ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Keppra 100 mg/ml oral solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 100 mg levetiracetam.
For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Oral solution.
Clear liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Keppra is indicated as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in patients with epilepsy.

4.2 Posology and method of administration

The oral solution should be diluted in a glass of water and may be taken with or without food. A graduated oral syringe and instructions for use in the package leaflet are provided with Keppra.
The daily dose is administered in two equally divided doses.

Adults and adolescents older than 16 years

The initial therapeutic dose is 500 mg twice daily. This dose can be started on the first day of treatment.
Depending upon the clinical response and tolerance, the daily dose can be increased up to 1,500 mg twice daily. Dose changes can be made in 500 mg twice daily increments or decrements every two to four weeks.

Elderly (65 years and older)

Adjustment of the dose is recommended in elderly patients with compromised renal function (see "Patients with renal impairment" below).

Children

There are insufficient data to recommend the use of levetiracetam in children and adolescents under 16 years of age.

Patients with renal impairment

The daily dose must be individualised according to renal function. Refer to the following table and adjust the dose as indicated. To use this dosing table, an estimate of the patient's creatinine clearance (CLcr) in ml/min is needed. The CLcr in ml/min may be estimated from serum creatinine (mg/dl) determination using the following formula:

$$CLcr = \frac{[140\text{-age (years)}] \times \text{weight (kg)}}{72 \times \text{serum creatinine (mg/dl)}} \quad (\times 0.85 \text{ for women})$$

Dosing adjustment for patients with impaired renal function

Group	Creatinine clearance (ml/min)	Dosage and frequency
Normal	> 80	500 to 1,500 mg twice daily
Mild	50-79	500 to 1,000 mg twice daily
Moderate	30-49	250 to 750 mg twice daily
Severe	< 30	250 to 500 mg twice daily
End-stage renal disease patients Undergoing dialysis (1)	-	500 to 1,000 mg once daily (2)

(1) A 750 mg loading dose is recommended on the first day of treatment with levetiracetam.
(2) Following dialysis, a 250 to 500 mg supplemental dose is recommended.

Patients with hepatic impairment

No dose adjustment is needed in patients with mild to moderate hepatic impairment. In patients with severe hepatic impairment, the creatinine clearance may underestimate the renal insufficiency. Therefore a 50 % reduction of the daily maintenance dose is recommended when the creatinine clearance is < 70 ml/min.

4.3 Contraindications

Hypersensitivity to levetiracetam or other pyrrolidone derivatives or any of the excipients.

4.4 Special warnings and special precautions for use

In accordance with current clinical practice, if Keppra has to be discontinued it is recommended to withdraw it gradually (*e.g.* 500 mg twice daily decrements every two to four weeks). There are insufficient data for the withdrawal of concomitant antiepileptic medicinal products, once seizure control with levetiracetam in the add-on situation has been reached, in order to reach monotherapy on levetiracetam.

An increase in seizure frequency of more than 25 % has been reported in 14 % and 26 % of the levetiracetam and placebo treated patients, respectively.

The administration of Keppra to patients with renal impairment may require dose adjustment. In patients with severely impaired hepatic function, assessment of renal function is recommended before dose selection (see section 4.2 “Posology”).

Amongst its excipients, Keppra includes glycerol which can cause headache, stomach upset and diarrhoea and maltitol which may have a mild laxative effect. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Pre-marketing data from clinical studies indicate that Keppra did not influence the serum concentrations of existing antiepileptic medicinal products (phenytoin, carbamazepine, valproic acid, phenobarbital, lamotrigine, gabapentin and primidone) and that these antiepileptic medicinal products did not influence the pharmacokinetics of Keppra.

Probenecid (500 mg four times daily), a renal tubular secretion blocking agent, has been shown to inhibit the renal clearance of the primary metabolite but not of levetiracetam. Nevertheless, the concentration of this metabolite remains low. It is expected that other drugs excreted by active tubular

secretion could also reduce the renal clearance of the metabolite. The effect of levetiracetam on probenecid was not studied and the effect of levetiracetam on other actively secreted drugs, *e.g.* NSAIDs, sulfonamides and methotrexate, is unknown.

Levetiracetam 1,000 mg daily did not influence the pharmacokinetics of oral contraceptives (ethinyl-estradiol and levonorgestrel); endocrine parameters (luteinizing hormone and progesterone) were not modified. Levetiracetam 2,000 mg daily did not influence the pharmacokinetics of digoxin and warfarin; prothrombin times were not modified. Co-administration with digoxin, oral contraceptives and warfarin did not influence the pharmacokinetics of levetiracetam.

