Sja Pharm Ltd	Lomadryl	Ranitidine Hydrochloride 75mg/5ml	Syrup	Oral use
Greece	Elpen Pharmaceutical Co. Inc.	Lumaren	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Greece	Elpen Pharmaceutical Co. Inc.	Lumaren	Ranitidine 25mg/ml	Solution for injection	Intramuscular use and intravenous use
Greece	Elpen Pharmaceutical Co. Inc.	Lumaren	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Greece	Vocate Φαρμακευτικη Αε	Narigen	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Greece	Vocate Φαρμακευτικη Αε	Narigen	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
Greece	Anfarm Hellas Sa	Nipodur	Ranitidine Hydrochloride 167mg Tablet	Film-coated tablet	Oral use
Greece	Anfarm Hellas Sa	Nipodur	Ranitidine Hydrochloride 334mg Tablet	Film-coated tablet	Oral use
Greece	Help Abee	Ptinolin	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Greece	Help Abee	Ptinolin	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Greece	Help Abee	Ptinolin	Ranitidine Hydrochloride 55.8mg/2ml	Solution for injection	Intramuscular use and intravenous use
Greece	Rafarm Sa.	Rafitaz	Ranitidine 30mg/ml	Oral solution	Oral use
Greece	Kleva Pharmaceuticals	Ranitidine Kleva	Ranitidine Hydrochloride 27.9mg/ml	Solution for injection	Intramuscular use and intravenous use
Greece	Mylan S.A.S	Ranitidine Mylan	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Greece	Pherakon Pc	Sveltanet	Ranitidine Hydrochloride 167mg Tablet	Film-coated tablet	Oral use
Greece	Medical Pharmaquality Pharmaceuticals S.A.	Tupast	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
Greece	Medical Pharmaquality Pharmaceuticals S.A.	Tupast	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
Greece	Rafarm Sa.	Verlost	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Greece	Rafarm Sa.	Verlost	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Greece	Rafarm Sa.	Verlost	Ranitidine Hydrochloride 83.5mg/ml	Syrup	Oral use
Greece	Medochemie Hellas Sa	Yara	Ranitidine 50mg/2ml	Solution for injection	Intramuscular use and intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Greece	Medochemie Hellas Sa	Yara	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Greece	Medochemie Hellas Sa	Yara	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Greece	Medochemie Hellas Sa	Yara	Ranitidine Hydrochloride 83.7mg Tablet	Film-coated tablet	Oral use
Greece	Glaxosmithkline Aebe	Zantac	Ranitidine 25mg/ml	Solution for injection	Intravenous use
Greece	Glaxosmithkline Aebe	Zantac	Ranitidine Hydrochloride 168mg Tablet	Effervescent tablet	Oral use
Greece	Glaxosmithkline Aebe	Zantac	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Zoliden	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Zoliden	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Zoliden	Ranitidine 300mg Sachet	Effervescent granules	Oral use
Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Zoliden	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Zoliden	Ranitidine 75mg Tablet	Effervescent tablet	Oral use
Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Zoliden	Ranitidine 75mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Greece	Lyofin Ltd, Greece	Zurfix	Ranitidine Hydrochloride 167mg Tablet	Film-coated tablet	Oral use
Greece	Lyofin Ltd, Greece	Zurfix	Ranitidine Hydrochloride 334mg Tablet	Film-coated tablet	Oral use
Hungary	Hexal Ag	Ranitic	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Hungary	Hexal Ag	Ranitic	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Hungary	1 A Pharma Gmbh	Ranitidin 1 A Pharma	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Hungary	1 A Pharma Gmbh	Ranitidin 1 A Pharma	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Hungary	Teva Gyógyszergyár Zrt	Ranitidin Teva	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Hungary	Teva Gyógyszergyár Zrt	Ranitidin Teva	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Hungary	Accord Healthcare Polska Sp. Z O.O.	Ranitidine Accord	Ranitidine Hydrochloride 167.5mg Tablet	Film-coated tablet	Oral use
Hungary	Accord Healthcare Polska Sp. Z O.O.	Ranitidine Accord	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use
Hungary	Teva Gyógyszergyár Zrt	Ulceran	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Hungary	Teva Gyógyszergyár Zrt	Ulceran	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Hungary	Egis Pharmaceuticals Plc	Umaren	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Hungary	Egis Pharmaceuticals Plc	Umaren	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Hungary	Glaxosmithkline Kft.	Zantac	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Hungary	Glaxosmithkline Kft.	Zantac	Ranitidine 300mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Hungary	Glaxosmithkline Kft.	Zantac	Ranitidine Hydrochloride 28mg/ml	Solution for injection	Intramuscular use and intravenous use
Iceland	Teva B.V	Asýran	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Iceland	Teva B.V	Asýran	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Iceland	Glaxosmithkline Pharma A/S	Zantac	Ranitidine 15mg/ml	Oral solution	Oral use
Iceland	Glaxosmithkline Pharma A/S	Zantac	Ranitidine 25mg/ml	Solution for injection	Intramuscular use and intravenous use
Ireland	Mcdermott Laboratories Ltd	Gertac	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Ireland	Mcdermott Laboratories Ltd	Gertac	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
Ireland	Rowex Ltd	Ranitic	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Ireland	Rowex Ltd	Ranitic	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Ireland	Rowex Ltd	Ranitic	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
Ireland	Accord Healthcare Ireland Limited	Ranitidine Accord	Ranitidine Hydrochloride 167.5mg Tablet	Film-coated tablet	Oral use
Ireland	Accord Healthcare Ireland Limited	Ranitidine Accord Healthcare	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use
Ireland	Accord Healthcare Limited	Ranitidine Accord Healthcare	Ranitidine Hydrochloride 168mg Tablet	Effervescent tablet	Oral use
Ireland	Accord Healthcare Limited	Ranitidine Accord Healthcare	Ranitidine Hydrochloride 335mg Tablet	Effervescent tablet	Oral use
Ireland	Alliance Pharma (Ireland) Limited	Ranitidine Alliance Pharma (Ireland)	Ranitidine 50mg/2ml	Solution for injection/infusion	Intramuscular use and intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Ireland	Rosemont Pharmaceuticals Limited	Ranitidine Rosemont Pharmaceuticals	Ranitidine Hydrochloride 83.75mg/5ml	Oral solution	Oral use
Ireland	Pinewood Laboratories Limited	Ranopine	Ranitidine 150mg Tablet	Tablet	Oral use
Ireland	Pinewood Laboratories Limited	Ranopine	Ranitidine 300mg Tablet	Tablet	Oral use
Ireland	Chefaro Ireland Limited	Zantac	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
Ireland	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Ireland	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Ireland	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine 150mg/10ml	Syrup	Oral use
Ireland	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine 25mg/ml	Solution for injection/infusion	Intramuscular use and intravenous use
Ireland	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Ireland	Chefaro Ireland Limited	Zantac Dissolve	Ranitidine 75mg Tablet	Effervescent tablet	Oral use
Italy	Farmakopea Spa	Gipsy	Ranitidine Hydrochloride 167.4mg Tablet	Effervescent tablet	Oral use
Italy	Farmakopea Spa	Gipsy	Ranitidine Hydrochloride 334.8mg Tablet	Effervescent tablet	Oral use
Italy	Farmakopea Spa	Isaprandil Antiacido	Ranitidine Hydrochloride 83.7mg Tablet	Effervescent tablet	Oral use
Italy	Fabbrica Italiana Ritrovati Medicinali Ed Affini F.I.R.M.A. - S.P.A.	Raniben	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Italy	Fabbrica Italiana Ritrovati Medicinali Ed Affini F.I.R.M.A. - S.P.A.	Raniben	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
Italy	I.B.N. Savio S.R.L.	Ranibloc	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
Italy	I.B.N. Savio S.R.L.	Ranibloc	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Italy	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Ranidil	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
Italy	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Ranidil	Ranitidine Hydrochloride 167.4mg Tablet	Effervescent tablet	Oral use
Italy	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Ranidil	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
Italy	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Ranidil	Ranitidine Hydrochloride 168mg/10ml	Syrup	Oral use
Italy	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Ranidil	Ranitidine Hydrochloride 334.8mg Tablet	Effervescent tablet	Oral use
Italy	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Ranidil	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
Italy	A. Menarini - Industrie Farmaceutiche Riunite - S.R.L.	Ranidil	Ranitidine Hydrochloride 55.8mg Ampoule	Solution for injection	Intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Italy	Abc Farmaceutici S.P.A.	Ranitidina Abc	Ranitidine Hydrochloride 170mg Tablet	Film-coated tablet	Oral use
Italy	Abc Farmaceutici S.P.A.	Ranitidina Abc	Ranitidine Hydrochloride 340mg Tablet	Film-coated tablet	Oral use
Italy	Almus S.R.L	Ranitidina Almus	Ranitidine Hydrochloride 170mg Tablet	Film-coated tablet	Oral use
Italy	Almus S.R.L	Ranitidina Almus	Ranitidine Hydrochloride 340mg Tablet	Film-coated tablet	Oral use
Italy	Laboratori Alter S.R.L.	Ranitidina Alter	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Italy	Laboratori Alter S.R.L.	Ranitidina Alter	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
