ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

IDflu 9 microgram/strain suspension for injection
Influenza vaccine (split virion, inactivated)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Split Influenza virus*, inactivated, containing antigens equivalent to the following strains:

A/New Caledonia/20/99 (H1N1) like strain (A/New Caledonia/20/99 (IVR-116)) 9 micrograms HA**

A/Wisconsin/67/2005 (H3N2) like strain (A/Wisconsin/67/2005 (NYMC X-161))
9 micrograms HA**

B/ Malaysia/2506/2004 like strain (B/Malaysia/2506/2004) 9 micrograms HA**

Per 0.1 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin

This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU decision for the 2006/2007 season.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Colourless and opalescent suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylaxis of influenza in adults up to 59 years of age, especially in those who run an increased risk of associated complications.

The use of IDflu should be based on official recommendations.

4.2 Posology and method of administration

Adults up to 59 years of age: 0.1 ml.

Children and adolescents:
IDflu is not recommended for use in children and adolescents below 18 years due to insufficient data on safety and efficacy.

Immunisation should be carried out by intradermal route.
The recommended site of administration is the region of the deltoid.

For instructions for use, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients, to egg, chicken proteins, neomycin, formaldehyde and octoxinol 9. IDflu does not contain more than 0.05 microgram ovalbumin per dose.

Immunisation shall be postponed in subjects with febrile illness or acute infection.

4.4 Special warnings and precautions for use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

IDflu should under no circumstances be administered intravascularly.

Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

In case of presence of liquid at the injection site after vaccine administration, re-vaccination is not required.

4.5 Interaction with other medicinal products and other forms of interaction

IDflu may be given at the same time as other vaccines. Immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified.

The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.

Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA test results. The transient false positive reactions could be due to the IgM response by the vaccine.

4.6 Pregnancy and lactation

For IDflu no clinical data on exposed pregnancies are available. In general data from intramuscular influenza vaccinations in pregnant women do not indicate adverse fetal and maternal outcomes attributable to the vaccine. One animal study with IDflu did not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/fetal development, parturition or postnatal development.

The use of IDflu may be considered from the second trimester of pregnancy. For pregnant women with medical conditions that increase their risk of complications from influenza, administration of the vaccine is recommended, irrespective of their stage of pregnancy.

The vaccine IDflu may be used during breast-feeding.

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.
The vaccine is unlikely to produce an effect on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions observed from clinical trials

The safety of IDflu has been assessed in 2 open-label randomised clinical trials in which 2,384 vaccinees received an injection of IDflu.

Safety evaluation was performed for all subjects during the first 3 weeks following vaccination and serious adverse reactions were collected during six months of follow-up.

The most common reactions occurring after vaccine administration were local reactions at injection site.
Apparent local reactions after intradermal administration were more frequent than after the comparator vaccine administered intramuscularly.
Most reactions resolved spontaneously within 1 to 3 days after onset.

Systemic safety profile of IDflu is similar to the comparator vaccine administered intramuscularly.

After repetitive yearly injections the safety profile of IDflu is similar to the previous injections.

The data below summarizes the frequencies of the adverse reactions that were recorded following vaccination, using the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from available data).

Organ class	**Very common**	**Common**	**Uncommon**	**Rare**	**Very rare**
Blood and lymphatic system disorders			Lymphadenopathy		
Nervous system disorders	Headache		Paresthesia		
Skin and subcutaneous tissue disorders			Pruritus, rash	Sweating	
Musculoskeletal and connective tissue disorders	Myalgia		Arthralgia		
General disorders and administration site conditions	Malaise, Local reactions: redness*, swelling, induration pain, pruritus	Shivering, fever, Local reactions: ecchymosis	Asthenia		

* In some cases, local redness lasted up to 7 days

Adverse reactions from Post-Marketing surveillance

There is no safety data from post-marketing experience with IDflu.

However, based on the experience with trivalent inactivated influenza vaccines administered by intramuscular or deep subcutaneous injection, systemic reactions, not listed above, may be reported:

Blood and lymphatic system disorders
Transient thrombocytopenia

Immune system disorders
Allergic reactions, in rare cases leading to shock, angioedema

Nervous system disorders
Neuralgia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome

Vascular disorders
Vasculitis associated in very rare cases with transient renal involvement

Skin and subcutaneous tissue disorders
Generalised skin reactions including urticaria

4.9 Overdose

Overdose is unlikely to have any untoward effect.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccines, ATC code: J07BB02

Immunogenicity

Seroprotection is generally obtained within 2 to 3 weeks. The duration of postvaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6-12 months.

In a randomised comparative phase III trial, 1,796 subjects from 18 to 59 years of age received 0.1 ml of IDflu by intradermal route and 453 subjects from 18 to 59 years of age received 0.5 ml of trivalent inactivated influenza vaccine administered by intramuscular route.

In this comparative trial the seroprotection rate*, seroconversion or significant increase rate** and the geometric mean titre ratio (GMTR) for anti-HA antibody (measured by HI) were assessed according to predefined criteria.

Data were as follows (values in brackets show the 95% confidence intervals):

Strain specific anti-HA antibody	**A/H1N1 A/New Caledonia/ 20/99 N=1,296**	**A/H3N2 A/Wisconsin/ 67/2005 N=1,297**	**B B/Malaysia/ 2506/2004 N=1,294**
Seroprotection rate	87.2% (85.2, 89.0)	93.5% (92.0, 94.8)	72.9% (70.4, 75.3)
Seroconversion/ Significant increase rate	57.5% (54.7, 60.2)	66.5% (63.8, 69.0)	56.7% (54.0, 59.4)
GMTR	9.17 (8.33, 10.1)	11.5 (10.4, 12.7)	6.39 (5.96, 6.84)

*Seroprotection = HI titre ≥ 40
** Seroconversion = negative pre-vaccination HI titre and post vaccination HI titre ≥ 40, Significant increase = positive pre-vaccination HI titre and at least a 4-fold increase in post-vaccination HI titre
GMTR: Geometric mean titre ratio of individual (post-/pre-vaccination titre).

IDflu is as immunogenic as the comparator trivalent inactivated influenza vaccine administered by intramuscular route for each of the 3 influenza strains in subjects from 18 to 59 years of age.

Across all three influenza strains, for the comparator intramuscular vaccine seroprotection rates ranged between 74.8% and 95.4%, seroconversion or significant increase rates ranged between 56.4% and 69.3% and GMTRs ranged between 6.63 and 11.2-fold over baseline HI titres.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Non-clinical data revealed no special hazard for humans based on animal studies. The vaccine was immunogenic in mice and rabbits. In repeated-dose toxicity studies in rabbits there was no significant evidence of systemic toxicity. Nevertheless, single and repeated administration led to transient local erythema and oedema. Genotoxicity and carcinogenic potential were not assessed because these studies are not appropriate for a vaccine. Fertility and toxicity studies to reproduction in females have not identified any specific potential hazard for humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Potassium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf-life

1 year

6.4 Special precautions for storage

Store in a refrigerator (2°C-8°C). Do not freeze.
Keep the syringe in the outer carton in order to protect from light.

6.5 Nature and contents of container

0.1 ml of suspension in a pre-filled syringe (type I glass) with a Micro-Injection System, with attached micro-needle, equipped with an elastomer plunger stopper (chlorobutyl), a tip cap (thermoplastic elastomer and polypropylene) and a needle shielding system. Pack size of 1 or 10 or 20.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused vaccine or waste material should be disposed of in accordance with local requirements.