No data on the influence of antacids on the absorption of levetiracetam are available.

The extent of absorption of levetiracetam was not altered by food, but the rate of absorption was slightly reduced.
No data on the interaction of levetiracetam with alcohol are available.

4.6 Pregnancy and lactation

There are no adequate data from the use of Keppra in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). The potential risk for human is unknown.
Keppra should not be used during pregnancy unless clearly necessary. Discontinuation of antiepileptic treatments may result in disease worsening, harmful to the mother and the foetus.

Levetiracetam is excreted in human breast milk. Therefore, breast-feeding is not recommended.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.
Due to possible different individual sensitivity, some patients might experience somnolence or other central nervous system related symptoms, at the beginning of treatment or following a dose increase. Therefore, caution is recommended in those patients when performing skilled tasks, *e.g*. driving vehicles or operating machinery.

4.8 Undesirable effects

Pooled safety data from clinical studies showed that 46.4 % and 42.2 % of the patients experienced undesirable effects in the Keppra and placebo groups, respectively, and that 2.4 % and 2.0 % of the patients experienced serious undesirable effects in the Keppra and placebo groups, respectively. The most commonly reported undesirable effects were somnolence, asthenia and dizziness. In the pooled safety analysis, there was no clear dose-response relationship but incidence and severity of the central nervous system related undesirable effects decreased over time.

Undesirable effects reported in clinical studies or from post-marketing experience are listed in the following table per System Organ Class and per frequency. For clinical trials, the frequency is defined as follows: very common: > 10 %; common: > 1 - 10 %; uncommon: > 0.1 % - 1 %; rare: 0.01 % - 0.1 %; very rare: < 0.01 %, including isolated reports. Data from post-marketing experience are insufficient to support an estimate of their incidence in the population to be treated.

- General disorders and administration site conditions

Very common: asthenia

- Nervous system disorders

Very common: somnolence

Common: amnesia, ataxia, convulsion, dizziness, headache, tremor

- Psychiatric disorders

Common: depression, emotional lability, hostility, insomnia, nervousness
Post-marketing experience: abnormal behaviour, aggression, anger, anxiety, confusion, hallucination, irritability, psychotic disorder

- Gastrointestinal disorders

Common: diarrhoea, dyspepsia, nausea

- Metabolism and nutrition disorders

Common: anorexia

- Ear and labyrinth disorders

Common: vertigo

- Eye disorders

Common: diplopia

- Injury, poisoning and procedural complications

Common: accidental injury

- Skin and subcutaneous tissue disorders

Common: rash

- Blood and lymphatic system disorders

Post-marketing experience: leukopenia, neutropenia, pancytopenia, thrombocytopenia.

4.9 Overdose

Symptoms
Somnolence, agitation and aggression were observed with Keppra overdoses.

Management of overdose
After an acute overdose, the stomach may be emptied by gastric lavage or by induction of emesis. There is no specific antidote for levetiracetam. Treatment of an overdose will be symptomatic and may include haemodialysis. The dialyser extraction efficiency is 60 % for levetiracetam and 74 % for the primary metabolite.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antiepileptics, ATC code: N03AX14
The active substance, levetiracetam, is a pyrrolidone derivative (S-enantiomer of α-ethyl-2-oxo-1-pyrrolidine acetamide), chemically unrelated to existing antiepileptic active substances.

Mechanism of action
The mechanism of action of levetiracetam is unknown but appears to be unrelated to the mechanisms of current drugs. *In vitro* and *in vivo* experiments suggest that levetiracetam does not alter basic cell characteristics and normal neurotransmission.

Pharmacodynamic effects
Levetiracetam induces seizure protection in a broad range of animal models of partial and primarily generalised seizures without having a pro-convulsant effect. The primary metabolite is inactive.
In man, an activity in both partial and generalised epilepsy conditions (epileptiform discharge/photoparoxysmal response) has confirmed the broad spectrum of the preclinical pharmacological profile.

5.2 Pharmacokinetic properties

Levetiracetam is a highly soluble and permeable compound. The pharmacokinetic profile is linear with low intra- and inter-subject variability. There is no modification of the clearance after repeated administration. There is no evidence for any relevant gender, race or circadian variability. The pharmacokinetic profile is comparable in healthy volunteers and in patients with epilepsy.

Due to its complete and linear absorption, plasma levels can be predicted from the oral dose of levetiracetam expressed as mg/kg bodyweight. Therefore there is no need for plasma level monitoring of levetiracetam.