Italy	Aurobindo Pharma (Italia) S.R.L.	Ranitidina Aurobindo	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Italy	Aurobindo Pharma (Italia) S.R.L.	Ranitidina Aurobindo	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Italy	Aurobindo Pharma (Italia) S.R.L.	Ranitidina Aurobindo Italia	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Italy	Aurobindo Pharma (Italia) S.R.L.	Ranitidina Aurobindo Italia	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Italy	Doc Generici S.R.L.	Ranitidina Doc Generici	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
Italy	Doc Generici S.R.L.	Ranitidina Doc Generici	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
Italy	Doc Generici S.R.L.	Ranitidina Doc Generici	Ranitidine Hydrochloride 75mg Tablet	Film-coated tablet	Oral use
Italy	Eg S.P.A.	Ranitidina Eg	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Italy	Eg S.P.A.	Ranitidina Eg	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Italy	Germed Pharma S.R.L.	Ranitidina Germed	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Italy	Germed Pharma S.R.L.	Ranitidina Germed	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
Italy	Germed Pharma S.R.L.	Ranitidina Germed	Ranitidine Hydrochloride 83.7mg Tablet	Film-coated tablet	Oral use
Italy	Sandoz S.P.A.	Ranitidina Hexal	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Italy	Sandoz S.P.A.	Ranitidina Hexal	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
Italy	Sandoz S.P.A.	Ranitidina Hexal	Ranitidine Hydrochloride 56mg Vial	Solution for injection	Intravenous use
Italy	Mylan S.P.A.	Ranitidina Mylan Generics	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Italy	Mylan S.P.A.	Ranitidina Mylan Generics	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Italy	Pensa Pharma S.P.A.	Ranitidina Pensa	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
Italy	Pensa Pharma S.P.A.	Ranitidina Pensa	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
Italy	Ranbaxy Italia S.P.A.	Ranitidina Ranbaxy Italia	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Italy	Ranbaxy Italia S.P.A.	Ranitidina Ranbaxy Italia	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Italy	Ratiopharm Gmbh	Ranitidina Ratiopharm	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Italy	Ratiopharm Gmbh	Ranitidina Ratiopharm	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Italy	S.A.L.F. Spa Laboratorio Farmacologico	Ranitidina S.A.L.F.	Ranitidine Hydrochloride 55.8mg Vial	Solution for infusion	Intravenous use
Italy	Tecnigen S.R.L.	Ranitidina Tecnigen	Ranitidine Hydrochloride 170mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Italy	Tecnigen S.R.L.	Ranitidina Tecnigen	Ranitidine Hydrochloride 340mg Tablet	Film-coated tablet	Oral use
Italy	Zentiva Italia Srl	Ranitidina Zentiva	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
Italy	Zentiva Italia Srl	Ranitidina Zentiva	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
Italy	Laboratori Guidotti S.P.A.	Ulcex	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
Italy	Laboratori Guidotti S.P.A.	Ulcex	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
Italy	Glaxosmithkline S.P.A.	Zantac	Ranitidine 150mg/10ml	Syrup	Oral use
Italy	Glaxosmithkline S.P.A.	Zantac	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Italy	Glaxosmithkline S.P.A.	Zantac	Ranitidine 50mg Vial	Solution for injection	Intravenous use
Italy	Glaxosmithkline S.P.A.	Zantac	Ranitidine Hydrochloride 167.4mg Tablet	Effervescent tablet	Oral use
Italy	Glaxosmithkline S.P.A.	Zantac	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
Latvia	Sia Unifarma	Aciloc	Ranitidine Hydrochloride 27.9mg/ml	Solution for injection	Intramuscular use and intravenous use
Latvia	Berlin-Chemie Ag	Raniberl	Ranitidine Hydrochloride 167mg Tablet	Film-coated tablet	Oral use
Latvia	Zaklady Farmaceutyczne "polpharma" Spolka Akcyjna	Ranigast	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Latvia	Zaklady Farmaceutyczne "polpharma" Spolka Akcyjna	Ranigast	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Latvia	Pro.Med.Cs Praha A.S.	Ranisan	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Latvia	Jsc Olainfarm	Ranitidin Olainfarm	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Latvia	Accord Healthcare B.V.	Ranitidine Accord	Ranitidine Hydrochloride 167.5mg Tablet	Film-coated tablet	Oral use
Latvia	Accord Healthcare B.V.	Ranitidine Accord	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use
Latvia	Sia Unifarma	Ultak	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Latvia	Sia Unifarma	Ultak	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Lithuania	Sun Pharmaceutical Industries Europe B.V.	Mediran	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Lithuania	Berlin-Chemie Ag	Raniberl	Ranitidine Hydrochloride 167mg Tablet	Film-coated tablet	Oral use
Lithuania	Zaklady Farmaceutyczne "polpharma" Spolka Akcyjna	Ranigast	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Lithuania	Zaklady Farmaceutyczne "polpharma" Spolka Akcyjna	Ranigast	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
Lithuania	Pro.Med.Cs Praha A.S.	Ranisan	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Lithuania	Pharmaswiss Česká Republika S.R.O.	Ranitidinas Sanitas	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Lithuania	Accord Healthcare B.V.	Ranitidine Accord	Ranitidine Hydrochloride 167.5mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Lithuania	Accord Healthcare B.V.	Ranitidine Accord	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use
Lithuania	Ibe Pharma	Ranitidine Siromed	Ranitidine Hydrochloride 167mg Tablet	Film-coated tablet	Oral use
Lithuania	Uab Polta	Ranitin	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Lithuania	Uab Polta	Ranitin	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Luxembourg	Eurogenerics N.V./S.A.	Acidine	Ranitidine 75mg Tablet	Effervescent tablet	Oral use
Luxembourg	Hexal Ag	Ranitic	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Luxembourg	Hexal Ag	Ranitic	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Luxembourg	Eurogenerics N.V./S.A.	Ranitidine Eg	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Luxembourg	Eurogenerics N.V./S.A.	Ranitidine Eg	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Luxembourg	Eurogenerics N.V./S.A.	Ranitidine Eg	Ranitidine 300mg Tablet	Effervescent tablet	Oral use
Luxembourg	Eurogenerics N.V./S.A.	Ranitidine Eg	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Luxembourg	Generics [uk] Limited	Ranitidine Mylan	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Luxembourg	Generics [uk] Limited	Ranitidine Mylan	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Luxembourg	Glaxosmithkline Pharmaceuticals Sa	Zantac	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Luxembourg	Glaxosmithkline Pharmaceuticals Sa	Zantac	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Luxembourg	Glaxosmithkline Pharmaceuticals Sa	Zantac	Ranitidine 150mg/10ml	Syrup	Oral use
Luxembourg	Glaxosmithkline Pharmaceuticals Sa	Zantac	Ranitidine 300mg Tablet	Effervescent tablet	Oral use
Luxembourg	Glaxosmithkline Pharmaceuticals Sa	Zantac	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Luxembourg	Glaxosmithkline Pharmaceuticals Sa	Zantac	Ranitidine 50mg/2ml	Solution for injection	Intramuscular use and intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Malta	Actavis Group Ptc Ehf.	Asyran	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Malta	Accord Healthcare Ireland Limited	Ranitidine Accord	Ranitidine Hydrochloride 167.5mg Tablet	Film-coated tablet	Oral use
Malta	Accord Healthcare Ireland Limited	Ranitidine Accord	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use
Malta	Syri Pharma Limited	Ranitidine Syri Pharma	Ranitidine 150mg/10ml	Oral solution	Oral use
Malta	Chefaro Ireland Limited	Zantac	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
Malta	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine 150mg Tablet	Tablet	Oral use
Malta	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine 25mg/ml	Solution for injection/infusion	Intramuscular use and intravenous use
Netherlands	Accord Healthcare B.V.	Ranitidine Accord	Ranitidine Hydrochloride 150mg Tablet	Effervescent tablet	Oral use
Netherlands	Accord Healthcare B.V.	Ranitidine Accord	Ranitidine Hydrochloride 167.5mg Tablet	Film-coated tablet	Oral use
Netherlands	Accord Healthcare B.V.	Ranitidine Accord	Ranitidine Hydrochloride 300mg Tablet	Effervescent tablet	Oral use
Netherlands	Accord Healthcare B.V.	Ranitidine Accord	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use
Netherlands	Apotex Europe B.V.	Ranitidine Apotex	Ranitidine Hydrochloride 167.4mg Tablet	Coated tablet	Oral use
Netherlands	Apotex Europe B.V.	Ranitidine Apotex	Ranitidine Hydrochloride 83.7mg Tablet	Coated tablet	Oral use
Netherlands	Leidapharm B.V.	Ranitidine Apotex	Ranitidine Hydrochloride 75mg Tablet	Coated tablet	Oral use
Netherlands	Marel B.V.	Ranitidine Apotex	Ranitidine 75mg Tablet	Coated tablet	Oral use
Netherlands	Marel B.V.	Ranitidine Apotex	Ranitidine Hydrochloride 75mg Tablet	Coated tablet	Oral use
Netherlands	Aurobindo Pharma B.V.	Ranitidine Aurobindo	Ranitidine 150mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Netherlands	Aurobindo Pharma B.V.	Ranitidine Aurobindo	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Netherlands	Ratiopharm Gmbh	Ranitidine Bruis Ratiopharm	Ranitidine Hydrochloride 168mg Tablet	Effervescent tablet	Oral use