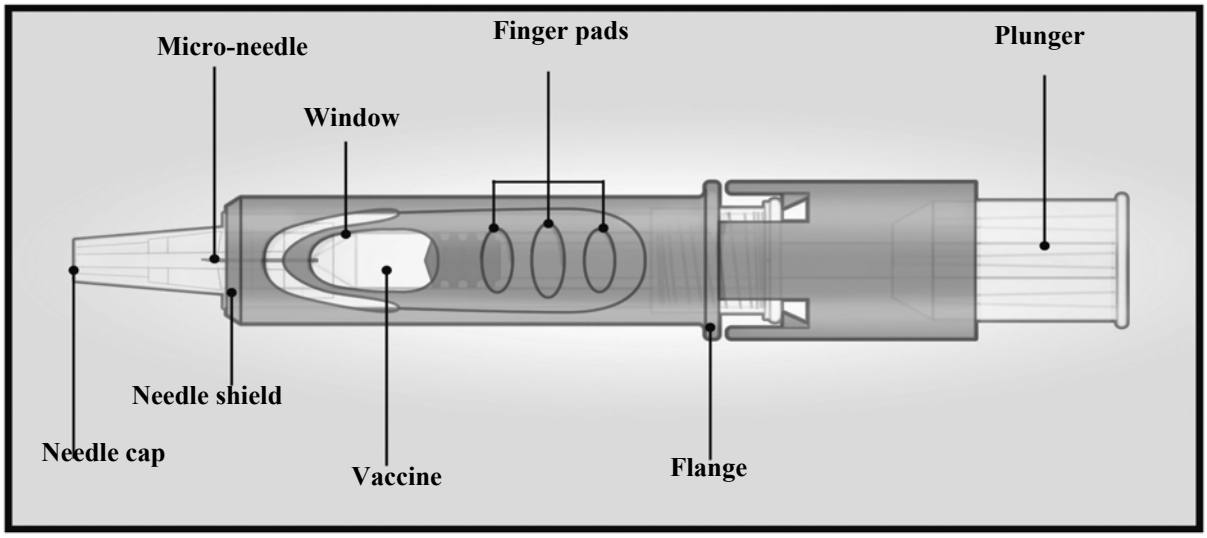
The vaccine should be allowed to reach room temperature before use.

The vaccine should not be used if foreign particles are present in the suspension.

It is not necessary to shake the vaccine before use.

The Micro-Injection System for intradermal injection consists of a pre-filled syringe with a micro-needle (1.5 mm) and a needle shielding system.
The needle shielding system is designed to cover the micro-needle after use.

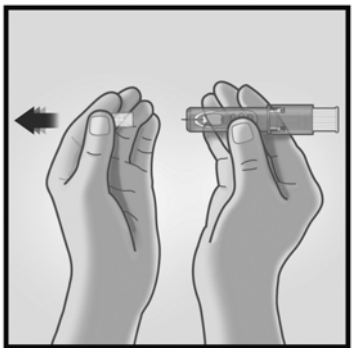
Micro-Injection System



INSTRUCTIONS FOR USE

Please read the instruction before use

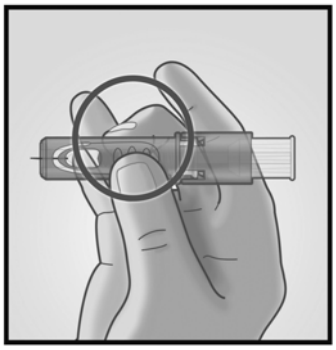
1/ REMOVE NEEDLE CAP



Remove the needle cap from the Micro-Injection System.

Do not purge air through the needle.

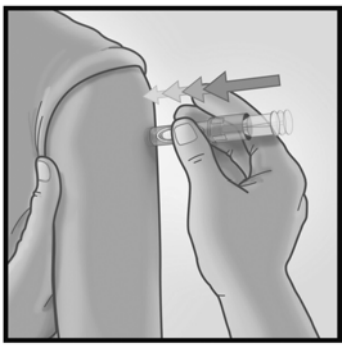
2/ HOLD MICRO-INJECTION SYSTEM BETWEEN THUMB & MIDDLE FINGER



Hold the system by placing the thumb and middle finger only on the finger pads; the index finger remains free.

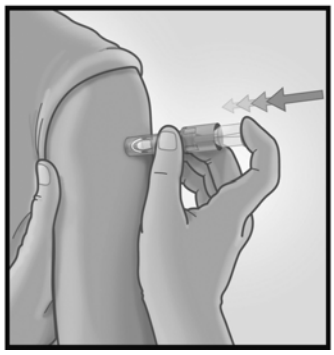
Do not place fingers on the windows.

3/ INSERT NEEDLE RAPIDLY PERPENDICULAR TO THE SKIN



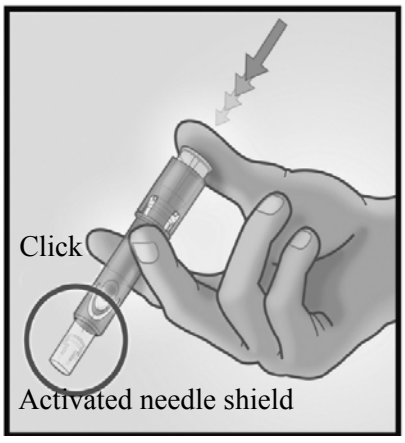
Insert the needle perpendicular to the skin, in the region of the deltoid, in a short, quick movement.

4/ INJECT USING THE INDEX FINGER



Once the micro-needle has been inserted, maintain a light pressure on the surface of the skin and inject using the index finger to push on the plunger. The vein test is unnecessary.

5/ ACTIVATE NEEDLE SHIELD BY PUSHING FIRMLY ON PLUNGER



Remove the needle from the skin.

Orient the needle away from you and others.

With the same hand, push very firmly with the thumb on the plunger to activate the needle shield.
You hear a click and a shield comes out to cover the needle.
Immediately dispose of the system in the nearest sharps collector.

Injection is considered successful whether or not the presence of a wheal is observed.

In case of presence of liquid at the injection site after vaccine administration, re-vaccination is not required.

7. MARKETING AUTHORISATION HOLDER

Sanofi Pasteur SA, 2, avenue Pont Pasteur, F-69007 Lyon, France.

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/08/507/001
EU/1/08/507/002
EU/1/08/507/003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24 February 2009

10. DATE OF REVISION OF THE TEXT

MM/YYYY

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

1. NAME OF THE MEDICINAL PRODUCT

IDflu 15 microgram/strain suspension for injection
Influenza vaccine (split virion, inactivated)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Split Influenza virus*, inactivated, containing antigens equivalent to the following strains:

A/New Caledonia/20/99 (H1N1) like strain (A/New Caledonia/20/99 (IVR-116))
15 micrograms HA**

A/Wisconsin/67/2005 (H3N2) like strain (A/Wisconsin/67/2005 (NYMC X-161))
15 micrograms HA**

B/Malaysia/2506/2004 like strain (B/Malaysia/2506/2004) 15 micrograms HA**

Per 0.1 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin

This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU decision for the 2006/2007 season.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Colourless and opalescent suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylaxis of influenza in individuals 60 years of age and over, especially in those who run an increased risk of associated complications.

The use of IDflu should be based on official recommendations.

4.2 Posology and method of administration

Individuals 60 years of age and over: 0.1 ml.

Immunisation should be carried out by intradermal route.
The recommended site of administration is the region of the deltoid.

For instructions for use, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients, to egg, chicken proteins, neomycin, formaldehyde and octoxinol 9. IDflu does not contain more than 0.05 microgram ovalbumin per dose.

