

PACKAGE LEAFLET: INFORMATION FOR THE USER

Inflexal[®] V, suspension for injection

Virosomal influenza vaccine (inactivated)

Read all of this leaflet carefully before you use this vaccine

- Keep this leaflet. You may need to read it again.
- If you have any questions or are not sure about anything, 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.

In this leaflet:

1. What Inflexal V is and what it is used for
2. Before you use Inflexal V
3. How to use Inflexal V
4. Possible side effects
5. How to store Inflexal V
6. Further information

Inflexal V

Suspension for injection

1. WHAT INFLEXAL V IS AND WHAT IT IS USED FOR

Inflexal V is a vaccine to protect adults and children older than 6 months from flu (*influenza*). When you are given the vaccine your body's immune system makes antibodies to protect you against the types of flu virus that are in the vaccine.

The vaccine does not contain any live virus particles, so it cannot give you the flu.

After receiving the vaccine, the immune system will make enough antibody to protect the body against the types of virus that are in the vaccine in two to three weeks. This protection against flu should last for 6–12 months.

This vaccine has been designed for this winter season, and can only help to protect you against the types of flu virus that have been used to make the vaccine. No vaccine can protect you to 100% against flu.

You may still get flu due to other types of flu virus (not included in this vaccine) that may be circulating in the population.

2. BEFORE YOU USE INFLEXAL V

Do not use Inflexal V

- If you have had an allergic reaction to a flu vaccine before. In this case your doctor or pharmacist may advise you not to have the flu vaccine again.
- If you are allergic to one of the ingredients of the vaccine.
- If you are allergic to eggs or to hen's proteins.
- If you are allergic to polymyxin B or neomycin (antibiotics).

Your vaccination should be postponed if you have fever or an acute infection.

Take special care with Inflexal V

Your doctor or your nurse may ask you to stay a few minutes in the medical office just to be sure that you have no allergic reaction after the injection of the vaccine.

If your immune system is poor (immunodeficient) due to a treatment with corticosteroids, cytotoxic drugs, radiotherapy or due to a disease (including AIDS), inform your doctor. In this case the vaccine could be less effective. Your child should not be vaccinated if it is less than 6 months old. Influenza vaccines are not recommended for use in children under this age.

Taking or using other medicines

Inflexal V can generally be given at the same time as other vaccines but at different injection sites. In this case side effects may be intensified.

Treatments which diminish immunity also diminish the efficacy of the vaccine (see also section «Take special care with Inflexal V»).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In the weeks after receiving this vaccine, it is possible that the results of some blood tests that your doctor might do to find out if you have certain types of infections (like certain types of hepatitis and AIDS) may be positive when, in fact, you do not really have these infections.

If your doctor suggests taking some blood to find out if you have any sort of infection soon after you have had Inflexal V, you should tell your doctor that you have been vaccinated recently. Your doctor may then decide to postpone the test.

Pregnancy and breast-feeding

You can use the vaccine from the second trimester of pregnancy onwards.

Limited data from vaccination in pregnant women do not indicate that adverse reactions for the mother and for the child were attributable to the vaccine.

If you are pregnant and your doctor has told you that you have a high risk of complications from flu virus infections, the vaccine could be given to you irrespective of the stage of pregnancy.

Ask your doctor or pharmacist for advice before being vaccinated.

Inflexal V may be used during breast-feeding.

Driving and using machines

The vaccine is not likely to interfere with your ability to drive or use machines.

3. HOW TO USE INFLEXAL V

Inflexal V will be given by doctors or nurses in the muscle (intramuscular injection) or deep under the skin (deep subcutaneous injection).

Adults and children aged 36 months and over, 1 dose (0.5 millilitre – ml) intramuscularly or deep subcutaneously (usually in the upper arm).

Children from 6 months to 35 months may be given a whole dose (0.5 ml) or a half dose (0.25 ml). A second dose of vaccine should be given to children who have not previously been vaccinated, at least 4 weeks after the first injection.

An accidental overdose is unlikely to have any untoward effect.

4. POSSIBLE SIDE EFFECTS

Like all vaccines Inflexal V can cause side effects, although not everybody gets them.

Common (more than 1 of 100, but less than 1 of 10) side effects are:

Redness, swelling, pain, bruising or a hard area at the site of injection (hard surface at the site of injection).