Netherlands	Ratiopharm Gmbh	Ranitidine Bruis Ratiopharm	Ranitidine Hydrochloride 336mg Tablet	Effervescent tablet	Oral use
Netherlands	Genrx B.V.	Ranitidine Genrx	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Netherlands	Genrx B.V.	Ranitidine Genrx	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Netherlands	Genrx B.V.	Ranitidine Genrx	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
Netherlands	Aurobindo Pharma B.V.	Ranitidine Hydrochloride Aurobindo	Ranitidine Hydrochloride 168mg Tablet, Ranitidine 150mg Tablet, Lactose 416mg Tablet, Sodium 120mg Tablet	Effervescent tablet	Oral use
Netherlands	Aurobindo Pharma B.V.	Ranitidine Hydrochloride Aurobindo	Ranitidine Hydrochloride 336mg Tablet, Ranitidine 300mg Tablet, Lactose 832mg Tablet, Sodium 240mg Tablet	Effervescent tablet	Oral use
Netherlands	Mylan B.V.	Ranitidine Mylan	Ranitidine 150mg Tablet	Tablet	Oral use
Netherlands	Mylan B.V.	Ranitidine Mylan	Ranitidine 300mg Tablet	Tablet	Oral use
Netherlands	Sandoz B.V.	Ranitidine Sandoz	Ranitidine 168mg Tablet	Effervescent tablet	Oral use
Netherlands	Sandoz B.V.	Ranitidine Sandoz	Ranitidine 336mg Tablet	Effervescent tablet	Oral use
Netherlands	Sandoz B.V.	Ranitidine Sandoz	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Netherlands	Sandoz B.V.	Ranitidine Sandoz	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
Netherlands	Teva B.V	Ranitidine Teva	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Netherlands	Teva B.V	Ranitidine Teva	Ranitidine Hydrochloride 300mg Tablet	Coated tablet	Oral use
Netherlands	Glaxosmithkline B.V.	Zantac	Ranitidine 150mg Tablet	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Netherlands	Glaxosmithkline B.V.	Zantac	Ranitidine 25mg/ml	Solution for injection	Intramuscular use and intravenous use
Netherlands	Omega Pharma Nederland B.V.	Zantac	Ranitidine 75mg Tablet	Coated tablet	Oral use
Norway	Ratiopharm Gmbh	Ranitidin Ratiopharm	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Norway	Ratiopharm Gmbh	Ranitidin Ratiopharm	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Norway	Ratiopharm Gmbh	Ranitidin Ratiopharm	Ranitidine Hydrochloride 83.75mg Tablet	Film-coated tablet	Oral use
Norway	Glaxosmithkline As	Zantac	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Norway	Glaxosmithkline As	Zantac	Ranitidine 150mg Tablet	Tablet	Oral use
Norway	Glaxosmithkline As	Zantac	Ranitidine 25mg/ml	Solution for injection	Intramuscular use and intravenous use
Norway	Glaxosmithkline As	Zantac	Ranitidine 300mg Tablet	Effervescent tablet	Oral use
Norway	Glaxosmithkline As	Zantac	Ranitidine 75mg Tablet	Effervescent tablet	Oral use
Norway	Glaxosmithkline As	Zantac	Ranitidine 75mg Tablet	Tablet	Oral use
Poland	Np Pharma Sp. Z O.O.	Gastranin Zdrovit	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Poland	Berlin-Chemie Ag	Raniberl Max	Ranitidine Hydrochloride 167mg Tablet	Film-coated tablet	Oral use
Poland	Sandoz Gmbh	Ranic	Ranitidine Hydrochloride 50mg/5ml	Solution for injection	Intravenous use
Poland	Zaklady Farmaceutyczne "polpharma" Spolka Akcyjna	Ranigast	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Poland	Zaklady Farmaceutyczne "polpharma" Spolka Akcyjna	Ranigast	Ranitidine Hydrochloride 56mg/100ml	Solution for infusion	Intravenous use
Poland	Zaklady Farmaceutyczne "polpharma" Spolka Akcyjna	Ranigast Fast	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Poland	Zaklady Farmaceutyczne "polpharma" Spolka Akcyjna	Ranigast Max	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Poland	Zaklady Farmaceutyczne "polpharma" Spolka Akcyjna	Ranigast Pro	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
Poland	Teva Pharmaceuticals Polska Sp. Z O.O.	Ranimax	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Poland	Pro.Med.Cs Praha A.S.	Ranisan	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Poland	Pro.Med.Cs Praha A.S.	Ranisan	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
Poland	Aurovitas Pharma Polska Sp. Z O.O	Ranitydyna Aurovitas	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Poland	Polfarmex S.A.	Riflux	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Poland	Polfarmex S.A.	Riflux	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Poland	Pharmaswiss Česká Republika S.R.O.	Solvertyl	Ranitidine 25mg/ml	Solution for injection	Intramuscular use and intravenous use
Poland	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Poland	Glaxosmithkline (Ireland) Limited	Zantac	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Portugal	Labesfal Laboratorios Almiro, S.A.	Bloculcer	Ranitidine Hydrochloride 0.56mg/ml	Solution for injection	Intravenous use
Portugal	Labesfal Laboratorios Almiro, S.A.	Bloculcer	Ranitidine Hydrochloride 1.12mg/ml	Solution for injection	Intravenous use
Portugal	Labesfal Laboratorios Almiro, S.A.	Bloculcer	Ranitidine Hydrochloride 167.4mg Tablet	Coated tablet	Oral use
Portugal	Labesfal Laboratorios Almiro, S.A.	Bloculcer	Ranitidine Hydrochloride 334.8mg Tablet	Coated tablet	Oral use
Portugal	Labesfal Laboratorios Almiro, S.A.	Bloculcer	Ranitidine Hydrochloride 55.8mg/2ml	Solution for injection	Intramuscular use and intravenous use
Portugal	Labesfal Laboratorios Almiro, S.A.	Bloculcer	Ranitidine Hydrochloride 55.8mg/50ml	Solution for injection	Intravenous use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A.	Pep-Rani	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A.	Pep-Rani	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
Portugal	Laboratório Medinfar - Produtos Farmacêuticos, S.A.	Pep-Rani	Ranitidine Hydrochloride 56mg/2ml	Solution for injection	Intramuscular use and intravenous use
Portugal	Almus, Lda	Ranitidina Almus	Ranitidine 150mg Tablet	Coated tablet	Oral use
Portugal	Almus, Lda	Ranitidina Almus	Ranitidine 300mg Tablet	Coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.	Ranitidina Aurovitas	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.	Ranitidina Aurovitas	Ranitidine 300mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Portugal	Bluepharma Genéricos - Comércio De Medicamentos, S.A.	Ranitidina Bluepharma	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Portugal	Bluepharma Genéricos - Comércio De Medicamentos, S.A.	Ranitidina Bluepharma	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Portugal	Cinfa Portugal, Lda.	Ranitidina Cinfa	Ranitidine 150mg Tablet	Coated tablet	Oral use
Portugal	Cinfa Portugal, Lda.	Ranitidina Cinfa	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Portugal	Cinfa Portugal, Lda.	Ranitidina Cinfa	Ranitidine 300mg Tablet	Coated tablet	Oral use
Portugal	Farmoz - Sociedade Técnico Medicinal, S.A.	Ranitidina Farmoz	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Portugal	Farmoz - Sociedade Técnico Medicinal, S.A.	Ranitidina Farmoz	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.	Ranitidina Generis	Ranitidine 150mg Tablet	Coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.	Ranitidina Generis	Ranitidine 300mg Tablet	Coated tablet	Oral use
Portugal	Hikma Farmacêutica (Portugal), S.A.	Ranitidina Hikma	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
Portugal	Hikma Farmacêutica (Portugal), S.A.	Ranitidina Hikma	Ranitidine Hydrochloride 25mg/ml	Solution for injection	Intramuscular use and intravenous use
Portugal	Hikma Farmacêutica (Portugal), S.A.	Ranitidina Hikma	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.	Ranitidina Labesfal	Ranitidine Hydrochloride 167.4mg Tablet	Coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.	Ranitidina Labesfal	Ranitidine Hydrochloride 334.8mg Tablet	Coated tablet	Oral use
Portugal	Mylan, Lda	Ranitidina Mylan	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Portugal	Mylan, Lda	Ranitidina Mylan	Ranitidine 300mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Portugal	Ratiopharm Lda	Ranitidina Ratiopharm	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Portugal	Ratiopharm Lda	Ranitidina Ratiopharm	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Portugal	Sandoz Farmacêutica Lda.	Ranitidina Sandoz	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Portugal	Sandoz Farmacêutica Lda.	Ranitidina Sandoz	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A.	Ranitine	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A.	Ranitine	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Portugal	Laboratórios Azevedos - Indústria Farmacêutica, S.A.	Ranitine	Ranitidine Hydrochloride 334mg Tablet	Film-coated tablet	Oral use
Portugal	Laboratórios Atral, S.A.	Stacer	Ranitidine 150mg Tablet	Coated tablet	Oral use
Portugal	Laboratórios Atral, S.A.	Stacer	Ranitidine 300mg Tablet	Coated tablet	Oral use
Portugal	Laboratórios Atral, S.A.	Stacer	Ranitidine 50mg/2ml	Solution for injection	Intramuscular use and intravenous use
Portugal	Glaxosmithkline - Produtos Farmaceuticos, Lda	Zantac	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Portugal	Glaxosmithkline - Produtos Farmaceuticos, Lda	Zantac	Ranitidine 25mg/ml	Solution for injection	Intramuscular use and intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Portugal	Glaxosmithkline - Produtos Farmaceuticos, Lda	Zantac	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Romania	Medochemie Ltd.	Arnetin	Ranitidine 50mg Vial	Solution for injection	Intramuscular use and intravenous use
Romania	Arena Group S.A	N-Ranitidin	Ranitidine Hydrochloride 167.5mg Tablet	Film-coated tablet	Oral use
Romania	Arena Group S.A	Ranitidin Arena	Ranitidine Hydrochloride 168mg Tablet	Tablet	Oral use
Romania	Laropharm Srl	Ranitidina Laropharm	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Romania	Magistra C&c	Ranitidina Magistra	Ranitidine Hydrochloride 168mg Tablet	Tablet	Oral use
