ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus (inactivated, split) of the following strains*:

A/California/7/2009 (H1N1)pdm09 - like strain (A/California/7/2009, NYMC X-179A) ..... 15 micrograms HA**

A/Hong Kong/4801/2014 (H3N2) - like strain (A/Hong Kong/4801/2014, NYMC X-263B) ..... 15 micrograms HA**

B/Brisbane/60/2008 - like strain (B/Brisbane/60/2008, wild type) ..... 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 2016/2017 season.

For the full list of excipients, see section 6.1.

INTANZA may contain residues of eggs such as ovalbumin and residues of neomycin, formaldehyde and octoxinol 9, which are used during the manufacturing process (see section 4.3).

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 INTANZA should be based on official recommendations.

4.2 Posology and method of administration

Posology
Individuals 60 years of age and over: 0.1 ml.

Paediatric population
INTANZA is not recommended for use in children and adolescents below 18 years due to insufficient data on safety and efficacy.

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

Precautions to be taken before handling or administering the medicinal product
For instructions on preparation of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients listed in section 6.1, or to any residues such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde and octoxinol 9.

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 (see section 4.8).

INTANZA should under no circumstances be administered intravascularly.

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

Very limited data in immunocompromised patients are available for INTANZA.

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

Interference with serological testing: See section 4.5.

4.5 Interaction with other medicinal products and other forms of interaction

INTANZA 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 Fertility, 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

INTANZA has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

a. Summary of the safety profile

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

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 INTANZA is similar to the comparator vaccine, adjuvanted or non-adjuvanted, administered intramuscularly.

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

b. Tabulated summary of adverse reactions

The data below summarizes the frequencies of the adverse reactions that were recorded following vaccination during clinical trials and worldwide post-marketing experience, 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	Not known
Immune system disorders						Allergic reactions including generalized skin reactions such as urticaria, anaphylactic reactions, angioedema, shock
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.

c. Potential adverse events

Based on the experience with trivalent inactivated influenza vaccines administered by intramuscular or deep subcutaneous injection, the following events may be reported:

Blood and lymphatic system disorders
Transient thrombocytopenia, transient lymphadenopathy

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

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

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 INTANZA 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).

INTANZA 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 INTANZA 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.

INTANZA 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 (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 medicinal product or waste material should be disposed of in accordance with local requirements.

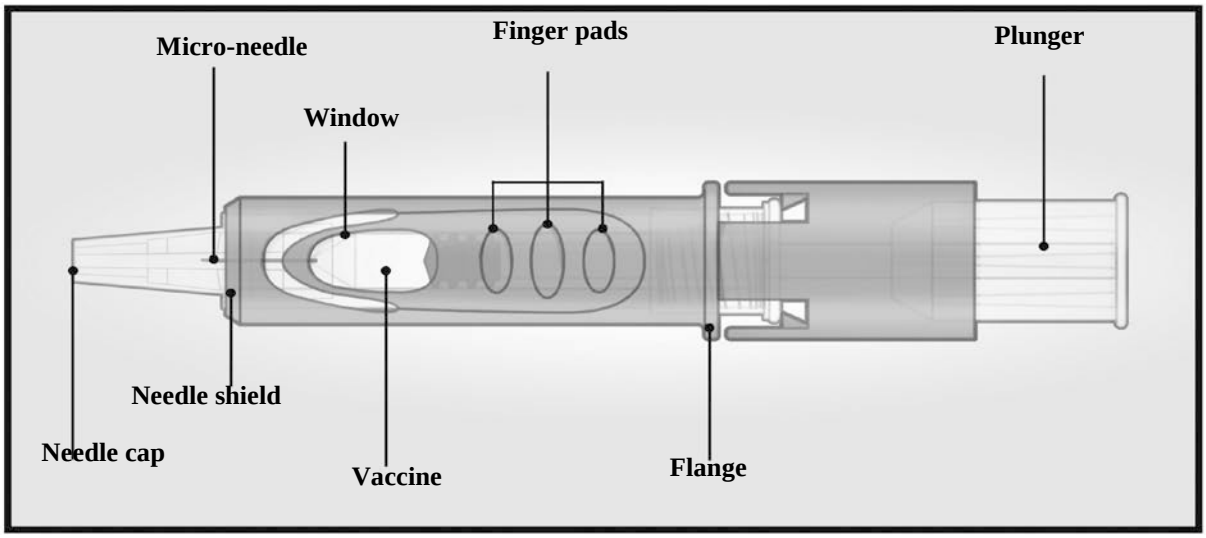
The vaccine should be allowed to reach room temperature before use.

