

INTANZA[®] 9µg/strain/0.1ml, suspension for injection in pre-filled syringe with a Micro-Injection system

Influenza vaccine (split virion, inactivated)

What is in this leaflet

Read all of this leaflet carefully before you are vaccinated.

- 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.

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What INTANZA 9µg is and what it is used for

INTANZA 9µg is a vaccine. Vaccines are used to protect you against infectious diseases. This vaccine is recommended to help to protect you against influenza.

The vaccine may be administered to persons 18 to 59 years of age, especially in

those who run an increased risk of associated complications. When an injection of **INTANZA 9µg** is given, the immune system (body's natural defences) will induce protection against Influenza infection. **INTANZA 9µg** will protect you against Influenza infection from about 2 to 3 weeks after the injection.

Influenza is a disease caused by different types of virus and can spread rapidly, especially in homes or institutions where it is very easy to catch and spread the infection. The greatest risk of catching influenza is during the cold months between May and October. Your doctor will be able to recommend you the best time to be vaccinated. Influenza is present every year even when epidemics or outbreaks are not reported.

INTANZA 9µg should be used in accordance with official recommendations for influenza vaccination.

The vaccine will only help to prevent influenza if it is caused by one of the three strains of virus contained in the vaccine, or other strains closely related to them. **INTANZA 9µg** will not prevent influenza if you are incubating the disease before vaccination or if it is caused by another virus.

You should also note that many germs can cause influenza-like illness and the vaccine will not protect you against these.

Previous injections of influenza vaccine are unlikely to have given you protection against the current strains of influenza virus which are most common this year, so you will need to receive a vaccine against influenza every year especially if you are at risk.

Before you are given INTANZA 9µg

When you must not be given it

Do not have INTANZA 9µg

- If you are allergic (hypersensitive) to:
 - the active substances or any of the other ingredients of **INTANZA 9µg** listed in 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 INTANZA 9µg

You should tell your doctor before vaccination if you have a poor immune response (immunosuppression) due to disease or medicines, because your response to the vaccine may be limited.

If, for any reason, you have a blood test within a few days

following an influenza vaccination, please tell your doctor.

Taking other medicines

- Other vaccines: **INTANZA 9µg** 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.
- 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. Tell your doctor if you have been treated with such medicines.

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, think you may be pregnant or are breastfeeding. Your doctor or pharmacist will be able to decide if you should receive **INTANZA 9µg**.

Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

The vaccine is unlikely to affect your ability to drive or use machines.

How INTANZA 9µg is given

INTANZA 9µg is administered to you by your doctor or nurse.

Dosage

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

Method and/or route(s) of administration

INTANZA 9µg is given as an injection into the upper layer of the skin (preferably over the muscle of the upper arm) using the Micro-Injection System.

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

Possible Side effects

Like all medicines, **INTANZA 9µg** can cause side effects, although not everybody gets them.

During clinical trials, the following side effects were reported with the use of **INTANZA 9µg**:

Very common (more than 1 in 10 persons),

- at the injection site: redness (erythema), hardness (induration), swelling, itching (pruritus) and pain.
- feeling unwell (malaise), headache and muscular pain (myalgia).

Common (more than 1 in 100 persons),

- bruising (ecchymosis) at the injection site
- fever (38.0°C or higher) and shivering.

Uncommon (less than 1 in 100 persons),

- fatigue (asthenia), swelling of the lymph nodes in the neck, armpit or groin (lymphadenopathy), joint pain

(arthralgia), itching (pruritis) and rash.

Rare (less than 1 in 1,000 persons),

- increased sweating

Based on the experience with other influenza vaccines administered by intramuscular or deep subcutaneous injection, other side effects, not listed above, may be reported:

- temporary reduction in the number of blood particles called platelets which can result in bruising or bleeding (transient thrombocytopenia)
- allergic reactions which can lead in rare cases:
 - to a failure of the circulatory system (shock) leading to medical emergency
 - to swelling most apparent in the head and neck, or any part of the body (angioedema)
- pain located on the nerve route (neuralgia), convulsions associated with fever, neurological disorders that may result in stiff neck, confusion, numbness, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all the body (encephalomyelitis, neuritis, Guillain-Barré Syndrome)
- vessel inflammation (vasculitis) which may result in very rare cases in temporary kidney problems
- skin reactions that may spread throughout the body including itchiness of the skin (urticaria).

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.

Storing INTANZA 9µg

Keep out of the reach and sight of children.

Do not use **INTANZA 9µg** 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.

Further Information

What INTANZA 9µg contains

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

- A/California/7/2009 (H1N1) -like strain
(A/California/7/2009-NYMC X-179A) 9 micrograms HA**
- A/Perth/16/2009 (H3N2)-like strain
(A/Victoria/210/2009 (NYMC X-187) 9 micrograms HA**
- B/Brisbane/60/2008-like strain (B/Brisbane/60/2008) 9 micrograms HA**

Per 0.1 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks

** haemagglutinin

This vaccine complies with the TGA recommendation (Southern Hemisphere) 2012 season.

The other ingredients are a buffer solution containing Sodium chloride, potassium chloride, sodium phosphate - dibasic dihydrate, Potassium phosphate - monobasic, and water for injections.

INTANZA 9µg does not contain more than 0.05 microgram ovalbumin per dose.

INTANZA 9µg may contain traces of octoxinol 9, formaldehyde and neomycin.

What INTANZA 9µg looks like and contents of the pack

The vaccine is a colourless and opalescent suspension.

INTANZA 9µg is a suspension for injection in a prefilled syringe of 0.1 ml with a Micro-Injection System in packs of 1 or 10.

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