Romania	Arena Group S.A	Ranitidină Arena	Ranitidine Hydrochloride 336mg Capsule	Capsule, hard	Oral use
Romania	Arena Group S.A	Ranitidină Arena	Ranitidine Hydrochloride 84mg Capsule	Capsule, hard	Oral use
Romania	Antibiotice Sa	Ranitidină Atb	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Romania	Labormed Pharma S.A.	Ranitidină Lph	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Romania	Slavia Pharm Srl	Ranitidină Slavia	Ranitidine Hydrochloride 150mg Tablet	Tablet	Oral use
Slovakia	Medochemie Ltd.	Arnetin	Ranitidine Hydrochloride 56mg/2ml	Solution for injection	Intramuscular use and intravenous use
Slovakia	Pro.Med.Cs Praha A.S.	Ranisan	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Slovakia	Pro.Med.Cs Praha A.S.	Ranisan	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Slovakia	Sandoz Pharmaceuticals D.D.	Ranital	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Slovakia	Sandoz Pharmaceuticals D.D.	Ranital	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Slovakia	Sandoz Pharmaceuticals D.D.	Ranital	Ranitidine 50mg/2ml	Solution for injection	Intramuscular use and intravenous use
Slovakia	Accord Healthcare Polska Sp. Z O.O.	Ranitidine Accord	Ranitidine Hydrochloride 167.5mg Tablet	Film-coated tablet	Oral use
Slovakia	Accord Healthcare Polska Sp. Z O.O.	Ranitidine Accord	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use
Slovenia	Lek Pharmaceuticals D.D. Ljubljana	Ranital	Ranitidine Hydrochloride 10mg/ml	Solution for injection	Intramuscular use and intravenous use
Slovenia	Lek Pharmaceuticals D.D. Ljubljana	Ranital	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
Slovenia	Lek Pharmaceuticals D.D. Ljubljana	Ranital	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
Slovenia	Lek Pharmaceuticals D.D. Ljubljana	Ranital S	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
Slovenia	Accord Healthcare Polska Sp. Z O.O.	Ranitidin Accord	Ranitidine Hydrochloride 167.5mg Tablet	Film-coated tablet	Oral use
Slovenia	Accord Healthcare Polska Sp. Z O.O.	Ranitidin Accord	Ranitidine Hydrochloride 335mg Tablet	Film-coated tablet	Oral use
Spain	Smithkline Beecham Farma, S.A.	Alquén	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Spain	Laboratorios Cinfa, S.A.	Ardoral	Ranitidine 75mg Tablet	Coated tablet	Oral use
Spain	Laboratorios Alter, S.A.	Ranitidina Alter	Ranitidine Hydrochloride 150mg Tablet	Tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Spain	Laboratorios Alter, S.A.	Ranitidina Alter	Ranitidine Hydrochloride 300mg Tablet	Tablet	Oral use
Spain	Apotex España, S.L.	Ranitidina Apotex Europe B.V.	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Spain	Apotex España, S.L.	Ranitidina Apotex Europe B.V.	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
Spain	Arafarma Group, S.A	Ranitidina Arafarma Group	Ranitidine Hydrochloride 150mg Tablet	Coated tablet	Oral use
Spain	Arafarma Group, S.A	Ranitidina Arafarma Group	Ranitidine Hydrochloride 300mg Tablet	Coated tablet	Oral use
Spain	Aristo Pharma Iberia, S.L.	Ranitidina Aristo	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Spain	Aristo Pharma Iberia, S.L.	Ranitidina Aristo	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
Spain	Aurovitas Spain,s.A.U.	Ranitidina Aurovitas	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Spain	Aurovitas Spain,s.A.U.	Ranitidina Aurovitas	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Spain	Laboratorios Cinfa, S.A.	Ranitidina Cinfa	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Spain	Laboratorios Cinfa, S.A.	Ranitidina Cinfa	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Spain	Laboratorios Francisco Durbán S.A.	Ranitidina Durbán	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Spain	Laboratorios Francisco Durbán S.A.	Ranitidina Durbán	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Spain	Kern Pharma, S.L.	Ranitidina Kern Pharma	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
Spain	Kern Pharma, S.L.	Ranitidina Kern Pharma	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
Spain	Mabo-Farma, S.A	Ranitidina Mabo	Ranitidine 150mg Tablet	Coated tablet	Oral use
Spain	Mabo-Farma, S.A	Ranitidina Mabo	Ranitidine 300mg Tablet	Coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Spain	Mylan Pharmaceuticals S.L.	Ranitidina Mylan	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Spain	Mylan Pharmaceuticals S.L.	Ranitidina Mylan	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Spain	Laboratorios Normon, S.A.	Ranitidina Normon	Ranitidine Hydrochloride 10mg/ml	Solution for injection	Intramuscular use and intravenous use
Spain	Laboratorios Normon, S.A.	Ranitidina Normon	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Spain	Laboratorios Normon, S.A.	Ranitidina Normon	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
Spain	Pensa Pharma, S.A.U.	Ranitidina Pensa	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Spain	Pensa Pharma, S.A.U.	Ranitidina Pensa	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
Spain	Ratiopharm España S.A.,	Ranitidina Ratio	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Spain	Ratiopharm España S.A.,	Ranitidina Ratio	Ranitidine Hydrochloride 300mg Tablet	Film-coated tablet	Oral use
Spain	Sandoz Farmacéutica, S.A.	Ranitidina Sandoz	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Spain	Sandoz Farmacéutica, S.A.	Ranitidina Sandoz	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Spain	Tarbis Farma, S.L.	Ranitidina Tarbis	Ranitidine 150mg Tablet	Coated tablet	Oral use
Spain	Tarbis Farma, S.L.	Ranitidina Tarbis	Ranitidine 300mg Tablet	Coated tablet	Oral use
Spain	Teva Pharma S.L.U.,	Ranitidina Teva	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Spain	Teva Pharma S.L.U.,	Ranitidina Teva	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Spain	Industria Química Y Farmaceútica Vir, S.A.	Ranitidina Vir	Ranitidine Hydrochloride 150mg Tablet	Coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Spain	Industria Química Y Farmaceútica Vir, S.A.	Ranitidina Vir	Ranitidine Hydrochloride 300mg Tablet	Coated tablet	Oral use
Spain	Industria Química Y Farmaceútica Vir, S.A.	Terposen	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Spain	Industria Química Y Farmaceútica Vir, S.A.	Terposen	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Spain	Neuraxpharm Spain, S.L.U.	Toriol	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Spain	Neuraxpharm Spain, S.L.U.	Toriol	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Spain	Glaxosmithkline S.A.	Zantac	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Spain	Glaxosmithkline S.A.	Zantac	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Spain	Glaxosmithkline, S.A.	Zantac	Ranitidine 10mg/ml	Solution for injection	Intramuscular use and intravenous use
Sweden	Meda Otc Ab	Inside	Ranitidine Hydrochloride 150mg Tablet	Film-coated tablet	Oral use
Sweden	Meda Otc Ab	Inside Brus	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Sweden	Mylan Ab	Rani-Q	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Sweden	Evolan Pharma Ab	Ranitidin Abece	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Sweden	Apofri Ab	Ranitidin Apofri	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Sweden	Apofri Ab	Ranitidin Apofri	Ranitidine Hydrochloride 168mg Tablet	Effervescent tablet	Oral use
Sweden	Mylan Ab	Ranitidin Mylan	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Sweden	Mylan Ab	Ranitidin Mylan	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Sweden	Sandoz A/S	Ranitidin Sandoz	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
Sweden	Sandoz A/S	Ranitidin Sandoz	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
Sweden	Sandoz Gmbh	Ranitidin Sandoz	Ranitidine Hydrochloride 168mg Tablet	Effervescent tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Sweden	Orifarm Generics A/S	Stomacid	Ranitidine Hydrochloride 168mg Tablet	Effervescent tablet	Oral use
Sweden	Orifarm Generics A/S	Stomacid	Ranitidine Hydrochloride 336mg Tablet	Effervescent tablet	Oral use
Sweden	Glaxosmithkline Ab	Zantac	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
Sweden	Glaxosmithkline Ab	Zantac	Ranitidine 150mg Tablet	Tablet	Oral use
Sweden	Glaxosmithkline Ab	Zantac	Ranitidine 15mg/ml	Oral solution	Oral use
Sweden	Glaxosmithkline Ab	Zantac	Ranitidine 25mg/ml	Solution for injection	Intravenous use
United Kingdom	Medreich Plc	Cooperative Pharmacy Indigestion Relief	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
United Kingdom	Ranbaxy (Uk) Limited	Em Pharma Indigestion Relief	Ranitidine Hydrochloride 83.75mg Tablet	Film-coated tablet	Oral use
United Kingdom	Noumed Life Sciences	Gavilast Heartburn And Indigestion	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
United Kingdom	Brown & Burk Uk Limited	Heartburn & Indigestion	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
United Kingdom	Bristol Laboratories Ltd (Berkhamsted)	Heartburn & Indigestion Relief	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
United Kingdom	Galpharm Healthcare Limited	Heartburn & Indigestion Relief	Ranitidine Hydrochloride 83.75mg	Tablet	Oral use
United Kingdom	Galpharm Healthcare Limited	Indigestion Relief	Ranitidine Hydrochloride 83.75mg	Tablet	Oral use
United Kingdom	Medreich Plc	Indigestion Relief	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
United Kingdom	Noumed Life Sciences	Indigestion Relief	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