Absorption

Levetiracetam is rapidly absorbed after oral administration. Oral absolute bioavailability is close to 100 %.
Peak plasma concentrations (C_{max}) are achieved at 1.3 hours after dosing. Steady-state is achieved after two days of a twice daily administration schedule.
Peak concentrations (C_{max}) are typically 31 and 43 µg/ml following a single 1,000 mg dose and repeated 1,000 mg twice daily dose, respectively.
The extent of absorption is dose-independent and is not altered by food.

Distribution

No tissue distribution data are available in humans.
Neither levetiracetam nor its primary metabolite are significantly bound to plasma proteins (< 10 %).
The volume of distribution of levetiracetam is approximately 0.5 to 0.7 l/kg, a value close to the total body water volume.

Biotransformation

Levetiracetam is not extensively metabolised in humans. The major metabolic pathway (24 % of the dose) is an enzymatic hydrolysis of the acetamide group. Production of the primary metabolite, ucb L057, is not supported by liver cytochrome P_{450} isoforms. Hydrolysis of the acetamide group was measurable in a large number of tissues including blood cells. The metabolite ucb L057 is pharmacologically inactive.

Two minor metabolites were also identified. One was obtained by hydroxylation of the pyrrolidone ring (1.6 % of the dose) and the other one by opening of the pyrrolidone ring (0.9 % of the dose). Other unidentified components accounted only for 0.6 % of the dose.

No enantiomeric interconversion was evidenced *in vivo* for either levetiracetam nor its primary metabolite.

In vitro, levetiracetam and its primary metabolite have been shown not to inhibit the major human liver cytochrome P_{450} isoforms (CYP3A4, 2A6, 2C8/9/10, 2C19, 2D6, 2E1 and 1A2), glucuronyl transferase (UGT1*6, UGT1*1 and UGT [pl6.2]) and epoxide hydroxylase activities. In addition, levetiracetam does not affect the *in vitro* glucuronidation of valproic acid.

In human hepatocytes in culture, levetiracetam did not cause enzyme induction. Therefore, the interaction of Keppra with other substances, or *vice versa,* is unlikely.

Elimination

The plasma half-life in adults was 7±1 hours and did not vary either with dose, route of administration or repeated administration. The mean total body clearance was 0.96 ml/min/kg.

The major route of excretion was via urine, accounting for a mean 95 % of the dose (approximately 93 % of the dose was excreted within 48 hours). Excretion *via* faeces accounted for only 0.3 % of the dose.
The cumulative urinary excretion of levetiracetam and its primary metabolite accounted for 66 % and 24 % of the dose, respectively during the first 48 hours.
The renal clearance of levetiracetam and ucb L057 is 0.6 and 4.2 ml/min/kg respectively indicating that levetiracetam is excreted by glomerular filtration with subsequent tubular reabsorption and that the primary metabolite is also excreted by active tubular secretion in addition to glomerular filtration. Levetiracetam elimination is correlated to creatinine clearance.

Elderly

In the elderly, the half-life is increased by about 40 % (10 to 11 hours). This is related to the decrease in renal function in this population (see section 4.2 “Posology”).

Children (6 to 12 years)

Following single dose administration (20 mg/kg) to epileptic children, the half-life of levetiracetam was 6.0 hours. The apparent body weight adjusted clearance was approximately 30 % higher than in epileptic adults.

Renal impairment

The apparent body clearance of both levetiracetam and of its primary metabolite is correlated to the creatinine clearance. It is therefore recommended to adjust the maintenance daily dose of Keppra, based on creatinine clearance in patients with moderate and severe renal impairment (see section 4.2 “Posology”).

In anuric end-stage renal disease subjects the half-life was approximately 25 and 3.1 hours during interdialytic and intradialytic periods, respectively.
The fractional removal of levetiracetam was 51 % during a typical 4-hour dialysis session.

Hepatic impairment

In subjects with mild and moderate hepatic impairment, there was no relevant modification of the clearance of levetiracetam. In most subjects with severe hepatic impairment, the clearance of levetiracetam was reduced by more than 50 % due to a concomitant renal impairment (see section 4.2 “Posology”).

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, genotoxicity and carcinogenicity.Although no evidence for carcinogenicity was seen, the potential carcinogenicity has not been fully evaluated due to some shortcomings in the studies performed.
Adverse effects not observed in clinical studies but seen in the rat and to a lesser extent in the mouse at exposure levels similar to human exposure levels and with possible relevance for clinical use were liver changes, indicating an adaptive response such as increased weight and centrilobular hypertrophy, fatty infiltration and increased liver serum enzymes.