Immunisation shall be postponed in subjects with febrile illness or acute infection.

4.4 Special warnings and precautions for use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

IDflu should under no circumstances be administered intravascularly.

Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

In case of presence of liquid at the injection site after vaccine administration, re-vaccination is not required.

4.5 Interaction with other medicinal products and other forms of interaction

IDflu may be given at the same time as other vaccines. Immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified.

The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.

Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA test results. The transient false positive reactions could be due to the IgM response by the vaccine.

4.6 Pregnancy and lactation

This vaccine is intended for individuals 60 years of age and over. Therefore, this information is not applicable.

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.
The vaccine is unlikely to produce an effect on the ability to drive and use machines.

4.8 Undesirable effects

<u>Adverse reactions observed from clinical trials</u>

The safety of IDflu has been assessed in 3 open-label randomised clinical trials, 3,372 vaccinees received an injection of IDflu.

Safety evaluation was performed for all subjects during the first 3 weeks following vaccination and serious adverse reactions were collected during six months of follow-up for 2,974 subjects (population of two out of the three clinical trials)..

The most common reactions occurring after vaccine administration were local reactions at injection site.
Apparent local reactions after intradermal administration were more frequent than after intramuscular administration of an adjuvanted or non-adjuvanted comparator vaccine.

Most reactions resolved spontaneously within 1 to 3 days after onset.

Systemic safety profile of IDflu is similar to the comparator vaccine, adjuvanted or non-adjuvanted, administered intramuscularly.

After repetitive yearly injections the safety profile of IDflu is similar to the previous injections.

The data below summarizes the frequencies of the adverse reactions that were recorded following vaccination, using the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1000); very rare (<1/10,000), not known (cannot be estimated from available data).

Organ class	**Very common**	**Common**	**Uncommon**	**Rare**	**Very rare**
Nervous system disorders	Headache			Paresthesia, neuritis	
Skin and subcutaneous tissue disorders			Sweating	Pruritus, rash	
Musculoskeletal and connective tissue disorders	Myalgia		Arthralgia		
General disorders and administration site conditions	Local reactions: redness*, induration swelling, pruritus, pain	Malaise, shivering, fever, Local reactions: ecchymosis	Fatigue		

*In some cases, local redness lasted up to 7 days.

Adverse reactions from Post-Marketing surveillance

There is no safety data from post-marketing experience with IDflu.
However, based on the experience with trivalent inactivated influenza vaccines administered by intramuscular or deep subcutaneous injection, systemic reactions, not listed above, may be reported:

Blood and lymphatic system disorders
Transient thrombocytopenia, transient lymphadenopathy

Immune system disorders
Allergic reactions, in rare cases leading to shock, angioedema

Nervous system disorders
Neuralgia, febrile convulsions, neurological disorders, such as encephalomyelitis and Guillain Barré syndrome

Vascular disorders
Vasculitis associated in very rare cases with transient renal involvement

Skin and subcutaneous tissue disorders
Generalised skin reactions including urticaria

4.9 Overdose

Overdose is unlikely to have any untoward effect.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccines, ATC code: J07BB02

Immunogenicity

Seroprotection is generally obtained within 2 to 3 weeks. The duration of postvaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6-12 months.

In a pivotal randomised comparative phase III trial, 2,606 subjects over 60 years of age received 0.1 ml of IDflu by intradermal route and 1,089 subjects over 60 years of age received 0.5 ml of a trivalent inactivated influenza vaccine administered by intramuscular route.

In this comparative trial the geometric mean titres (GMTs), seroprotection rate*, seroconversion or significant increase rate** and the geometric mean titre ratio (GMTR) for anti-HA antibody (measured by HI) were assessed according to predefined criteria.

Data were as follows (values in brackets show the 95% confidence intervals):

	Intradermal 15µg		
	A/H1N1	**A/H3N2**	**B**
	A/New Caledonia/ 20/99	**A/Wisconsin/ 67/2005**	**B/Malaysia/ 2506/2004**
	N = 2,585	**N = 2,586**	**N = 2,582**
Geometric mean of titre (1/dil)	81.7 (78.0 ; 85.6)	298.0 (282 ; 315)	39.9 (38.3 ; 41.6)
Seroprotection rate (%) *	77.0 (75.3 ; 78.6)	93.3 (92.3 ; 94.3)	55.7 (53.8 ; 57.6)
Seroconversion or significant increase rate (%) **	38.7 (36.8 ; 40.6)	61.3 (59.3 ; 63.1)	36.4 (34.5 ; 38.3)
Geometric mean of titre ratio (GMTR)	3.97 (3.77 ; 4.18)	8.19 (7.68 ; 8.74)	3.61 (3.47 ; 3.76)

*Seroprotection = HI titre ≥ 40
** Seroconversion = negative pre-vaccination HI titre and post vaccination HI titre ≥ 40, Significant increase = positive pre-vaccination HI titre and at least a 4-fold increase in post-vaccination HI titre
GMTR: Geometric mean titre ratio of individual (post-/pre-vaccination titre).

IDflu is at least as immunogenic as the comparator trivalent inactivated influenza vaccine administered by intramuscular route for each of the 3 influenza strains in subjects from 60 years of age and over.

Across all three influenza strains, for the comparator intramuscular vaccine GMTs ranged between 34.8 (1/dil) and 181.0 (1/dil), seroprotection rates ranged between 48.9% and 87.9%, seroconversion or significant increase rates ranged between 30.0% and 46.9% and GMTRs ranged between 3.04 and 5.35-fold over baseline HI titres.

In a randomised comparative phase III trial, 398 subjects over 65 years of age received 0.1 ml of IDflu by intradermal route and 397 subjects over 65 years of age received 0.5 ml of a trivalent inactivated adjuvanted (MF-59 containing) influenza vaccine at the same dosage administered by intramuscular route.

IDflu is as immunogenic as the comparator trivalent adjuvanted (MF-59 containing) vaccine in terms of GMT for each of the 3 influenza strains with the SRH method and for 2 strains with the HI method.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Non-clinical data revealed no special hazard for humans based on animal studies. The vaccine was immunogenic in mice and rabbits. In repeated-dose toxicity studies in rabbits there was no significant evidence of systemic toxicity. Nevertheless, single and repeated administrations led to transient local erythema and oedema. Genotoxicity and carcinogenic potential were not assessed because these studies are not appropriate for a vaccine. Fertility and toxicity studies to reproduction in females have not identified any specific potential hazard for humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Potassium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf-life

1 year

6.4 Special precautions for storage

Store in a refrigerator (2°C-8°C). Do not freeze.
Keep the syringe in the outer carton in order to protect from light.

6.5 Nature and contents of container

0.1 ml of suspension in a pre-filled syringe (type I glass) with a Micro-Injection System, with attached micro-needle, equipped with an elastomer plunger stopper (chlorobutyl), a tip cap (thermoplastic elastomer and polypropylene) and a needle shielding system. Pack size of 1 or 10 or 20.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused vaccine or waste material should be disposed of in accordance with local requirements.

