

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about Influvac vaccine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. Please read it carefully and keep it for future reference.

All medicines and vaccines have risks and benefits. Your doctor has weighed the possible risks of you having Influvac against the expected benefits.

Talk to your doctor, nurse or pharmacist if you have any concerns about receiving Influvac.

Your doctor and pharmacist have more information.

WHAT INFLUVAC IS USED FOR

Influvac is used to prevent certain types of influenza (commonly called flu). The vaccine works by causing the body to produce its own protection (antibodies) against three different types of influenza virus.

Each year new types of influenza virus can appear, so every year Influvac is changed to contain fragments of the new types of virus. Therefore, influenza vaccination is recommended every year.

Please note that Influvac will only protect you against the three types of influenza virus used to make the vaccine. It will not protect you from influenza caused by other types of influenza virus or from infections with other agents causing flu-like symptoms (such as the common cold).

Influenza is an infectious illness. Influenza is spread by small droplets from the nose, throat or mouth of an infected person. Symptoms of influenza begin 48 hours after coming into contact with the virus. These consist of chills, fever, generalised aches and pains, headache and respiratory symptoms (sore throat, runny nose, cough). The severity and type of symptoms can vary. Most people recover completely within a week. The risk of serious complications (eg. pneumonia and death) is greater in very young, very old and chronically ill persons.

Influvac can be used in adults and in children over the age of 6 months.

For full details regarding recommendations for influenza vaccination, please refer to the relevant National Immunisation Guidelines.

Influvac may also be prescribed for other persons at risk of influenza infection.

Talk to your doctor if you have any questions.

BEFORE YOU RECEIVE INFLUVAC

Do not have Influvac if:

- you have had an allergic reaction to Influvac, or any ingredient contained in this vaccine. The ingredients are listed at the end of this leaflet
Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- you have had an allergic reaction or became unwell after any other influenza vaccine (Fluvax or Fluarix or Fluvirin or Vaxigrip)
- you are allergic to chicken proteins such as in eggs or feathers
- you are allergic to gentamicin
- you have a severe infection with a high temperature
A minor infection such as a cold should not be a problem, but talk to your doctor or nurse about this before being vaccinated.
- the expiry date printed on the pack has passed

- the packaging is torn or shows signs of tampering.

Talk to your doctor or nurse if you are not sure whether you should have Influvac.

Do not give this vaccine to anyone else.

Your doctor has prescribed it specifically for you.

Before having Influvac

Tell your doctor if:

- you have been allergic to any other medicines, foods, dyes or preservatives
- you have had Influvac before and became unwell, tell your doctor, nurse or pharmacist before the next dose is given
- you are pregnant or intend to become pregnant. Your doctor will discuss with you the benefits and risks of taking Influvac when pregnant
- you are breast feeding
Your doctor will discuss the risks and benefits of vaccination, however the vaccine is not expected to cause problems for breast-fed babies
- you have ever had an illness affecting the nervous system, especially Guillain-Barre Syndrome (GBS)
If you have had GBS, you may be more likely to develop GBS following influenza vaccination than someone who has never had GBS.
- you have any medical conditions, such as an immune deficiency condition or a bleeding disorder.

Interactions with other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop, or have received another vaccine.

HOW INFLUVAC IS GIVEN

The doctor or nurse will give Influvac as an injection.

Talk to your doctor, nurse or pharmacist if you have any concerns about how this vaccine is to be given.

How much is given

Adults and children over the age of 36 months: 0.5 mL

Children from 6 to 35 months: 0.25 mL

How it is given

The injection may be given in the upper arm muscle.

For some people with bleeding problems, the injection may need to be given under the skin (subcutaneously).

Influvac should never be given intravenously.

When it is given

Influvac is generally given as a single dose each year during autumn.

For some people, particularly those with low immunity, who are receiving influenza vaccination for the first time, a second dose should be given 4 weeks after the first dose. However, one dose is sufficient for most people and especially those who have been vaccinated against influenza in an earlier year.

If a dose is missed

Talk to your doctor or nurse and arrange another visit as soon as possible.

AFTER RECEIVING INFLUVAC

Things to be careful of

Be careful driving or operating machinery until you know how Influvac affects you.

Influvac should not normally interfere with your ability to drive a car or operate machinery. But in some people vaccination can cause dizziness or light-headedness. Make sure you know how you react to Influvac before you drive a car, operate machinery, or do anything that could be dangerous if you are dizzy or light-headed.

SIDE EFFECTS

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well during or after having had a dose of Influvac.

Influvac helps protect most people from influenza, but it may have unwanted side effects in a few people. All medicines and vaccines can have side effects. Sometimes they are serious; most of the time they are not. Some side effects may need medical treatment.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Most unwanted effects with Influvac are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site.

MILD EVENTS

Tell your doctor as soon as possible if you notice any of the following:

- redness, swelling, a hard lump, soreness, bruising or itching around the injection site
- fever, chills, headache, malaise (generally unwell)
- muscle aches and pains

MORE SERIOUS EFFECTS THAT MAY OCCUR RARELY

As with all vaccines given by injection there is a very small risk of serious allergic reaction. Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- swelling of limbs, face, eyes, inside of nose, mouth or throat
- shortness of breath, breathing or swallowing difficulties
- hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions
- unusual tiredness or weakness that is sudden and severe.

As with all vaccines given by injection there is a very small risk of such reactions. Allergy to Influvac is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur during or soon after a dose of vaccine.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

STORAGE

Influvac is usually stored at the pharmacy or at the doctor's clinic or surgery.

If you need to store the vaccine, always:

- **Keep Influvac in the refrigerator stored between +2°C and +8°C. THE PACK SHOULD NEVER BE FROZEN. FREEZING DESTROYS THE VACCINE.**
- **Keep the vaccine out of the reach of children.**

- Keep Influvac in the original pack until it is time for it to be given.

Ask your pharmacist what to do with any left over Influvac that has expired or has not been used.

PRODUCT DESCRIPTION

What it looks like

Influvac is a clear, colourless, liquid.

Packs of 1 or 10 pre-filled (0.5 mL) glass syringes. AUST R 81465

Ingredients

Each 0.5 mL dose of Influvac contains three types of influenza virus fragments in a phosphate buffered salt solution.

- H₁N₁ strain 15 micrograms
- H₃N₂ strain 15 micrograms
- B strain 15 micrograms

And:

- potassium chloride, potassium phosphate monobasic, sodium phosphate-dibasic dihydrate, sodium chloride, calcium chloride, magnesium chloride and water for injections.

The vaccine also contains limited quantities of egg protein, formaldehyde, cetrimonium bromide, polysorbate 80 and gentamicin.

Influvac is not made with any human blood or blood products, or any other substances of human origin.

Sponsor

Influvac is manufactured in The Netherlands for:

Sponsor

Australia:

Solvay Pharmaceuticals

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A division of Solvay Biosciences Pty. Ltd.

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