In reproductive toxicity studies in the rat, levetiracetam induced developmental toxicity (increase in skeletal variations/minor anomalies, retarded growth, increased pup mortality) at exposure levels similar to or greater than the human exposure. In the rabbit foetal effects (embryonic death, increased skeletal anomalies, and increased malformations) were observed in the presence of maternal toxicity. The systemic exposure at the observed no effect level in the rabbit was about 4 to 5 times the human exposure.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium citrate
Citric acid monohydrate
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Ammonium glycyrrhizinate
Glycerol (E422)
Maltitol (E965)
Acesulfame potassium (E950)
Grape flavour
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store in the original container.

6.5 Nature and contents of container

300 ml amber glass bottle (type III) with a white child resistant closure (polypropylene) in a cardboard box also containing a graduated oral syringe (polyethylene, polystyrene) and a patient information leaflet.

6.6 Instructions for use and handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

UCB S.A.
Allée de la Recherche 60
B-1070 Bruxelles
Belgium

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

ANNEX II

A. MANUFACTURING AUTHORISATION HOLDERS RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

A. MANUFACTURING AUTHORISATION HOLDERS RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers responsible for batch release

Tablets

UCB PHARMA, S.A.

Chemin du Foriest

1420 Braine l'Alleud

Belgium

Oral Solution

UCB PHARMA, S.A.

17, Rue de Meullan

F-78520 Limay

France

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OF THE MARKETING AUTHORISATION

- **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

Medicinal product subject to medical prescription

- **OTHER CONDITIONS**

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

{NATURE/TYPE}

BOTTLE of 300 ml

1. NAME OF THE MEDICINAL PRODUCT

Keppra 100 mg/ml oral solution
Levetiracetam

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each ml contains 100 mg levetiracetam.

3. LIST OF EXCIPIENTS

Other ingredients include glycerol and maltitol. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

300 ml oral solution

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

Exp : {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Store in the original container.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder
UCB S.A.
Allée de la Recherche 60
B-1070 Bruxelles
BELGIUM

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/146/xxx

13. MANUFACTURER'S BATCH NUMBER

Batch : {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription

15. INSTRUCTIONS ON USE

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

Keppra 100 mg/ml oral solution.
Levetiracetam

- The active substance is called levetiracetam. Each ml contains 100 mg of levetiracetam.
- Keppra also contains the following additional ingredients:
  Sodium citrate, Citric acid monohydrate, Methyl parahydroxybenzoate (E218), Propyl parahydroxybenzoate (E216), Ammonium glycyrrhizinate, Glycerol (E422), Maltitol (E965), Acesulfame potassium (E950), Grape flavour, Purified water.

Marketing Authorisation Holder: UCB S.A., Allée de la Recherche 60, B-1070 Bruxelles, Belgium.
Manufacturer: UCB Pharma S.A., 17 Route de Meulan, F-78520 Limay, France.

1. WHAT KEPPRA IS AND WHAT IT IS USED FOR

Keppra 100 mg/ml oral solution is an antiepileptic medicine.
Keppra is packed in a 300 ml glass bottle in a cardboard box containing a graduated oral syringe.
The oral solution is a clear liquid.

Keppra is used for the treatment of partial seizures in patients who are already taking another antiepileptic medicine.

2. BEFORE YOU TAKE KEPPRA

Keppra is used in adults and adolescents over 16 years of age. It is not recommended for children and adolescents less than 16 years old.

Do not take Keppra:
- if you are hypersensitive (allergic) to levetiracetam or any of the other ingredients of Keppra. In such a case you must not use Keppra.

Take special care with Keppra:
- if you suffer from kidney problems, follow your doctor's instructions. He/she may decide if your dose should be adjusted.

Taking Keppra with food and drink:
You may take Keppra with or without food. Don't use Keppra with alcohol.

Pregnancy and breast-feeding:

Ask your doctor or pharmacist for advice before taking any medicine.
If you are pregnant or if you think you may be pregnant, please inform your doctor.
Keppra should not be used during pregnancy unless clearly necessary.
Breast-feeding is not recommended during treatment.

Driving and using machines:
Caution is recommended if you drive or operate any tools or machines since Keppra may make you feel sleepy. This is more likely at the beginning of treatment or after an increase in the dose.

Important information about some of the ingredients of Keppra:
Keppra contains glycerol and maltitol which can cause headache, stomach upset and diarrhoea.
Patients with rare hereditary problems of fructose intolerance should not take this medicine.