United Kingdom	Medreich Plc	Morrisons Indigestion Relief	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
United Kingdom	Medreich Plc	Peach Ethical Indigestion Relief	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
United Kingdom	Bristol Laboratories Ltd (Berkhamsted)	Ranicalm	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
United Kingdom	Claris Lifesciences (Uk) Limited	Ranitidine	Ranitidine Hydrochloride 25mg/Ml	Solution for injection/infusion	Intravenous use
United Kingdom	Accord Healthcare Limited	Ranitidine Accord Healthcare	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
United Kingdom	Accord Healthcare Limited	Ranitidine Accord Healthcare	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
United Kingdom	Accord Healthcare Limited	Ranitidine Accord Healthcare	Ranitidine Hydrochloride 168mg Tablet	Effervescent tablet	Oral use
United Kingdom	Accord Healthcare Limited	Ranitidine Accord Healthcare	Ranitidine Hydrochloride 335mg Tablet	Effervescent tablet	Oral use
United Kingdom	Actavis Uk Limited	Ranitidine Accord-Uk	Ranitidine Hydrochloride 168mg Tablet	Effervescent tablet	Oral use
United Kingdom	Actavis Uk Limited	Ranitidine Accord-Uk	Ranitidine Hydrochloride 336mg Tablet	Effervescent tablet	Oral use
United Kingdom	Activase Pharmaceuticals Limited	Ranitidine Activase Pharmaceuticals	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
United Kingdom	Activase Pharmaceuticals Limited	Ranitidine Activase Pharmaceuticals	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
United Kingdom	Alliance Pharmaceuticals Ltd	Ranitidine Alliance Pharmaceuticals	Ranitidine 50mg/2ml	Solution for injection/infusion	Intramuscular use and intravenous use
United Kingdom	Medreich Plc	Ranitidine Asda Medreich	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
United Kingdom	Bristol Laboratories Ltd (Berkhamsted)	Ranitidine Bristol Laboratories	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
United Kingdom	Bristol Laboratories Ltd (Berkhamsted)	Ranitidine Bristol Laboratories	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
United Kingdom	Bristol Laboratories Ltd (Berkhamsted)	Ranitidine Bristol Laboratories	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
United Kingdom	Brown & Burk Uk Limited	Ranitidine Brown & Burk Uk	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
United Kingdom	Brown & Burk Uk Limited	Ranitidine Brown & Burk Uk	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
United Kingdom	Brown & Burk Uk Limited	Ranitidine Brown & Burk Uk	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
United Kingdom	Creo Pharma Ltd	Ranitidine Creo Pharma	Ranitidine 30mg/ml	Oral solution	Oral use
United Kingdom	Crescent Pharma Limited	Ranitidine Crescent Pharma	Ranitidine Hydrochloride 167.4mg Tablet	Film-coated tablet	Oral use
United Kingdom	Crescent Pharma Limited	Ranitidine Crescent Pharma	Ranitidine Hydrochloride 168mg/10ml	Oral solution	Oral use
United Kingdom	Crescent Pharma Limited	Ranitidine Crescent Pharma	Ranitidine Hydrochloride 334.8mg Tablet	Film-coated tablet	Oral use
United Kingdom	Dawa Limited	Ranitidine Dawa	Ranitidine 150mg Tablet	Coated tablet	Oral use
United Kingdom	Dawa Limited	Ranitidine Dawa	Ranitidine 300mg Tablet	Coated tablet	Oral use
United Kingdom	Dawa Limited	Ranitidine Dawa	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
United Kingdom	Ennogen Pharma Limited	Ranitidine Ennogen Pharma	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
United Kingdom	Ennogen Pharma Limited	Ranitidine Ennogen Pharma	Ranitidine 300mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
United Kingdom	Flamingo Pharma Uk Ltd	Ranitidine Flamingo Pharma Uk	Ranitidine Hydrochloride 168mg Tablet	Film-coated tablet	Oral use
United Kingdom	Flamingo Pharma Uk Ltd	Ranitidine Flamingo Pharma Uk	Ranitidine Hydrochloride 336mg Tablet	Film-coated tablet	Oral use
United Kingdom	Flamingo Pharma Uk Ltd	Ranitidine Flamingo Pharma Uk	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
United Kingdom	Focus Pharmaceuticals Limited	Ranitidine Focus Pharmaceuticals	Ranitidine 150mg/10ml	Oral solution	Oral use
United Kingdom	Galpharm Healthcare Limited	Ranitidine Galpharm Healthcare	Ranitidine Hydrochloride 83.75mg	Tablet	Oral use
United Kingdom	Galpharm Healthcare Limited	Ranitidine Galpharm Healthcare	Ranitidine Hydrochloride 83.75mg Tablet	Film-coated tablet	Oral use
United Kingdom	Generics [uk] Limited	Ranitidine Generics Uk	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
United Kingdom	Medley Pharma Limited	Ranitidine Medley Pharma	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
United Kingdom	Medley Pharma Limited	Ranitidine Medley Pharma	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
United Kingdom	Medreich Plc	Ranitidine Medreich	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
United Kingdom	Medreich Plc	Ranitidine Medreich	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
United Kingdom	Medreich Plc	Ranitidine Medreich	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
United Kingdom	Mercury Pharma International Ltd	Ranitidine Mercury Pharma International	Ranitidine 50mg/2ml	Solution for injection	Intramuscular use and intravenous use
United Kingdom	Milpharm Limited	Ranitidine Milpharm	Ranitidine 150mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
United Kingdom	Milpharm Limited	Ranitidine Milpharm	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
United Kingdom	North Star Healthcare Limited	Ranitidine North Star Healthcare	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
United Kingdom	North Star Healthcare Limited	Ranitidine North Star Healthcare	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
United Kingdom	Noumed Life Sciences	Ranitidine Noumed Life Sciences	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
United Kingdom	Noumed Life Sciences	Ranitidine Noumed Life Sciences	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
United Kingdom	Medreich Plc	Ranitidine Numark Medreich	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
United Kingdom	Otc Concepts Ltd	Ranitidine Otc Concepts	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
United Kingdom	Ranbaxy (Uk) Limited	Ranitidine Ranbaxy (Uk)	Ranitidine Hydrochloride 83.75mg Tablet	Film-coated tablet	Oral use
United Kingdom	Ratiopharm Gmbh	Ranitidine Ratiopharm	Ranitidine Hydrochloride 168mg Tablet	Effervescent tablet	Oral use
United Kingdom	Ratiopharm Gmbh	Ranitidine Ratiopharm	Ranitidine Hydrochloride 336mg Tablet	Effervescent tablet	Oral use
United Kingdom	Ratiopharm Gmbh	Ranitidine Ratiopharm	Ranitidine Hydrochloride 83.75mg Tablet	Film-coated tablet	Oral use
United Kingdom	Relon Chem Limited	Ranitidine Relonchem	Ranitidine 150mg Tablet	Tablet	Oral use
United Kingdom	Relon Chem Limited	Ranitidine Relonchem	Ranitidine 300mg Tablet	Tablet	Oral use
United Kingdom	Relon Chem Limited	Ranitidine Relonchem	Ranitidine 75mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
United Kingdom	Rosemont Pharmaceuticals Limited	Ranitidine Rosemont Pharmaceuticals	Ranitidine Hydrochloride 83.75mg/5ml	Oral solution	Oral use
United Kingdom	Syri Limited T/A Thame Laboratories	Ranitidine Syri	Ranitidine 150mg/10ml	Oral solution	Oral use
United Kingdom	Teva Uk Limited	Ranitidine Teva Uk	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
United Kingdom	Teva Uk Limited	Ranitidine Teva Uk	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
United Kingdom	Tillomed Laboratories Ltd	Ranitidine Tillomed Laboratories	Ranitidine 150mg Tablet	Film-coated tablet	Oral use
United Kingdom	Tillomed Laboratories Ltd	Ranitidine Tillomed Laboratories	Ranitidine 300mg Tablet	Film-coated tablet	Oral use
United Kingdom	Waymade Plc	Ranitidine Waymade	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
United Kingdom	Waymade Plc	Ranitidine Waymade	Ranitidine 300mg Tablet	Effervescent tablet	Oral use
United Kingdom	Otc Concepts Ltd	Ranzac	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
United Kingdom	Medreich Plc	Sainsbury’s Indigestion Relief	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
United Kingdom	Medreich Plc	Superdrug Indigestion And Heartburn Relief	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
United Kingdom	Relon Chem Limited	Tesco Health Heartburn & Indigestion Relief	Ranitidine 75mg Tablet	Film-coated tablet	Oral use
United Kingdom	Relon Chem Limited	Tesco Health Heartburn And Indigestion Relief	Ranitidine 75mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
United Kingdom	Medreich Plc	Tesco Indigestion Relief	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
United Kingdom	Medreich Plc	Waitrose Indigestion And Heartburn Relief	Ranitidine Hydrochloride 84mg Tablet	Film-coated tablet	Oral use
United Kingdom	Glaxo Wellcome Uk Limited	Zantac	Ranitidine 150mg Tablet	Effervescent tablet	Oral use
United Kingdom	Glaxo Wellcome Uk Limited	Zantac	Ranitidine 150mg Tablet	Tablet	Oral use
United Kingdom	Glaxo Wellcome Uk Limited	Zantac	Ranitidine 300mg Tablet	Effervescent tablet	Oral use
United Kingdom	Glaxo Wellcome Uk Limited	Zantac	Ranitidine 300mg Tablet	Tablet	Oral use
United Kingdom	Glaxo Wellcome Uk Limited	Zantac	Ranitidine Hydrochloride 168mg/10ml	Syrup	Oral use
United Kingdom	Glaxo Wellcome Uk Limited	Zantac	Ranitidine Hydrochloride 56mg/2ml	Solution for injection	Intramuscular use and intravenous use
United Kingdom	Omega Pharma Ltd	Zantac	Ranitidine Hydrochloride 84mg Tablet	Tablet	Oral use
United Kingdom	Omega Pharma Ltd	Zantac Relief	Ranitidine Hydrochloride 84mg Tablet	Tablet	Oral use