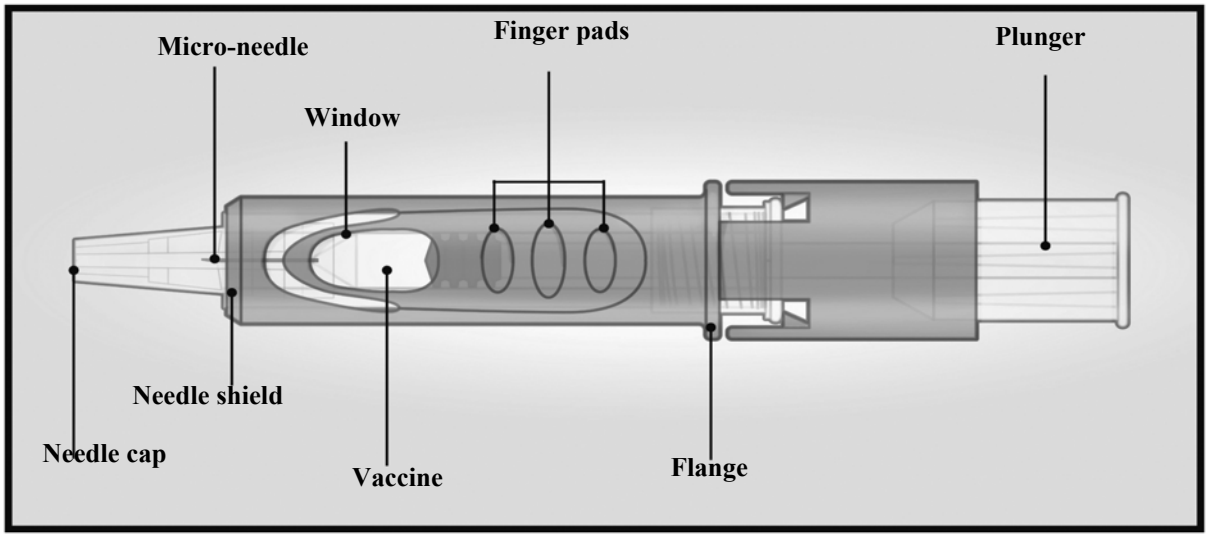
The vaccine should be allowed to reach room temperature before use.

The vaccine should not be used if foreign particles are present in the suspension.

It is not necessary to shake the vaccine before use.

The Micro-Injection System for intradermal injection consists of a pre-filled syringe with a micro-needle (1.5 mm) and a needle shielding system.
The needle shielding system is designed to cover the micro-needle after use.

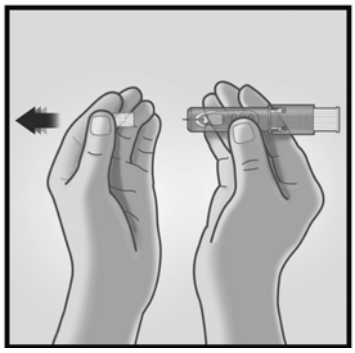
Micro-Injection System



INSTRUCTIONS FOR USE

Please read the instruction before use

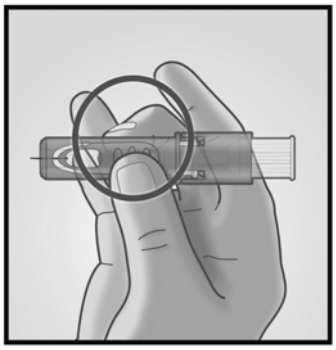
1/ REMOVE NEEDLE CAP



Remove the needle cap from the Micro-Injection System.

Do not purge air through the needle.

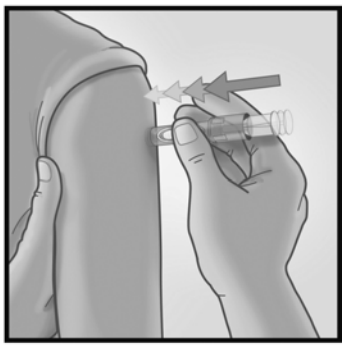
2/ HOLD MICRO-INJECTION SYSTEM BETWEEN THUMB & MIDDLE FINGER



Hold the system by placing the thumb and middle finger only on the finger pads; the index finger remains free.

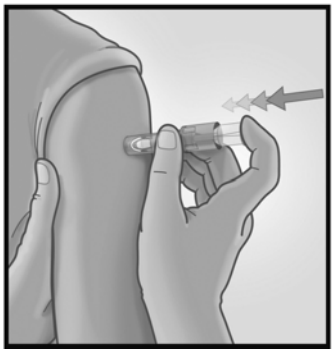
Do not place fingers on the windows.

3/ INSERT NEEDLE RAPIDLY PERPENDICULAR TO THE SKIN



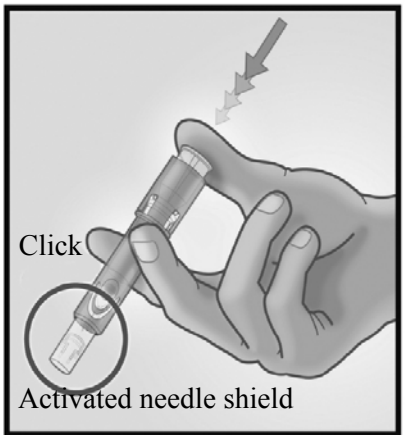
Insert the needle perpendicular to the skin, in the region of the deltoid, in a short, quick movement.

4/ INJECT USING THE INDEX FINGER



Once the micro-needle has been inserted, maintain a light pressure on the surface of the skin and inject using the index finger to push on the plunger. The vein test is unnecessary.

5/ ACTIVATE NEEDLE SHIELD BY PUSHING FIRMLY ON PLUNGER



Remove the needle from the skin.

Orient the needle away from you and others.

With the same hand, push very firmly with the thumb on the plunger to activate the needle shield.
You hear a click and a shield comes out to cover the needle.
Immediately dispose of the system in the nearest sharps collector.

Injection is considered successful whether or not the presence of a wheal is observed.

In case of presence of liquid at the injection site after vaccine administration, re-vaccination is not required.

7. MARKETING AUTHORISATION HOLDER

Sanofi Pasteur SA, 2, avenue Pont Pasteur, F-69007 Lyon, France.

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/08/507/004
EU/1/08/507/005
EU/1/08/507/006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24 February 2009

10. DATE OF REVISION OF THE TEXT

MM/YYYY

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDERS RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

Sanofi Pasteur
Parc Industriel d'Incarville
27100 Val-de-Reuil
France

Name and address of the manufacturers responsible for batch release

Sanofi Pasteur
Parc Industriel d'Incarville
27100 Val-de-Reuil
France

Sanofi Pasteur
Campus Mérieux
1541, avenue Marcel Mérieux
69280 Marcy l'Etoile
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.

- **CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

Not applicable.

- **OTHER CONDITIONS**

Pharmacovigilance system
The MAH must ensure that the system of pharmacovigilance, as described in version 8.0 presented in Module 1.8.1. of the Marketing Authorisation Application, is in place and functioning before and whilst the product is on the market.

Risk Management Plan
The MAH commits to performing the studies and additional pharmacovigilance activities detailed in the Pharmacovigilance Plan, as agreed in version 3.0 of the Risk Management Plan (RMP) presented in Module 1.8.2. of the Marketing Authorisation Application and any subsequent updates of the RMP agreed by the CHMP.

As per the CHMP Guideline on Risk Management Systems for medicinal products for human use, the updated RMP should be submitted at the same time as the next Periodic Safety Update Report (PSUR).

