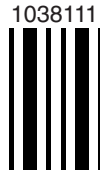


# *influvac sub-unit*



## **Suspension for injection (influenza vaccine, surface antigen, inactivated)**

### **What you should know about Influvac.**

Please read this leaflet about your vaccine, Influvac: it gives you important information. Please keep the leaflet as you may want to read it again in the future. If you have any questions or are not sure about anything, ask your doctor or a pharmacist.

### **What's in your vaccine?**

Influvac is made from viruses grown in chicken eggs. The viruses are killed with formaldehyde. Some of the virus proteins (haemagglutinin and neuraminidase antigens) are separated out to make the vaccine. These proteins are not infectious.

Influvac comes ready-to-use in a disposable syringe. Each syringe contains a total of 45 micrograms haemagglutinin antigen in 0.5 ml.

This is made up of 15 micrograms each of two different 'A' virus strains and one 'B' virus strain.

A/Wisconsin/67/2005 (H<sub>3</sub>N<sub>2</sub>)-like strain (A/Hiroshima/52/2005 IVR-142 reass.)

A/New Caledonia/20/99 (H<sub>1</sub>N<sub>1</sub>)-like strain (A/New Caledonia/20/99 IVR-116 reass.)

B/Malaysia/2506/2004-like strain (B/Malaysia/2506/2004)

Other ingredients used in the preparation of this vaccine are: potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, sodium chloride, calcium chloride, magnesium chloride hexahydrate and water for injections.

Influvac pre-filled syringes are available singly and in packs of ten.

### **Marketing authorisation holder:**

Solvay Healthcare Limited  
Southampton SO18 3JD UK

### **Manufacturer:**

Solvay Pharmaceuticals B.V.  
8121 AA OLS  
The Netherlands

Influvac is a vaccine used to prevent people developing influenza (the flu).

### **Before you are vaccinated.**

If you think the answer is **yes** to any of the following questions, please tell your doctor, nurse or pharmacist before the vaccine is administered:

- Are you allergic to eggs or products made from chicken?
- Do you have a fever, or do you think you may be getting a fever?
- Are you allergic to any of the ingredients of the vaccine?
- Are you allergic to any of the following: formaldehyde; cetyltrimethylammonium bromide; polysorbate 80 or gentamicin?
- Have you had a serious reaction to any flu vaccine in the past?

### **Important information about some of the ingredients in Influvac:**

Influvac contains less than 1 µg ovalbumin (an egg protein) per dose.

Tell your doctor if you/your child have/has any known allergies.

Tell your doctor if you/your child have/has experienced any health problems after previous administration of a vaccine.

Pregnancy: ask your doctor for advice.

Breast-feeding: the vaccine may be given while breast-feeding.

### **Giving influenza vaccine.**

Your doctor or nurse will inject this vaccine deep under your skin or into muscle. The vaccine should be allowed to reach room temperature first.

The needle guard is removed.



The air is then pushed out with the syringe held upright.

The vaccine is then ready to be given.



### **Dosage:**

Adults, including the elderly,  
and children over 36 months: 0.5 ml, single dose.

Children (6 months - 35 months): 0.25 ml or 0.5 ml.

For children who have not been previously vaccinated, a second dose should be given after an interval of at least 4 weeks.

It is unlikely for anyone to receive an overdose. It is known that ten times the normal dose

has been given without ill effects, so accidental overdose is unlikely to need special treatment.

### Possible side effects.

During production, parts of the virus which are not essential for the vaccine are removed. This reduces the possibility of side effects occurring.

Occasionally people have side effects with influenza vaccines. The most common of these are fever, feeling unwell, shivering, tiredness, headache, sweating, muscle and joint pain. Skin reactions include redness, swelling, pain, ecchymosis (blue/black staining of the skin) and a hardening of the skin at the injection site. These reactions will normally disappear without treatment in a day or two. Uncommonly, itching and/or a rash have been reported.

Rarely, neuralgia (nerve pain), paraesthesia (numbness and tingling), convulsions (fits) and temporary thrombocytopenia (a blood disorder) have been reported.

In rare cases, allergic reactions may lead to shock. Very rarely, vasculitis (inflammation of blood vessels) temporarily affecting the kidneys, neurological disorders (affecting the nerves and brain), such as encephalomyelitis, neuritis and Guillain Barré syndrome have been reported.

If you think that you have a side effect not mentioned here, please tell your doctor or a pharmacist.

### Storage of Influvac.

Store Influvac at +2°C to +8°C (in a refrigerator).

Protect from light and do not freeze.

Do not use after the expiry date.

This vaccine is effective against this year's influenza virus. It will not protect you completely against influenza next winter, as the virus is likely to be different.

This leaflet was revised in 2006.

### For information in Ireland contact:

Solvay Healthcare Limited  
United Drug House  
Magna Business Park  
Citywest Road  
Dublin 24

### Further information on Influvac.

Like other influenza vaccines, Influvac causes the body to produce antibodies against the virus.

This means that when your body is exposed to live influenza virus, the body is able to defend itself. The antibodies neutralise the attacking virus. You cannot catch influenza from Influvac as it only contains pieces of virus, and not whole live virus.

Your body takes 10 to 21 days to produce antibodies after vaccination. The incubation

period for influenza is a few days, so if you are exposed to influenza immediately before or after your vaccination, you could still develop the illness. The vaccine will not protect you against the common cold, even though some of the symptoms are similar to influenza.

Influenza viruses change all the time, so different vaccines are made every year. To stay protected against influenza, you need to be re-vaccinated every year before the winter season.

It is particularly important for some groups of people to be vaccinated. These include people with certain medical conditions, elderly people, people who are likely to be exposed to the infection and people with crucial work to carry out. If you are in doubt as to whether you should be vaccinated, talk to your local health professionals.

Influvac complies with the WHO (World Health Organisation) recommendation for the northern hemisphere and European Union decision for the 2006/2007 season.

### Administration of 0.25 ml dose

The Influvac 0.5 ml syringe is not graduated.

To estimate half a dose ie 0.25 ml:

- 1 Eject the air from the syringe.
- 2 Approximately half of the liquid is visible and the rest is hidden by the plastic hub of the syringe. Discard the first half of the liquid by pushing the plunger until the tip of the plunger is level with the rim of the plastic hub (see diagram).
- 3 Inject the remaining vaccine in the normal way.