Annex II

Scientific conclusions

Scientific conclusions

In July 2019, findings from a private laboratory in the United States (US) indicated that ranitidine can generate NDMA as a decomposition product. In August 2019, preliminary results in a random selection and testing by official medicinal control laboratories (OMCLs) of ranitidine API batches and finished products available in the EU showed levels of NDMA in a range that raised concerns according to the principles of ICH-M7. In addition, *in vitro* studies were performed with different pH solutions of ranitidine with and without nitrite to evaluate if similar pH conditions as to the *in vivo* conditions would lead to the formation of NDMA. Although the nitrite levels used were far above those usually present in human stomach, the results seem to indicate that NDMA could be formed from ranitidine at acidic pH in the presence of nitrite. Based on the analytical results available at the start of the referral procedure, it appeared that NDMA can also be formed from ranitidine during certain analytical procedures, especially those using high temperatures.

Overall, it was considered possible that NDMA could be generated under certain conditions when DMA released from ranitidine is exposed to a source of nitrite (e.g. sodium nitrite).

The European Commission considered it necessary to evaluate the relevance of these findings, the potential root causes and their impact on the benefit–risk balance of the medicinal products containing ranitidine.

In view of the above, the European Commission triggered on 12 September 2019 a referral procedure under Article 31 of Directive 2001/83/EC to evaluate the relevance of these findings, the potential root causes and their impact on the benefit-risk balance of medicinal products containing ranitidine and take any subsequent action as required.

Overall summary of the scientific evaluation

NDMA is a potent mutagenic carcinogen in a number of different animal species and on the basis of animal data, NDMA is classified by the International Agency for Research on Cancer (IARC) as "probably carcinogenic to humans". Despite of the fact that the impact of NDMA on human health is currently only extrapolated from animal studies, it is prudent to assume that effects seen in animals may also occur in humans.

Almost all batches of ranitidine API and drug products that have been tested for NDMA, contain NDMA above 0.16 ppm, which is based on an acceptable intake of 96 ng/day for a lifetime and a maximum daily ranitidine dose of 600 mg for a lifetime. Necessary information related to the presence of NDMA in the final product, including formation of NDMA as a degradation product and/or metabolite, is still lacking. The risk of contamination with potential carcinogenic nitrosamines, especially with NDMA, above the acceptable daily intake, is unresolved.

Based on the review of all available data on safety and efficacy and additional information received during the oral explanations, the CHMP considers that the risk of presence of NDMA cannot be adequately addressed at this stage, and therefore avoiding the use of ranitidine containing products until the above uncertainties are addressed is the only acceptable risk minimisation measure. The CHMP concluded that the benefit-risk balance of medicinal products containing ranitidine is negative in view of the uncertainties on the root causes for the presence of NDMA in the active substance and drug products, and in view of the fact that the risk of endogenous formation of NDMA following administration of ranitidine to patients cannot be excluded at this stage.