In addition, an updated RMP should be submitted

- When new information is received that may impact on the current Safety Specification, Pharmacovigilance Plan or risk minimisation activities
- Within 60 days of an important (pharmacovigilance or risk minimisation) milestone being reached
- At the request of the European Medicines Agency

Official batch release: in accordance with Article 114 Directive 2001/83/EC as amended, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Pack of 1 or 10 or 20 pre-filled syringe(s) with a Micro-Injection System

1. NAME OF THE MEDICINAL PRODUCT

IDflu 9 microgram/strain, suspension for injection
Influenza vaccine (split virion, inactivated).
Strains 2006/2007

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Split Influenza virus*, inactivated, containing antigens equivalent to the following strains:

A/New Caledonia/20/99 (H1N1) like strain (IVR-116) 9 micrograms HA**

A/Wisconsin/67/2005 (H3N2) like strain (NYMC X-161) 9 micrograms HA**

B/Malaysia/2506/2004 like strain 9 micrograms HA**

Per 0.1 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin

3. LIST OF EXCIPIENTS

Sodium chloride, potassium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate and water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Suspension for injection
Pre-filled syringe with a Micro-Injection System (0.1 ml) - pack of 1
Pre-filled syringe with a Micro-Injection System (0.1 ml) - pack of 10
Pre-filled syringe with a Micro-Injection System (0.1 ml) - pack of 20

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intradermal use.
Read the package leaflet before 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

IDflu does not contain more than 0.05 microgram ovalbumin per dose.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.
Keep the syringe in the outer carton in order to protect from light.

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

Sanofi Pasteur SA,
2, avenue Pont Pasteur
F-69007 Lyon
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/08/507/001 - pack of 1 pre-filled syringe with a Micro-Injection System
EU/1/08/507/002 - pack of 10 pre-filled syringes with a Micro-Injection System
EU/1/08/507/003 - pack of 20 pre-filled syringes with a Micro-Injection System

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille is accepted.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Pack of 1 or 10 or 20 pre-filled syringe(s) with a Micro-Injection System

1. NAME OF THE MEDICINAL PRODUCT

IDflu 15 microgram/strain, suspension for injection
Influenza vaccine (split virion, inactivated).
Strains 2006/2007

2. STATEMENT OF ACTIVE SUBSTANCES

Split Influenza virus*, inactivated, containing antigens equivalent to the following strains:

A/New Caledonia/20/99 (H1N1) like strain (IVR-116) 15 micrograms HA**

A/Wisconsin/67/2005 (H3N2) like strain (NYMC X-161) 15 micrograms HA**

B/Malaysia/2506/2004 like strain 15 micrograms HA**

Per 0.1 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin

3. LIST OF EXCIPIENTS

Sodium chloride, potassium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate and water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Suspension for injection
Pre-filled syringe with a Micro-Injection System (0.1 ml) - pack of 1
Pre-filled syringe with a Micro-Injection System (0.1 ml) - pack of 10
Pre-filled syringe with a Micro-Injection System (0.1 ml) - pack of 20

5. METHOD AND ROUTE OF ADMINISTRATION

Intradermal use.
Read the package leaflet before 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

IDflu does not contain more than 0.05 microgram ovalbumin per dose.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in refrigerator. Do not freeze.
Keep the syringe in the outer carton in order to protect from light.

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

Sanofi Pasteur SA,
2, avenue Pont Pasteur
F-69007 Lyon
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/08/507/004 - pack of 1 pre-filled syringe with a Micro-Injection System
EU/1/08/507/005 - pack of 10 pre-filled syringes with a Micro-Injection System
EU/1/08/507/006 - pack of 20 pre-filled syringes with a Micro-Injection System

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille is accepted.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Pre-filled syringe label text

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

IDflu 9 µg/strain 2006/2007
Influenza vaccine
Intradermal use

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

0.1 ml

6. OTHER

Sanofi Pasteur SA

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Pre-filled syringe label text

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

IDflu 15 µg/strain 2006/2007
Influenza vaccine
Intradermal use

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

0.1 ml

6. OTHER

Sanofi Pasteur SA

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

IDflu 9 microgram/strain suspension for injection
Influenza vaccine (split virion, inactivated)

Read all of this leaflet carefully before you receive this vaccine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you. Do not pass it on to others.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT IDflu IS AND WHAT IT IS USED FOR

IDflu is a vaccine. This vaccine is recommended to help to protect you against flu.
The vaccine may be administered to adults up to 59 years of age, especially in those who run an increased risk of associated complications.

When an injection of IDflu is given, the immune system (body's natural defences) will develop protection against flu infection.
IDflu will help to protect you against the three strains of virus contained in the vaccine, or other strains closely related to them. Full effect of the vaccine is generally achieved 2-3 weeks after the vaccination.

2. BEFORE YOU USE IDflu

Do not use IDflu

- If you are allergic (hypersensitive) to:
  - The active substances, or any of the other ingredients of IDflu listed in section 6 of this leaflet in the section "FURTHER INFORMATION",
  - To eggs, chicken proteins, neomycin, formaldehyde and octoxinol 9.
- If you have an illness with fever or acute infection, the vaccination shall be postponed until after you have recovered.

Take special care with IDflu

- You should tell your doctor before vaccination if you have a poor immune response (immunosuppression) due to disease or medicines, because the vaccine may not work very well in this case.

- IDflu should under no circumstances be administered into a vein (intravascularly).

- If, for any reason, you have a blood test within a few days following an influenza vaccination, please tell your doctor. Tests for HIV-1, hepatitis C virus and HTLV-1 may be affected.

- Children and adolescents:
  IDflu is not recommended for use in children and adolescents below 18 years.

Using other medicines

- Other vaccines: IDflu can be given at the same time as other vaccines by using separate limbs. It should be noted that the side effects may be intensified.
- Tell your doctor if you have been treated with medicines that may reduce your immune response such as corticosteroids (for example cortisone), medicines against cancer (chemotherapy), radiotherapy or other medicines affecting the immune system. In this case, the vaccine may not work very well.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Tell your doctor or pharmacist if you are pregnant or think you may be pregnant.
Your doctor or pharmacist will be able to decide if you should receive IDflu.
The vaccine IDflu may be used during breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.
The vaccine is unlikely to affect your ability to drive or use machines.

3. HOW TO USE IDflu

IDflu is administered to you by your doctor or nurse.

Adults from 18 to 59 of age receive one 0.1 ml dose.

IDflu is given as an injection into the upper layer of the skin (preferably the muscle of the upper arm).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, IDflu can cause side effects, although not everybody gets them.
During clinical trials, the following side effects were reported with the use of IDflu.

The frequency of possible side effects listed below is defined using the following convention:
very common (affects more than 1 user in 10)
common (affects 1 to 10 users in 100)
uncommon (affects 1 to 10 users in 1,000)
rare (affects 1 to 10 users in 10,000)
very rare (affects less than 1 user in 10,000)
not known (frequency cannot be estimated from the available data).

Very common
- At the injection site: redness, swelling, hardness, itching and pain.
- Feeling generally unwell, headache and muscular pain.

Common
- Bruising at the injection site
- Shivering and fever (38.0°C or higher).

Uncommon
- Tiredness, swelling of the glands in the neck, armpit or groin, tingling or numbness, joint pain, itching and rash.

Rare
- Increased sweating.

The following side effects have been reported with other influenza vaccines:
- temporary reduction in the number of blood particles called platelets which can result in bruising or bleeding
- allergic reactions which can lead in rare cases:
  - to a failure of the circulatory system (shock) leading to medical emergency
  - to swollen face, tongue or pharynx, difficulty to swallow, hives and difficulties to breathe (angioedema)
- pain located on the nerve route, convulsions associated with fever, nervous system disorders including inflammation of the brain or spinal cord, inflammation of nerves, or Guillain-Barré syndrome which causes extreme weakness and paralysis
- vessel inflammation which may result in very rare cases in temporary kidney problems
- skin reactions that may spread throughout the body including hives.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You should see your doctor immediately if you experience symptoms of angioedema, such as:
- swollen face, tongue or pharynx
- difficulty to swallow
- hives and difficulties to breathe.

