

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>.

Medicinal product no longer authorised

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.

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ANNEX III

LABELLING AND PACKAGE LEAFLET

Medicinal product no longer authorised

A. LABELLING

Medicinal product no longer authorised

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 2017/2018

2. STATEMENT OF ACTIVE SUBSTANCES

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

A/Michigan/45/2015 (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:

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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 2017/2018
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

Medicinal product no longer authorised

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
2. What you need to know before you use INTANZA
3. How to use INTANZA
4. Possible side effects
5. How to store INTANZA
6. Contents of the pack and other information

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.

Very common reactions (may affect more than 1 in 10 people)

- 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/Michigan/45/2015 (H1N1)pdm09 - like strain (A/Michigan/45/2015, NYMC X-275)
 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 2017/2018 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 - 1341, 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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This leaflet was last revised in {MM/YYYY}.

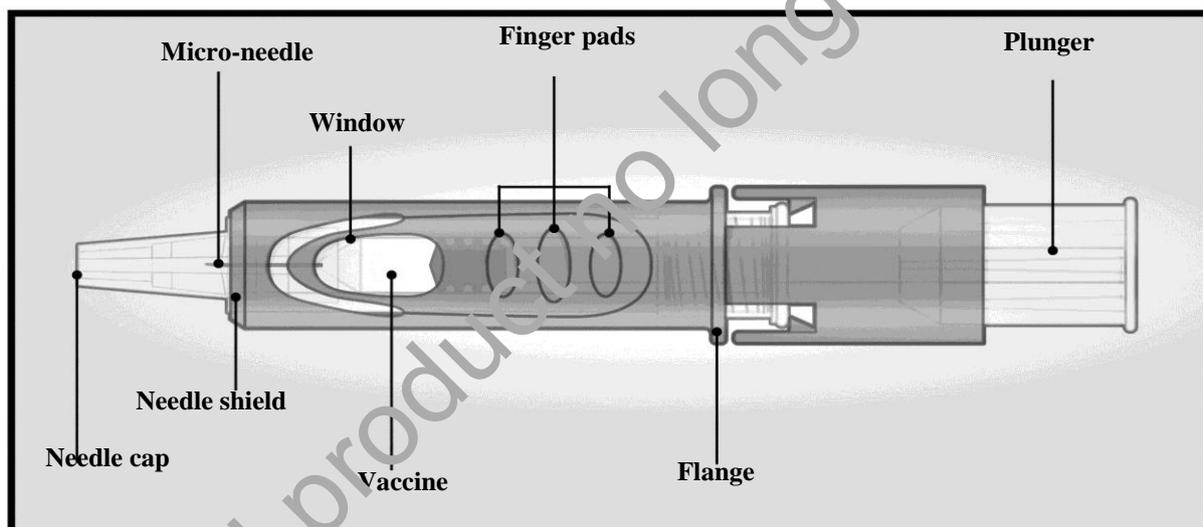
Other sources of information

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.

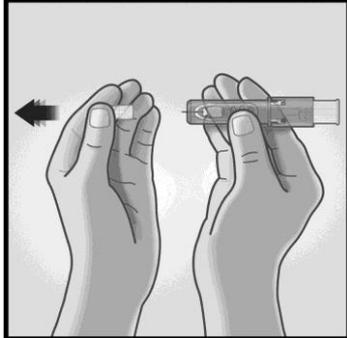
Micro-Injection System



INSTRUCTIONS FOR USE

Please read the instruction before use

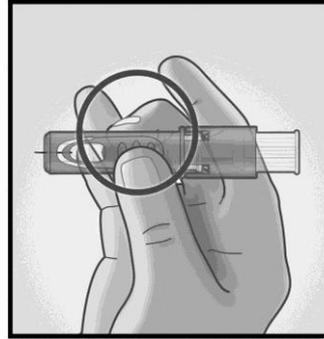
1/ REMOVE NEEDLE CAP



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.

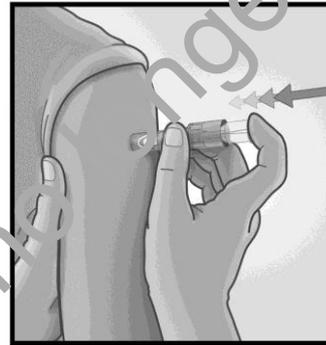
Do not place fingers on the windows.

3/ INSERT NEEDLE RAPIDLY PERPENDICULAR TO THE SKIN



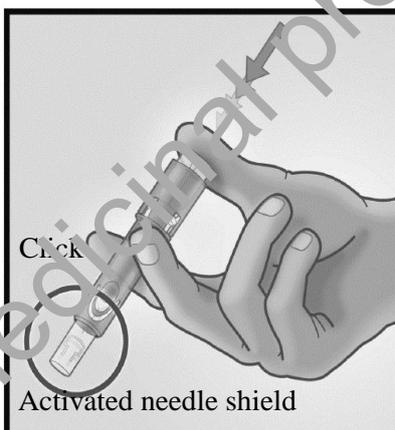
Insert the needle perpendicular to the skin, in the region of the deltoid, in a short, quick movement.

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