These elements related to the formation of NDMA as a degradation product and/or metabolite and the potential for endogenous formation need to be answered. As a consequence, the CHMP has recommended to suspend all marketing authorisations for ranitidine-containing medicinal products. The CHMP noted that treatment alternatives for ranitidine are available.

In order to lift the suspension of the marketing authorisation (MA), all the following conditions must be fulfilled:

- the MAH(s) shall investigate the potential endogenous formation and demonstrate that it supports a positive benefit/risk balance,
- introduce in the MA dossier an adequate limit to control presence of nitrosamines and
- to put in place a control strategy.
- The limit at release will need to be based on the maximum daily dose of ranitidine free base taking into account the route of administration in accordance with the ICH M7(R1) guideline, with a maximum daily intake of NDMA of 96 ng/day. This limit at release should take into account any increase in NDMA levels observed during stability studies. The MAH(s) shall also provide batch data for the drug products to demonstrate that the degradation of the drug substance is controlled throughout shelf-life.

The ICH M7(R1) guideline sets out principles for determining limits for mutagenic / DNA-reactive impurities. N-nitrosamines belong to a "cohort of concern" compounds in this guideline. Based on the principles in ICH M7, a daily exposure to NDMA of 96 ng was previously set as Acceptable Intake (AI), which is associated with an additional tumour risk of 10-5. Assuming a maximum daily dose of 600 mg for a lifetime (or in excess of 10 years) this AI leads to a limit of 0.16 ppm in ranitidine containing medicinal products.

A limit based on the AI would be toxicologically justifiable since the excess tumour risk would not exceed 10-5 (or 1:100,000 patients). Considering that NDMA is a degradant, lower limits are unlikely to be achievable in the case of ranitidine. This is different from case of the sartans where a change of the methods of synthesis could sufficiently circumvent the formation of N-nitrosamines.

This limit is based on an exposure throughout life. The 'Less-than-Lifetime' (LTL) approach that would include a correction factor leading to a higher limit is not acceptable in view of the risks of NDMA, the unclear degradation profile, the benefits of ranitidine and the potential repeated use throughout life or chronic use.

The MAH(s) should also put in place a control strategy which should include current and prospective measures to minimise the risk of generation/contamination with any nitrosamine (e.g. change of manufacturing process, introduction of appropriate specifications and development of appropriate methods, measures on the premise and equipment, such as cleaning procedures, environmental monitoring) and control any future change that may impact on this risk (e.g. change of supplier, change of manufacturer process, change of packaging).

As part of the control strategy, the MAH(s) should introduce every necessary change to control the risk of presence of N-nitrosamines and to minimise as much as possible their presence below the limit based on the acceptable intake.

Re-examination procedure

Following the adoption of the CHMP Opinion during the April 2020 PRAC meeting, one MAH (S.A.L.F.) expressed its disagreement with the initial CHMP Opinion, and subsequently to the request for re-examination, grounds for re-examination have been submitted by S.A.L.F. The CHMP confirmed it had considered the totality of the data submitted by the MAHs in the context of the initial referral procedure. Notwithstanding this, and given the detailed grounds provided by the MAH, the CHMP carried out a new assessment of the available data in the context of the re-examination.

CHMP conclusions on grounds for re-examination

Clinical aspects

It is scientifically plausible that the underlying disease increases the risk for gastric and pancreatic cancers in patients treated with H2-receptor antagonists. The impact of NDMA on human health is therefore, extrapolated from animal studies. DNA damage mechanisms documented in animal studies are also relevant in humans, it is plausible to assume that effects seen in animals may also occur in humans after exposure to sufficiently large amounts of this nitrosamine. Besides exposure through ranitidine when containing NDMA as impurity, it cannot be excluded that additional exposure to NDMA can be due to endogenous formation of NDMA from ranitidine. These should be seen as additional risk factors adding to the total tumour risk associated with nitrosamine background exposure. However, any potential cancer risk due to NDMA exposure associated with ranitidine use is of a low level and will probably not be detected with conventional animal studies or epidemiological studies considering the latency of cancer onset and that any potential cancer risk due to NDMA exposure associated with ranitidine use is of a low level compared to the background cancer risk over lifetime. Therefore, whilst epidemiological or clinical trial data did not indicate an increased risk of cancer in humans after the use of ranitidine, a theoretical risk cannot be excluded.

Less-than-Lifetime (LTL) approach

In view of the MAH's proposal to use the LTL approach considering the duration of use for Ranitidina S.A.L.F, the CHMP reconfirmed its position that this approach is only accepted for N-nitrosamine contaminations in exceptional circumstances. The CHMP did not identify such exceptional circumstances in this case. It is also noted that there are uncertainties on potential endogenous formation of NDMA from intake of ranitidine, which prevent the use of the LTL approach.

In agreement with the CHMP's previous opinion, a limit for NDMA in ranitidine based on the maximum daily dose, assuming exposure throughout life is considered scientifically robust. Where the duration of use is shorter, this would further mitigate the actual risks for the patients, but not allow for setting higher limits. The CHMP also noted that for a single dose administration, considering an NDMA limit of 96 ng/day and a 50 mg single dose used in the setting of a single use application prior to surgery for prevention of Mendelson's syndrome the limit would be 1.92 ppm NDMA.

NDMA is not only present in ranitidine finished products as an impurity but also appears to increase over time as a consequence of degradation of the active substance over shelf-life of the finished product. In addition, the possibility that endogenous formation of NDMA arises from ranitidine administration cannot be excluded. Assessment of the clinical safety of ranitidine products therefore cannot be fully elucidated and further investigations into endogenous formation of NDMA should be carried out.

For the above reasons the CHMP considered that the MAH's proposal to use the LTL approach cannot be accepted for the reasons explained in the paragraphs above, and that any limits – once adequate data on degradation are available – should be guided by lifetime exposure, i.e. 96 ng NDMA /day.

Use of parenteral ranitidine in prevention of Mendelson syndrome only

The MAH proposed as an alternative of defining NDMA limit for their products based on LTL approach, to limit the current therapeutic indications only to the anaesthesia premedication for those patients who risk developing an acid aspiration syndrome (Mendelson syndrome). The MAH argued that since it is a single administration, the nitrosamine content is irrelevant.

In this re-examination procedure, the only risk minimisation measure identified by the MAH to reduce exposure with NDMA was limiting the use of ranitidine to a single administration for anaesthesia premedication to those patients who risk developing an acid aspiration syndrome (Mendelson

syndrome). As mentioned above, the proposed measure would reduce the exposure but not the risk for the patients exposed. The CHMP also did not identify exceptional circumstances for this indication that would justify the LTL approach in this setting for the same reasons discussed above.

The CHMP considered that there are too many uncertainties on the risk of endogenous NDMA formation from ranitidine and degradation over time from the active substance leading to NDMA. The CHMP considered that these risks outweigh the benefits, therefore the CHMP confirmed its initial position that the benefit-risk balance in all ranitidine formulations (including parenteral) is currently negative.

The CHMP however acknowledged the MAH's argument that the risk might be lower for the use of ranitidine when given parenterally as a single low dose administration. The rationale for this, is that it could be plausible that with the lower dose administered (and as a single use), there is a lower relevance of potential NDMA endogenous formation in kidney in this clinical setting due to the lower exposure following single use administration. It can therefore not be excluded that the potential risk with single use is very small or negligible.

The CHMP agreed to take this element in the requirements to establish a positive benefit-risk balance and to adapt the expected data to be submitted in order to justify a positive benefit-risk of these products. Hence the 1st condition for lifting the suspension of ranitidine-containing medicinal products for single parenteral use only requests the MAH to discuss the relevance of endogenous NDMA formation based for these products as follows:

1. In order to support a positive benefit-risk balance of these products the MAH should discuss the relevance of endogenous NDMA formation based on e.g. data on endogenous formation of NDMA in humans from ranitidine, additional experimental data (*in vitro*/*in vivo*) or literature information.

The other conditions requested in the initial phase of this procedure are maintained for all products:

2. "A limit for NDMA should be set in the release specification of the medicinal product. This limit should take into account any increase in NDMA levels observed during stability studies. The limit at the end of shelf life should be based on the maximum daily dose of Ranitidine free base taking into account the route of administration in accordance with ICH M7(R1), with a maximum daily intake of NDMA of 96 ng/day.
3. Compliance with the limit for NDMA up to the end of shelf-life of the medicinal product should be demonstrated through appropriate data from batches of the medicinal product.
4. The MAH should implement a control strategy regarding N-nitrosamines for ranitidine containing medicinal products."