5. HOW TO STORE IDflu

Keep out of the reach and sight of children.

Do not use IDflu after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the syringe in the outer carton in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What IDflu contains

The active substances are split Influenza virus*, inactivated, containing antigens equivalent to the following strains:

A/New Caledonia/20/99 (H1N1) like strain (A/New Caledonia/20/99 (IVR-116)) 9 micrograms HA**

A/Wisconsin/67/2005 (H3N2) like strain (A/Wisconsin/67/2005 (NYMC X-161))
9 micrograms HA**

B/ Malaysia/2506/2004 like strain (B/Malaysia/2506/2004) 9 micrograms HA**

Per 0.1 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin

This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU decision for the 2006/2007 season.

The other ingredients are: sodium chloride, potassium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate and water for injections.

What IDflu looks like and contents of the pack

The vaccine is a colourless and opalescent suspension.

IDflu is a suspension for injection in a pre-filled syringe of 0.1 ml with a Micro-Injection System in packs of 1, 10 or 20.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Sanofi Pasteur SA, 2, avenue Pont Pasteur, F-69007 Lyon, France.

Manufacturer:
Sanofi Pasteur – Parc Industriel d'Incarville - 27100 Val-de-Reuil - France
Sanofi Pasteur, Campus Mérieux – 1541, avenue Marcel Mérieux – 69280 Marcy l'Etoile – France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/France/Belgien Sanofi Pasteur MSD Tél/Tel: +32 2 726.9584	**Luxembourg/Luxemburg** Sanofi Pasteur MSD Tél: +32 2 726.9584
България Sanofi Pasteur representative Office Тел.: +359 2 980 08 33	**Magyarország** sanofi-aventis zrt Tel.: +36 1 505 2723

Česká republika Sanofi Pasteur Odd. Vakcín Sanofi-aventis, s.r.o. Tel.: +420 222 522 523 Tel: +420 233 086 111	**Malta** Cherubino Ltd Tel.: +356 21 343270
Danmark Sanofi Pasteur MSD Tlf: +45 23 32 69 29	**Nederland** Sanofi Pasteur MSD Tel: +31.23.567.96.00
Deutschland Sanofi Pasteur MSD GmbH Tel: +49 6224.594.0	**Norge** Sanofi Pasteur MSD Tlf: +47.67.50.50.20
Eesti Sanofi-Aventis Estonia OÜ Tel.: +372 627 3488	**Österreich** Sanofi Pasteur MSD GmbH Tel: +43.1.866.70.22.202
Ελλάδα BIANEΞ A.E. Τηλ: +30.210.8009111	**Polska** Sanofi Pasteur Sp. Z o.o. Tel.: +48 22 280 05 00
España Sanofi Pasteur MSD S.A. Tel: +34.91.371.78.00	**France** Sanofi Pasteur MSD, SA Tel: +351 21 470 4550
France Sanofi Pasteur MSD SNC Tél: +33.4.37.28.40.00	**România** Sanofi pasteur – Representative Office Tel.: +40(21) 317 31 36
Ireland Sanofi Pasteur MSD Ltd Tel: +353 1 468 5600	**Slovenija** ALPE s.p. Tel.: +386 (0)1 432 62 38
Ísland Sanofi Pasteur MSD Sími: +32.2.726.95.84	**Slovenská republika** Sanofi Aventis, divízia vakcíny Tel.: +421 2 57 103 777
Italia Sanofi Pasteur MSD Spa Tel: +39 06.664.09.211	**Suomi/Finland** Sanofi Pasteur MSD Puh/Tel: +358.9.565.88.30
Κύπρος Γ. Α. Σταμάτης & Σια Λτδ. Τηλ.: +357 – 22 76 62 76	**Sverige** Sanofi Pasteur MSD Tel: +46.8.564.888.60
Latvija Sanofi Aventis Latvia SIA Vakcīnu nodaļa Tel.: +371 7103010	**United Kingdom** Sanofi Pasteur MSD Ltd Tel: +44.1.628.785.291
Lietuva Sanofi – Aventis Lietuva, UAB Tel.: +370 5 2730967	

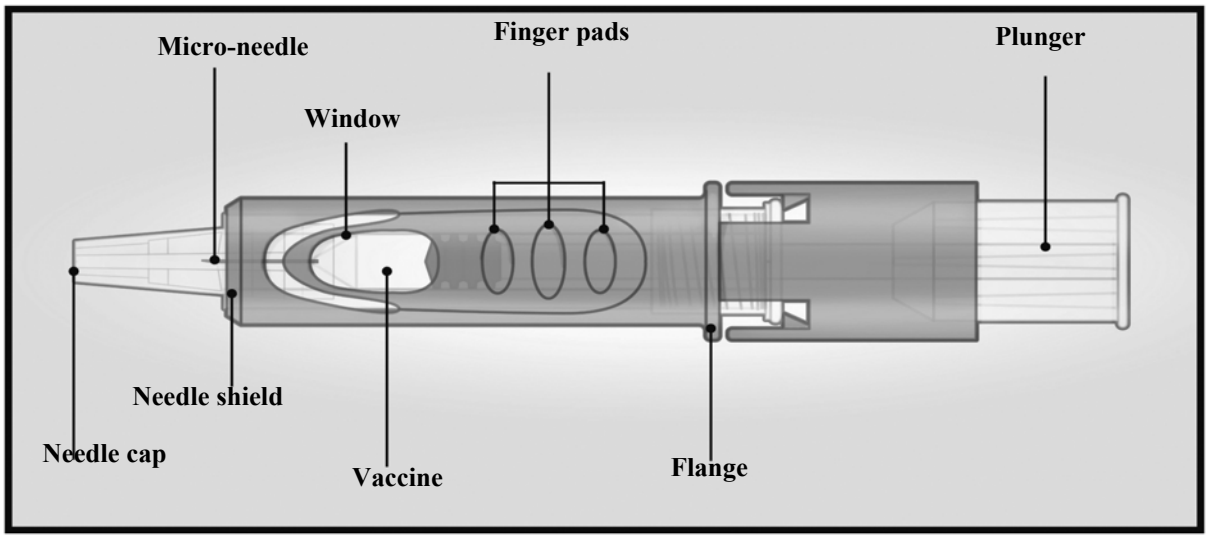
This leaflet was last approved in {MM/YYYY}.

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/

The following information is intended for medical or healthcare professionals only:

- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of anaphylactic event following the administration of the vaccine.
- The vaccine should be allowed to reach room temperature before use.
- The vaccine should not be used if foreign particles are present in the suspension.
- It is not necessary to shake the vaccine before use.
- The Micro-Injection System for intradermal injection consists of a pre-filled syringe with a micro-needle (1.5 mm) and a needle shielding system.
  The needle shielding system is designed to cover the micro-needle after use.

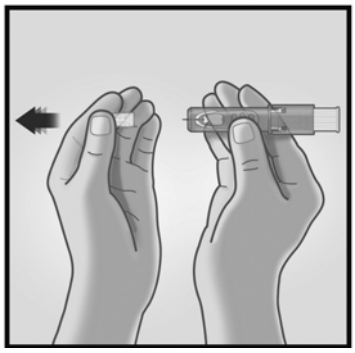
Micro-Injection System



INSTRUCTIONS FOR USE

Please read the instruction before use

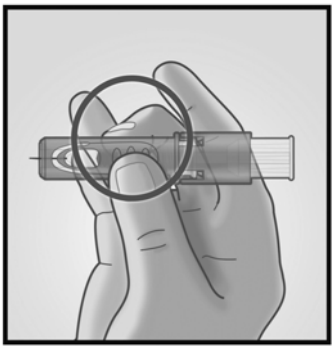
1/ REMOVE NEEDLE CAP



Remove the needle cap from the Micro-Injection System.