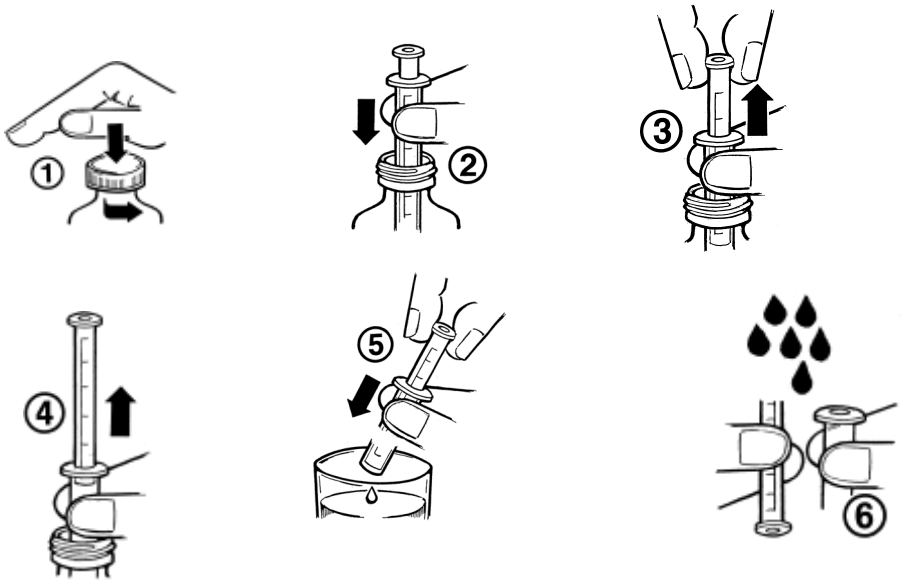
Taking other medicines:
Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. HOW TO TAKE KEPPRA

Dosage:
Take the oral solution following your doctor's instructions.
- General dose: between 1,000 mg (10 ml) and 3,000 mg (30 ml) each day.
- Keppra must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

Example: if your daily dose is 1,000 mg, you must take 500 mg (equal to 5 ml) in the morning and 500 mg (equal to 5 ml) in the evening.

Administration:
Keppra oral solution has to be diluted in a glass of water.
Instruction for use:
- Open the bottle : press the cap and turn it anticlockwise (figure ①)
- Take the syringe and put it in the bottle (figure ②)
- Fill the syringe with the liquid by pulling the piston up to the graduation mark corresponding to the quantity in milligrams (mg) prescribed by your doctor (figure ③)
- Remove the syringe from the bottle (figure ④)
- Empty the contents of the syringe in a glass of water by pushing the piston to the bottom (figure ⑤)
- Drink the whole contents of the glass
- Wash the syringe with water (figure ⑥)
- Close the bottle with the plastic screw cap.



Duration of treatment:
- Keppra is used as a chronic treatment. You should continue Keppra treatment for as long as your doctor has told you.
- Do not discontinue your treatment without your doctor's advice. Should your doctor decide to discontinue your Keppra treatment, he/she will instruct you about the gradual withdrawal of Keppra.

If you take more Keppra than you should:
Contact your doctor if you took more Keppra than you should.

If you forget to take Keppra:
Contact your doctor if you have missed one or more doses.
Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with Keppra is stopped:
If stopping treatment, as with other antiepileptic medicines, Keppra should be discontinued gradually to avoid an increase of seizures.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Keppra can have side effects.
Tell your doctor if you have any of the following and they worry you.
Most frequent side effects (>10%) reported with Keppra are:
- somnolence (sleepiness);
- asthenia (tiredness).

Other side effects reported with Keppra are:
- nervous system disorders: dizziness (sensation of unsteadiness), convulsion, headache, ataxia (impaired coordinated movements), tremor (involuntary trembling), amnesia (loss of memory);
- psychiatric disorders: abnormal behaviour, aggression, anger, anxiety, confusion, depression, emotional instability, hallucination, hostility, insomnia, irritability, nervousness and mental disorder;
- digestive disorders: nausea, dyspepsia (indigestion), diarrhoea;
- nutrition disorders: anorexia (loss of appetite);
- ear and labyrinth disorders: vertigo (sensation of rotation);
- eye disorders: diplopia (double vision);

- injury: accidental injury;
- skin disorders: rash;
- blood disorders: decreased number of red blood cells, white blood cells and/or blood platelets.

Some of the side effects like sleepiness, tiredness and dizziness may be more common at the beginning of the treatment or at dosage increase.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING KEPPRA

- Keep out of the reach and sight of children.
- Due to sensitivity to light, store in the original container.

Do not use after the expiry date stated on the cardboard box and bottle.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last approved on {date}