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.

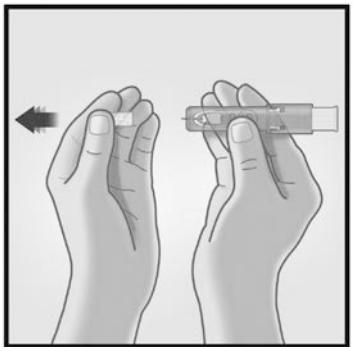
Micro-Injection System



INSTRUCTIONS FOR USE

Please read the instruction before use

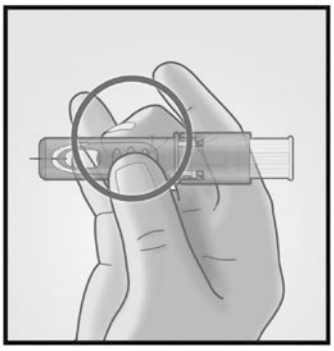
1/ REMOVE NEEDLE CAP



Remove the needle cap from the Micro-Injection System.

Do not purge air through the needle.

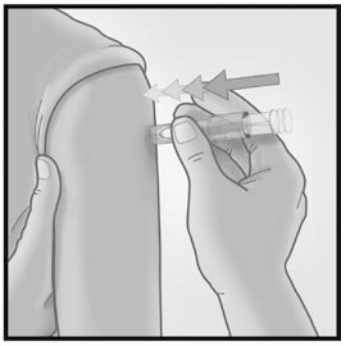
2/ HOLD MICRO-INJECTION SYSTEM BETWEEN THUMB & MIDDLE FINGER



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

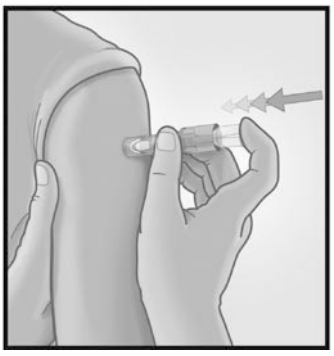
Do not place fingers on the windows.

3/ INSERT NEEDLE RAPIDLY PERPENDICULAR TO THE SKIN



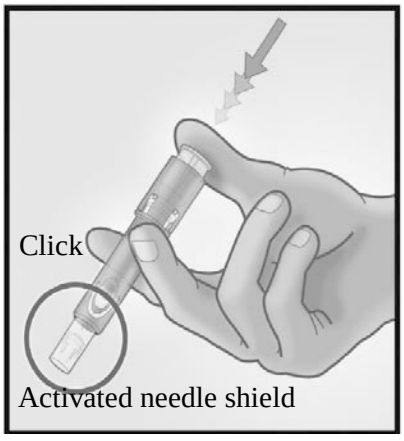
Insert the needle perpendicular to the skin, in the region of the deltoid, in a short, quick movement.

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 Europe, 2 Avenue Pont Pasteur, 69007 Lyon, France.

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/08/505/004
EU/1/08/505/005
EU/1/08/505/006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 February 2009
Date of latest renewal: 24 February 2014

10. DATE OF REVISION OF THE TEXT

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(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) of the biological active substance(s)

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

Name and address of the manufacturer(s) 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 OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

- **Official batch release**

In accordance with Article 114 of Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic Safety Update Reports**

The requirements for submission of periodic safety update reports for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk Management Plan (RMP)**

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information is received that may lead to a significant change to benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

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

INTANZA 15 microgram/strain, suspension for injection
Influenza vaccine (split virion, inactivated)
Strains 2015/2016

2. STATEMENT OF ACTIVE SUBSTANCES

Influenza virus (inactivated, split) of the following strains:

A/California/7/2009 (H1N1)pdm09 - like strain
A/Hong Kong/4801/2014 (H3N2) - like strain
B/Brisbane/60/2008 - like strain
15 µg haemagglutinin per strain per 0.1 ml dose

3. LIST OF EXCIPIENTS

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

4. PHARMACEUTICAL FORM AND CONTENTS

Suspension for injection
1 pre-filled syringe (0.1 ml) with a Micro-Injection System
10 pre-filled syringes (0.1 ml) with a Micro-Injection System
20 pre-filled syringes (0.1 ml) with a Micro-Injection System

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 SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

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 Europe
2 Avenue Pont Pasteur
69007 Lyon
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/08/505/004 - pack of 1 pre-filled syringe with a Micro-Injection System
EU/1/08/505/005 - pack of 10 pre-filled syringes with a Micro-Injection System
EU/1/08/505/006 - pack of 20 pre-filled syringes with a Micro-Injection System

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille is accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:

NN:

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

INTANZA 15 µg/strain 2016/2017
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 Europe

B. PACKAGE LEAFLET

Package leaflet: Information for the user

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

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This vaccine has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What INTANZA is and what it is used for

INTANZA 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 INTANZA is given, the immune system (body's natural defences) will develop protection against flu infection.
INTANZA 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. What you need to know before you use INTANZA

Do not use INTANZA:
- If you are allergic to:
  - The active substances,
  - Any of the other ingredients of this vaccine (listed in section 6),
  - Any component that may be present in very small amounts such as eggs (ovalbumin, 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.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using INTANZA.

- 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.

- This vaccine 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
INTANZA is not recommended for use in children and adolescents below 18 years.

Other vaccines or medicines and INTANZA
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

- Other vaccines: INTANZA 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.

Pregnancy, breast-feeding and fertility
This vaccine is intended for individuals 60 years of age and over. Therefore, this information is not applicable.

Driving and using machines
This vaccine has no or negligible influence on the ability to drive and use machines.

3. How to use INTANZA

Always use this vaccine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 0.1 ml for individuals 60 years of age and over.

INTANZA is administered to you by your doctor or nurse.

INTANZA 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 vaccine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

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.

During clinical trials and after the vaccine came on the market, the following side effects were reported with the use of INTANZA.

<u>Very common reactions (may affect more than 1 in 10 people)</u>
- At the injection site: redness, hardness, swelling, itching and pain.
- Headache and muscular pain.

Common reactions (may affect up to 1 in 10 people)
- Bruising at the injection site.
- Feeling generally unwell, fever (38.0°C or higher) and shivering.

Uncommon reactions (may affect up to 1 in 100 people)
- Tiredness, joint pain and increased sweating.

Rare reactions (may affect up to 1 in 1000 people)
- Tingling or numbness, inflammation of nerves, itching and rash.

Reactions of not known frequency (frequency cannot be estimated from the available data)
- Allergic reactions including skin reactions that may spread throughout the body such as hives, severe allergic reactions (anaphylactic reactions), swollen face, tongue or pharynx, difficulty to swallow, hives and difficulties to breathe (angioedema), failure of the circulatory system (shock) leading to medical emergency.

Most of side effects listed above disappeared without treatment within 1 to 3 days after onset. In some cases, redness at the injection site lasted up to 7 days.

The following side effects have been reported with other vaccines given to prevent flu. These side effects may occur with INTANZA.
- 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.
- Pain located on the nerve route, convulsions associated with fever, nervous system disorders including inflammation of the brain or spinal cord or Guillain-Barré syndrome which causes extreme weakness and paralysis.
- Vessel inflammation which may result in very rare cases in temporary kidney problems.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store INTANZA

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What INTANZA contains

The active substances are Influenza virus (inactivated split) of the following strains*:

A/California/7/2009 (H1N1)pdm09 - like strain (A/California/7/2009, NYMC X-179A) .....15 micrograms HA**
A/Hong Kong/4801/2014 (H3N2) - like strain (A/Hong Kong/4801/2014, NYMC X-263B) .....15 micrograms HA**
B/Brisbane/60/2008 - like strain (B/Brisbane/60/2008, wild type) .....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 2016/2017 season.