Do not purge air through the needle.

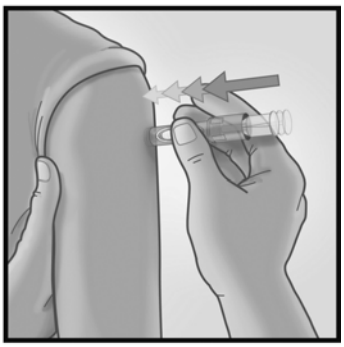
2/ HOLD MICRO-INJECTION SYSTEM BETWEEN THUMB & MIDDLE FINGER



Hold the system by placing the thumb and middle finger only on the finger pads; the index finger remains free.

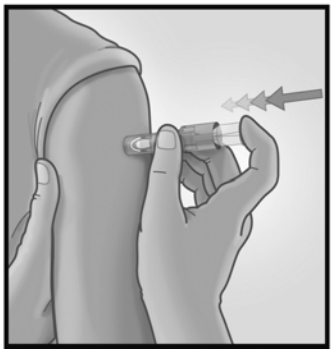
Do not place fingers on the windows.

3/ INSERT NEEDLE RAPIDLY PERPENDICULAR TO THE SKIN



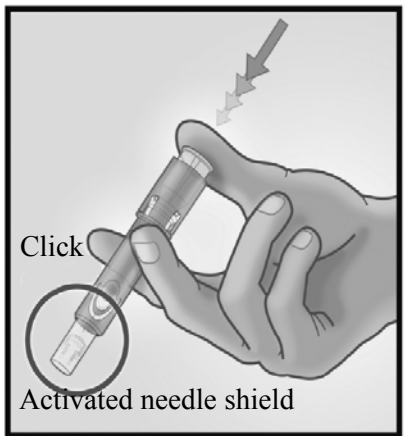
Insert the needle perpendicular to the skin, in the region of the deltoid, in a short, quick movement.

4/ INJECT USING THE INDEX FINGER



Once the micro-needle has been inserted, maintain a light pressure on the surface of the skin and inject using the index finger to push on the plunger. The vein test is unnecessary.

5/ ACTIVATE NEEDLE SHIELD BY PUSHING FIRMLY ON PLUNGER



Remove the needle from the skin.

Orient the needle away from you and others.

With the same hand, push very firmly with the thumb on the plunger to activate the needle shield.
You hear a click and a shield comes out to cover the needle.
Immediately dispose of the system in the nearest sharps collector.

Injection is considered successful whether or not the presence of a wheal is observed.

In case of presence of liquid at the injection site after vaccine administration, re-vaccination is not required.

See also section 3. HOW TO USE IDflu

PACKAGE LEAFLET: INFORMATION FOR THE USER

IDflu 15 microgram/strain suspension for injection
Influenza vaccine (split virion, inactivated)

Read all of this leaflet carefully before you receive this vaccine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you. Do not pass it on to others.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT IDflu IS AND WHAT IT IS USED FOR

IDflu is a vaccine.
This vaccine is recommended to help to protect you against flu.
The vaccine may be administered to individuals of 60 years of age and over, especially in those who run an increased risk of associated complications.

When an injection of IDflu is given, the immune system (body's natural defences) will develop protection against flu infection.
IDflu will help to protect you against the three strains of virus contained in the vaccine, or other strains closely related to them. Full effect of the vaccine is generally achieved 2-3 weeks after the vaccination.

2. BEFORE YOU USE IDflu

Do not use IDflu

- If you are allergic (hypersensitive) to:
  - The active substances or any of the other ingredients of IDflu listed in section 6 of this leaflet in the section "FURTHER INFORMATION",
  - To eggs, chicken proteins, neomycin, formaldehyde and octoxinol 9.
- If you have an illness with fever or acute infection, the vaccination shall be postponed until after you have recovered.

Take special care with IDflu

- You should tell your doctor before vaccination if you have a poor immune response (immunosuppression) due to disease or medicines, because the vaccine may not work very well in this case.

- IDflu should under no circumstances be administered into a vein (intravascularly).

- If, for any reason, you have a blood test within a few days following an influenza vaccination, please tell your doctor. Tests for HIV-1, hepatitis C virus and HTLV-1 may be affected.

Using other medicines

- Other vaccines: IDflu can be given at the same time as other vaccines by using separate limbs. It should be noted that the side effects may be intensified.
- Tell your doctor if you have been treated with medicines that may reduce your immune response such as corticosteroids (for example cortisone), medicines against cancer (chemotherapy), radiotherapy or other medicines affecting the immune system. In this case, the vaccine may not work very well.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

This vaccine is intended for individuals 60 years of age and over. Therefore, this information is not applicable.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.
The vaccine is unlikely to affect your ability to drive or use machines.

3. HOW TO USE IDflu

IDflu is administered to you by your doctor or nurse.

Individuals 60 years of age and over receive one 0.1 ml dose.

IDflu is given as an injection into the upper layer of the skin (preferably the muscle of the upper arm).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, IDflu can cause side effects, although not everybody gets them.
During clinical trials, the following side effects were reported with the use of IDflu.

The frequency of possible side effects listed below is defined using the following convention:
very common (affects more than 1 user in 10)
common (affects 1 to 10 users in 100)
uncommon (affects 1 to 10 users in 1,000)
rare (affects 1 to 10 users in 10,000)
very rare (affects less than 1 user in 10,000)
not known (frequency cannot be estimated from the available data).

<u>Very common</u>
- At the injection site: redness, hardness, swelling, itching and pain.
- Headache and muscular pain.

<u>Common</u>
- Bruising at the injection site
- Feeling generally unwell, fever (38.0°C or higher) and shivering.

Uncommon
- Tiredness, joint pain and increased sweating.

Rare
- tingling or numbness, pain, loss of reflexes, paralysis on a nerve route, itching and rash.

The following side effects have been reported with other influenza vaccines:
- temporary reduction in the number of blood particles called platelets which can result in bruising or bleeding, temporary swelling of the glands in the neck, armpit or groin
- allergic reactions which can lead in rare cases:
  - to a failure of the circulatory system (shock) leading to medical emergency
  - to swollen face, tongue or pharynx, difficulty to swallow, hives and difficulties to breathe (angioedema)
- pain located on the nerve route, convulsions associated with fever, nervous system disorders including inflammation of the brain or spinal cord, inflammation of nerves, or Guillain-Barré syndrome which causes extreme weakness and paralysis
- vessel inflammation which may result in very rare cases in temporary kidney problems
- skin reactions that may spread throughout the body including hives.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You should see your doctor immediately if you experience symptoms of angioedema, such as:
- swollen face, tongue or pharynx
- difficulty to swallow
- hives and difficulties to breathe.

5. HOW TO STORE IDflu

Keep out of the reach and sight of children.

Do not use IDflu after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze. Keep the syringe in the outer carton in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What IDflu contains

The active substances are split Influenza virus*, inactivated, containing antigens equivalent to the following strains:

A/New Caledonia/20/99 (H1N1) like strain (A/New Caledonia/20/99 (IVR-116))
15 micrograms HA**

A/Wisconsin/67/2005 (H3N2) like strain (A/Wisconsin/67/2005 (NYMC X-161))
15 micrograms HA**

B/ Malaysia/2506/2004 like strain (B/Malaysia/2506/2004) 15 micrograms HA**

Per 0.1 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin

This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU decision for the 2006/2007 season.