For all other cases (oral formulations or other indications for parenteral formulations), the 1st condition for lifting a suspension agreed in the initial phase of the referral should apply:

1. "The MAH should submit quantitative data on the endogenous formation of NDMA in humans from ranitidine and demonstrate whether the results support a positive benefit-risk balance of the product."

Final benefit-risk balance

On 3 June 2020 one MAH (S.A.L.F.) submitted detailed grounds for re-examination of the initial CHMP opinion.

The CHMP, having reviewed the grounds from the MAH and the available clinical safety data confirmed its previous position that there is no evidence of a causal association between ranitidine therapy and the development of cancer in patients and that therefore the corresponding statement does not need to be changed. However, any potential cancer risk due to NDMA exposure associated with ranitidine

use is of a low level and will probably not be detected with conventional animal studies or epidemiological studies. Whilst epidemiological or clinical trial data did not indicate an increased risk of cancer in humans after the use of ranitidine, a theoretical risk cannot be excluded.

Based on all the available data and having carefully assessed the grounds for re-examination, the CHMP confirmed that the LTL approach is not appropriate to justify a higher amount of NDMA in ranitidine-containing parenteral formulations.

No other risk minimisation measure than limiting the use as a single administration for anaesthesia premedication to those patients who risk developing an acid aspiration syndrome (Mendelson syndrome) was identified by the MAH. However, whilst a shorter duration of use would further mitigate the actual risks for the patients, this cannot allow for setting higher limits.

Therefore, in view of the uncertainties on the risk of endogenous NDMA formation from ranitidine and degradation over time from the active substance leading to NDMA, the CHMP considered that the risks related to the presence of NDMA in ranitidine containing products outweighs the benefits. Consequently, the CHMP considers that the benefit/risk balance for all medicinal products containing ranitidine is negative.

The CHMP considered that for single use IV formulations, it could be plausible that with the lower dose administered (and as a single use), there is a lower relevance of potential NDMA endogenous formation in kidney due to the lower exposure following single use administration. The CHMP revised the conditions for lifting the suspension of the MAs to take this element into account for these specific medicinal products.

Grounds for CHMP opinion

Whereas,

- The CHMP considered the procedure under Article 31 of Directive 2001/83/EC for medicinal products containing ranitidine.
- Tests carried out by Marketing Authorisation Holders, API manufacturers, Official Medicines Control Laboratories and international competent authorities showed that NDMA, classified by the IARC as "probably carcinogenic to humans" (Class 2A carcinogen), was found in almost all batches of ranitidine drug substances and medicinal products tested above the acceptable level based on the current principles established in ICH M7(R1).
- The CHMP reviewed all available data to evaluate the potential root causes that may lead to the presence of NDMA in the ranitidine drug substance and medicinal product. The CHMP also considered the grounds submitted by one MAH (S.A.L.F) as basis for their request for re-examination of the CHMP opinion.
- The CHMP concluded that NDMA is not only present in ranitidine-containing medicinal products as an impurity that may form during the manufacturing process, but also due to degradation of ranitidine as a drug substance. The degradation of ranitidine in drug substance and medicinal product is currently insufficiently characterised.
- In addition, the CHMP concluded that the risk of endogenous formation of NDMA following administration of ranitidine cannot be excluded at this stage and that further investigation should be carried out.
- While epidemiological or clinical trial data did not indicate an increased risk of cancer in humans after the use of ranitidine, a risk cannot be excluded, as the currently available data may not be able to detect such a risk.

- The extent of formation of NDMA especially due to degradation of the drug substance and the potential endogenous formation raise serious concerns related to the safety of ranitidine-containing medicinal products. In view of these uncertainties on the presence of NDMA in the medicinal product, the risk of *in vivo* formation as well as its extent, the CHMP did not identify risk minimisation measures other than avoiding its use that could minimise the risk to an acceptable level at this stage. Therefore, the CHMP considered that the risks related to the presence of NDMA in ranitidine containing products outweighs the benefits. Furthermore, due to the above concerns, the CHMP did not support using a less -than-lifetime (LTL) approach for setting future NDMA limits for ranitidine.
- The CHMP considered that for single use parenteral formulations, it could be plausible that there is a lower relevance of potential NDMA endogenous formation in kidney due to the lower exposure following single use administration.

CHMP opinion

The CHMP, as a consequence, considers that the risk-benefit balance of ranitidine-containing medicinal products is not favourable.

Therefore, pursuant to Article 116 of Directive 2001/83/EC, the CHMP recommends the suspension of the marketing authorisations for ranitidine-containing medicinal products.

For the suspension of ranitidine-containing medicinal products to be lifted, the marketing authorisation holder(s) shall submit:

<u>For ranitidine containing medicinal products for single use:</u>

1. In order to support a positive benefit-risk balance of these products the MAH should discuss the relevance of endogenous NDMA formation based on e.g. data on endogenous formation of NDMA in humans from ranitidine, additional experimental data (in vitro/in vivo) or literature information.
2. A limit for NDMA should be set in the release specification of the medicinal product. This limit should take into account any increase in NDMA levels observed during stability studies. The limit at the end of shelf life should be based on the maximum daily dose of Ranitidine free base taking into account the route of administration in accordance with ICH M7(R1), with a maximum daily intake of NDMA of 96 ng/day.
3. Compliance with the limit for NDMA up to the end of shelf-life of the medicinal product should be demonstrated through appropriate data from batches of the medicinal product.
4. The MAH should implement a control strategy regarding N-nitrosamines for ranitidine containing medicinal products.

<u>For all other ranitidine containing products</u>

1. The MAH should submit quantitative data on the endogenous formation of NDMA in humans from ranitidine and demonstrate whether the results support a positive benefit-risk balance of the product.
2. A limit for NDMA should be set in the release specification of the medicinal product. This limit should take into account any increase in NDMA levels observed during stability studies. The limit at the end of shelf life should be based on the maximum daily dose of Ranitidine free base taking into account the route of administration in accordance with ICH M7(R1), with a maximum daily intake of NDMA of 96 ng/day.
3. Compliance with the limit for NDMA up to the end of shelf-life of the medicinal product should be demonstrated through appropriate data from batches of the medicinal product.

4. The MAH should implement a control strategy regarding N-nitrosamines for ranitidine containing medicinal products.

Annex III

Conditions for lifting the suspension of the marketing authorisation(s)

Conditions for lifting the suspension of the marketing authorisation(s)

For the suspension of ranitidine containing medicinal products to be lifted, the competent authorities shall ensure that the below conditions have been completed by the marketing authorisation holder(s).

Conditions to lift the suspension of the marketing authorisation for parenteral ranitidine preparations **for single use only** are as follows:

	Condition for lifting suspension
1.	In order to support a positive benefit-risk balance of these products the MAH should discuss the relevance of endogenous NDMA formation based on e.g. data on endogenous formation of NDMA in humans from ranitidine, additional experimental data (in vitro/in vivo) or literature information.
2.	A limit for NDMA should be set in the release specification of the medicinal product. This limit should take into account any increase in NDMA levels observed during stability studies. The limit at the end of shelf life should be based on the maximum daily dose of Ranitidine free base taking into account the route of administration in accordance with ICH M7(R1), with a maximum daily intake of NDMA of 96 ng/day.
3.	Compliance with the limit for NDMA up to the end of shelf-life of the medicinal product should be demonstrated through appropriate data from batches of the medicinal product.
4.	The MAH should implement a control strategy regarding N-nitrosamines for ranitidine containing medicinal products.

For all other ranitidine containing products for the suspension to be lifted, the Marketing Authorisation Holder(s) shall provide the following:

	Condition for lifting suspension
1.	The MAH should submit quantitative data on the endogenous formation of NDMA in humans from ranitidine and demonstrate whether the results support a positive benefit-risk balance of the product.
2.	A limit for NDMA should be set in the release specification of the medicinal product. This limit should take into account any increase in NDMA levels observed during stability studies. The limit at the end of shelf life should be based on the maximum daily dose of Ranitidine free base taking into account the route of administration in accordance with ICH M7(R1), with a maximum daily intake of NDMA of 96 ng/day.
3.	Compliance with the limit for NDMA up to the end of shelf-life of the medicinal product should be demonstrated through appropriate data from batches of the medicinal product.
4.	The MAH should implement a control strategy regarding N-nitrosamines for ranitidine containing medicinal products.