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

What INTANZA looks like and contents of the pack

The vaccine is a colourless and opalescent suspension.

INTANZA 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 Europe, 2 Avenue Pont Pasteur, 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/Belgique/Belgien Sanofi Belgium tel.: +32 2 710.54.00	**Lietuva** Sanofi – Aventis Lietuva, UAB Tel.: +370 5 2730967
България Sanofi Bulgaria EOOD Тел.: +359 2 970 53 00	**Luxembourg/Luxemburg** Sanofi Belgium tel.: +32 2 710.54.00
Česká republika Sanofi Pasteur divize vakcín sanofi-aventis, s.r.o. Tel: +420 233 086 111	**Magyarország** sanofi-aventis zrt Tel.: +36 1 505 0055
Danmark sanofi-aventis Denmark A/S Tel: +45 4516 7000	**Malta** Cherubino Ltd Tel.: +356 21 343270

Deutschland Sanofi-Aventis Deutschland GmbH Tel.: 0800 54 54 010 Tel. aus dem Ausland: +49 69 305 21 130	**Nederland** sanofi-aventis Netherlands B.V. Tel: +31 182 557 755
Eesti Sanofi-Aventis Estonia OÜ Tel.: +372 627 3488	**Norge** Sanofi-aventis Norge AS Tel: + 47 67 10 71 00
Ελλάδα BIANEΞ A.E. Τηλ: +30.210.8009111	**Österreich** Sanofi-Aventis GmbH Tel: +43 (1) 80185-0.
España sanofi-aventis, S.A. Tel: +34 93 485 94 00	**Polska** Sanofi Pasteur Sp. z o.o. Tel.: +48 22 280 05 00
France Sanofi Pasteur Europe Tél: 0800 42 43 46 Appel depuis l'étranger : +33 1 57 63 23 23	**Portugal** Sanofi – Produtos Farmacêuticos, Lda. Tel: + 351 21 35 89 400
Hrvatska sanofi-aventis Croatia d.o.o Tel: + 385 1 6003 400	**România** sanofi - aventis Romania SRL Tel.: +40(21) 317 31 36
Ireland sanofi-aventis Ireland T/A SANOFI Tel: + 353 (0) 1 4035 600	**Slovenija** ALPE s.p. Tel.: +386 (0)1 432 62 38
Ísland Vistor Tel : +354 535 7000	**Slovenská republika** sanofi-aventis Pharma Slovakia s.r.o. divízia vakcín Sanofi Pasteur Tel.: +421 2 33 100 100
Italia Sanofi S.p.A. Tel: 800536389 Tel dall'estero: +39 02 39394983	**Suomi/Finland** Sanofi Oy Tel: +358 (0) 201 200 300
Κύπρος Γ. Α. Σταμάτης & Σια Λτδ. Τηλ.: +357 - 22 76 62 76	**Sverige** Sanofi AB Tel: +46 8-634 50 00
Latvija Sanofi Aventis Latvia SIA Vakcīnu nodaļa Tel.: +371 67114978	**United Kingdom** Sanofi Tel: +44 845 372 7101