The other ingredients are: sodium chloride, potassium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate and water for injections.

What IDflu looks like and contents of the pack

The vaccine is a colourless and opalescent suspension.

IDflu is a suspension for injection in a pre-filled syringe of 0.1 ml with a Micro-Injection System in packs of 1, 10 or 20.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Sanofi Pasteur SA, 2, avenue Pont Pasteur, F-69007 Lyon, France.

Manufacturer:
Sanofi Pasteur - Parc Industriel d'Incarville - 27100 Val-de-Reuil - France
Sanofi Pasteur, Campus Mérieux – 1541, avenue Marcel Mérieux – 69280 Marcy l'Etoile - France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Latvija Sanofi Aventis Latvia SIA Vakcīnu nodaļa Tel.: +371 7103010	**United Kingdom** Sanofi Pasteur MSD Ltd Tel: +44.1.628.785.291
Lietuva Sanofi – Aventis Lietuva, UAB Tel.: +370 5 2730967	

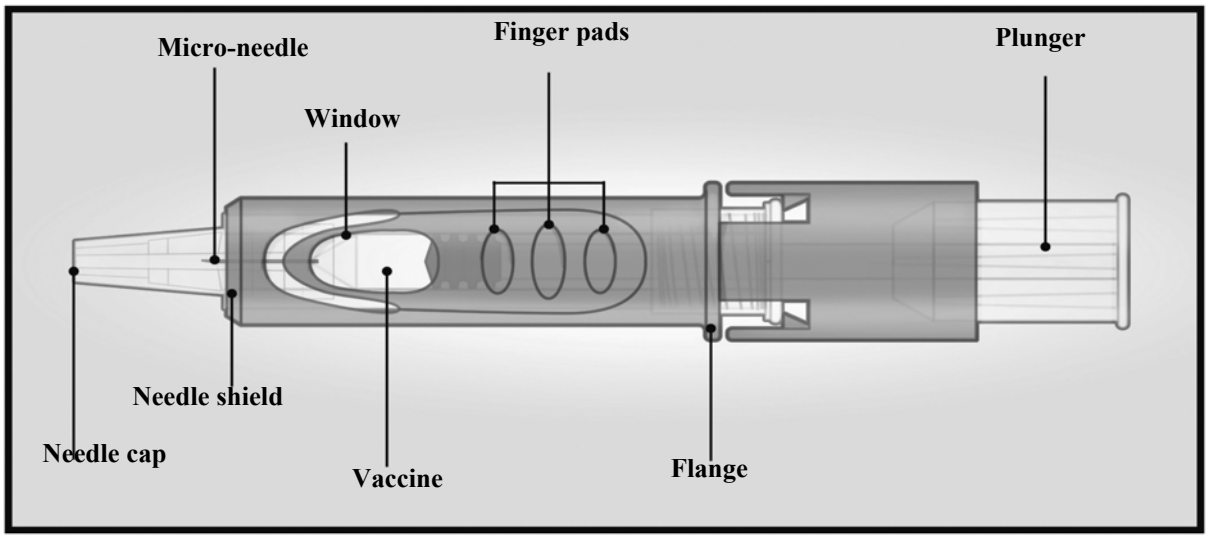
This leaflet was last approved in {MM/YYYY}.

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/

The following information is intended for medical or healthcare professionals only:

- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of anaphylactic event following the administration of the vaccine.
- The vaccine should be allowed to reach room temperature before use.
- The vaccine should not be used if foreign particles are present in the suspension.
- It is not necessary to shake the vaccine before use.
- The Micro-Injection System for intradermal injection consists of a pre-filled syringe with a micro-needle (1.5 mm) and a needle shielding system.
  The needle shielding system is designed to cover the micro-needle after use.

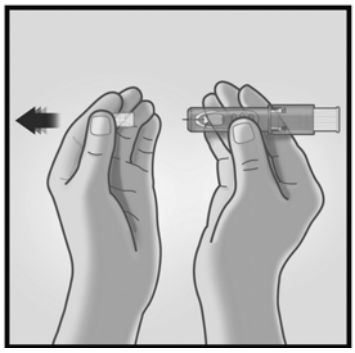
Micro-Injection System



INSTRUCTIONS FOR USE

Please read the instruction before use

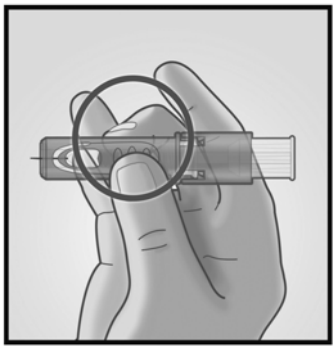
1/ REMOVE NEEDLE CAP



Remove the needle cap from the Micro-Injection System.

Do not purge air through the needle.

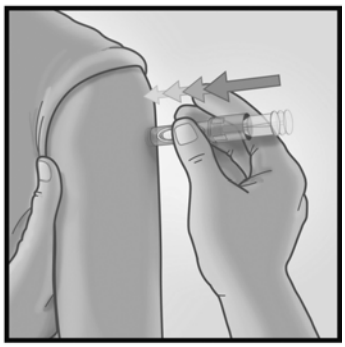
2/ HOLD MICRO-INJECTION SYSTEM BETWEEN THUMB & MIDDLE FINGER



Hold the system by placing the thumb and middle finger only on the finger pads; the index finger remains free.

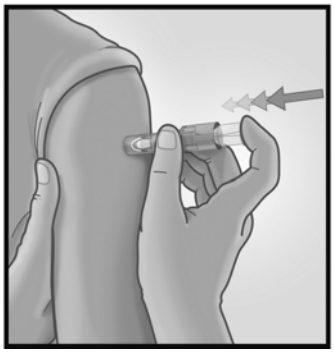
Do not place fingers on the windows.

3/ INSERT NEEDLE RAPIDLY PERPENDICULAR TO THE SKIN



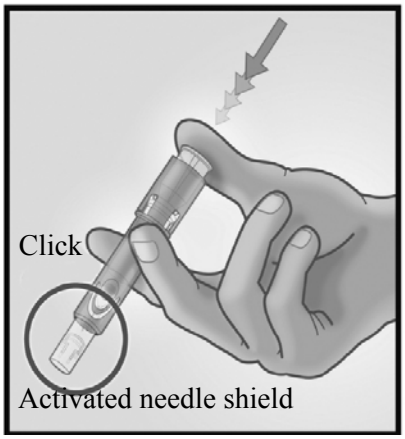
Insert the needle perpendicular to the skin, in the region of the deltoid, in a short, quick movement.

4/ INJECT USING THE INDEX FINGER



Once the micro-needle has been inserted, maintain a light pressure on the surface of the skin and inject using the index finger to push on the plunger. The vein test is unnecessary.

5/ ACTIVATE NEEDLE SHIELD BY PUSHING FIRMLY ON PLUNGER



Remove the needle from the skin.

Orient the needle away from you and others.

With the same hand, push very firmly with the thumb on the plunger to activate the needle shield.
You hear a click and a shield comes out to cover the needle.
Immediately dispose of the system in the nearest sharps collector.

Injection is considered successful whether or not the presence of a wheal is observed.

In case of presence of liquid at the injection site after vaccine administration, re-vaccination is not required.

See also section 3. HOW TO USE IDflu