The following side effects are also common: fever, feeling generally unwell, shivering, tiredness, headache, sweating, and muscle or joint pain.

These reactions usually disappear within 1–2 days without treatment.

Uncommon side effects (more than 1 of 1000, but less than 1 of 100):

- General skin reactions including itching, hives or rash.

The following side effects are rare (more than 1 of 10 000, but less than 1 of 1000):

- Sharp pain in or along a nerve, pins and needles, fits.
- Unexplained or frequent easy bruising due to a lowering of the number of thrombocytes, which are blood cells responsible for blood clotting.
- Unexplained transient swelling of the lymph nodes.

The following side effects are very rare (less than 1 of 10 000):

- Inflammation of the lining of some blood vessels, with transient inflammation of the kidneys.
- Neurological disorders such as encephalomyelitis, neuritis and Guillain-Barré syndrome (ascending paralysis up to respiratory paralysis).

Very occasionally, people who are extremely allergic to one of the components of the vaccine can suffer a severe allergic reaction (anaphylactic) that occurs very shortly (minutes or hours) after vaccination and which can lead to:

- Swelling of the face and lips (Quincke oedema),
- Difficulty in breathing,
- Feeling dizzy and not well,
- Drop of blood pressure,
- Loss of consciousness.

Your doctor may ask you to stay in the medical office for a short time after vaccination to make sure that everything is all right.

If you notice any of these symptoms or any other changes in your health after leaving the medical office, tell your doctor immediately.

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.

5. HOW TO STORE INFLEXAL V

Keep Inflexal V out of the reach and sight of children.

Store in a refrigerator (2 °C–8 °C).

Do not freeze. A vaccine that has been frozen must not be used. Keep the pre-filled syringe in the original carton and protected from light.

Do not use Inflexal V after the expiry date which is stated on the label. The expiry date refers to the last day of that month printed next to Exp. (month-year).

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.

6. FURTHER INFORMATION

What Inflexal V contains

The active substances in the vaccine are proteins called haemagglutinins, isolated from the surface of the flu virus. To make the vaccine, the flu viruses are grown in chicken eggs, then they are inactivated (with β -propiolactone) and the haemagglutinins are purified. Finally these are combined with natural lipids to form particles called virosomes. The virosomes act as carrier and adjuvant in the vaccine.

The composition of the vaccine complies with the recommendation of the Health Authorities for this winter. For the 2008/2009 winter season, the virus types chosen are:

- A/Brisbane/59/2007 (H1N1) like strain (A/Brisbane/59/2007 IVR-148)
- A/Brisbane/10/2007 (H3N2) like strain (A/Uruguay/716/2007 NYMC X-175C)
- B/Florida/4/2006 like strain (B/Florida/4/2006)

Each 0.5 ml dose of Inflexal V contains 15 micrograms of haemagglutinin from each of these three virus types.

The other ingredients of Inflexal V are:

Sodium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate, lecithin and water for injections. There may also be trace amounts of polymyxin B and neomycin. Inflexal V does not contain more than 0.05 microgram of ovalbumin (egg protein) per 0.5 ml dose.

What Inflexal V looks like and contents of the pack

Inflaxal V is a suspension for injection in pre-filled syringe of 0.5 ml and is sold in packs of 1 or 10 syringes. Inflaxal V is a slightly opalescent liquid.

Marketing Authorisation Holder:

Berna Biotech Italia S.r.l., Via Zambelletti 25, 20021 Baranzate (MI), Italy

Manufacturer:

Berna Biotech España S.A., Carretera de Irún, km 20,900, E-28700 San Sebastián de los Reyes, Madrid, Spain.
For more information about this product, please contact the local distributor of the Marketing Authorisation Holder.

The following information is intended for medical or health care professionals only

The vaccine should under no circumstances be injected into a vein.

When a dose of 0.25 ml is indicated, the pre-filled syringe should be held in upright position and half of the volume should be eliminated up to the 0.25 ml mark. The remaining volume should be injected in a muscle or deep under the skin.

Inflaxal V should reach room temperature before use. The syringe should be gently shaken before use. Inflaxal V must not be mixed with other medicinal products before use.

This leaflet was last approved in: June 2008