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

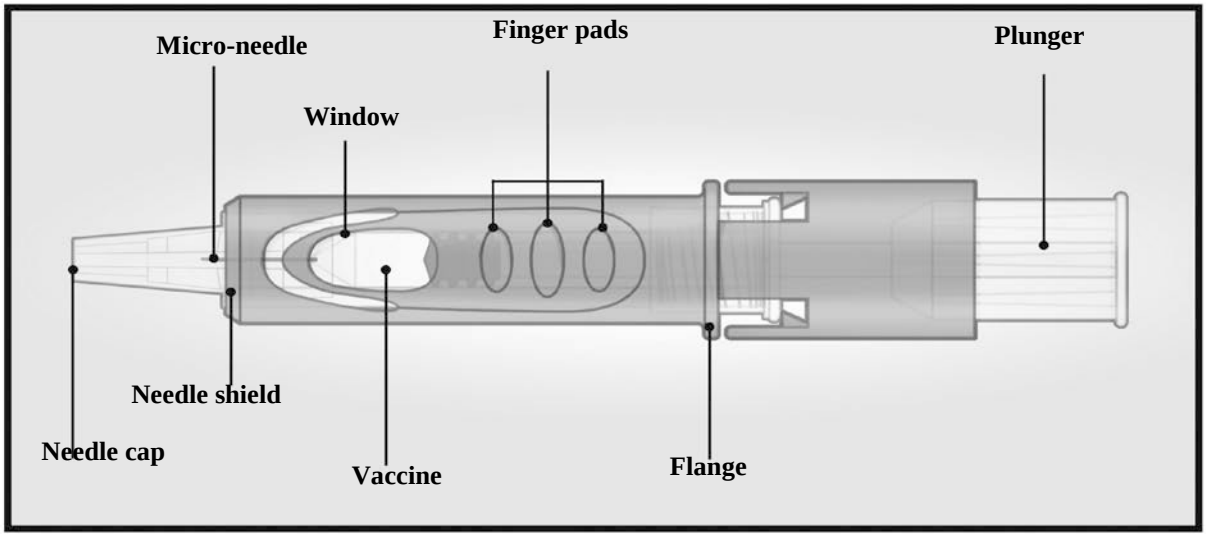
Other sources of information

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

The following information is intended for 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.

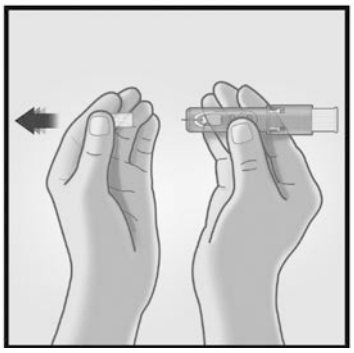
Micro-Injection System



INSTRUCTIONS FOR USE

Please read the instruction before use

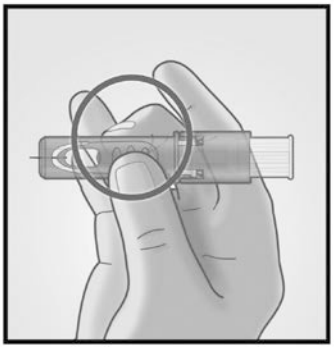
1/ REMOVE NEEDLE CAP



Remove the needle cap from the Micro-Injection System.

Do not purge air through the needle.

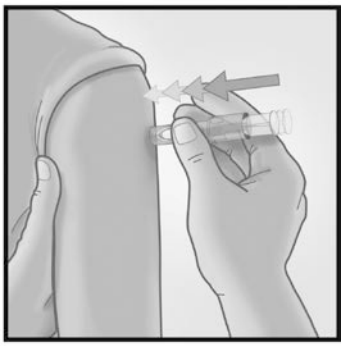
2/ HOLD MICRO-INJECTION SYSTEM BETWEEN THUMB & MIDDLE FINGER



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

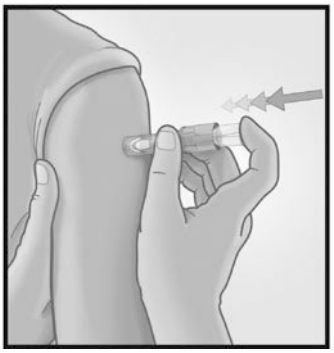
Do not place fingers on the windows.

3/ INSERT NEEDLE RAPIDLY PERPENDICULAR TO THE SKIN



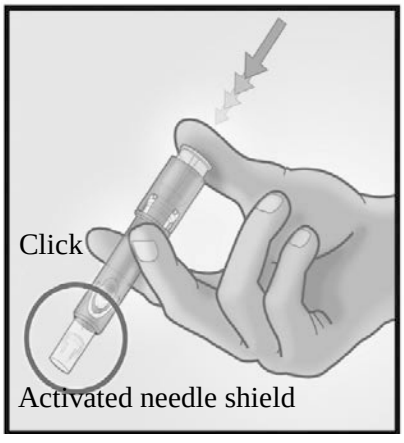
Insert the needle perpendicular to the skin, in the region of the deltoid, in a short, quick movement.

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 INTANZA