

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Inflexal[®] V, suspension for injection

Influenza vaccine (surface antigen, inactivated, virosome)

Read all of this leaflet carefully before you or your child are/is 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 or your child. 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

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

Inflexal V is a vaccine. This vaccine helps to protect you or your child against influenza (flu), particularly in subjects who run a high risk of associated complications. The use of Inflexal V should be based on official recommendations.

When a person is given the vaccine Inflexal V, the immune system (the body's natural defence system) will produce its own protection (antibodies) against the disease. None of the ingredients in the vaccine can cause flu.

Flu is a disease that can spread rapidly and is caused by different types of strains that can change every year. Therefore, this is why you or your child might need to be vaccinated every year. The greatest risk of catching flu is during the cold months between October and March. If you or your child were/was not vaccinated in the autumn, it is still sensible to be vaccinated up until the spring since you or your child run/runs the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

Inflexal V will protect you or your child against the three strains of virus contained in the vaccine from about 2 to 3 weeks after the injection.

The incubation period for flu is a few days, so if you or your child are/is exposed to flu immediately before or after your vaccination, you or your child could still develop the illness.

The vaccine will not protect you or your child against the common cold, even though some of the symptoms are similar to flu.

2. BEFORE YOU OR YOUR CHILD USE/USES INFLEXAL V

To make sure that Inflexal V is suitable for you or your child, it is important to tell your doctor or pharmacist if any of the points below apply to you or your child. If there is anything you do not understand, ask your doctor or pharmacist to explain.

Do not use Inflexal V

- If you or your child are/is allergic (hypersensitive) to:
 - the active substances, or
 - any of the other ingredients of Inflexal V, see section 6 “Further information”, or
 - any component that may be present in very small amounts such as eggs (ovalbumin or chicken proteins) or polymyxin B.
- If you or your child have/has an illness with a high temperature or acute infection, the vaccination shall be postponed until after you or your child have/has recovered.

Take special care with Inflexal V

Due to the risk of high fever, consideration should be given to the use of alternative seasonal influenza vaccines in children under the age of 5 years.

In case it is used in children, parents should be advised to monitor for fever for 2 -3 days following vaccination.

You should tell your doctor before vaccination if you or your child have/has a poor immune response (immunodeficiency or taking medicines affecting the immune system).

Your doctor will decide if you or your child should receive the vaccine.

If, for any reason, you or your child have/has a blood test within a few days following a flu vaccination, please tell your doctor. This is because false positive blood test results have been observed in a few patients who had recently been vaccinated.

As with all vaccines, Inflexal V may not fully protect all persons who are vaccinated.

Using other medicines

- Please tell your doctor or pharmacist if you or your child are/is taking or have/has recently taken other vaccines or any other medicines, including medicines obtained without a prescription.
- Inflexal V can be given at the same time as other vaccines by using separate limbs.
It should be noted that the side effects may be stronger.
- The immunological response may decrease in case of immunosuppressant treatment, such as corticosteroids, cytotoxic drugs or radiotherapy.

Pregnancy and breast-feeding

Tell your doctor or pharmacist if you are pregnant or think you may be pregnant.

Flu vaccines can be used in all stages of pregnancy. Larger datasets on safety are available for the second and third trimester, compared with the first trimester; however, data from worldwide use of flu vaccines do not indicate that the vaccine would have harmful effects on the pregnancy or the baby.

Inflexal V may be used during breast-feeding.

Your doctor/pharmacist will be able to decide if you should receive Inflexal V.

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

Driving and using machines

Inflexal V has no or negligible influence on the ability to drive or use machines.

3. HOW TO USE INFLEXAL V

Dosage

Adults receive one 0.5 ml dose.

Use in children

Children from 36 months and older receive one 0.5 ml dose.

Children from 6 months to 35 months may receive either one 0.25 ml dose or one 0.5 ml dose.

If your child has not been previously vaccinated against flu, a second dose should be given after at least 4 weeks.

Method and/or route(s) of administration

Your doctor will administer the recommended dose of the vaccine as an injection into the muscle or deep under the skin.

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

4. POSSIBLE SIDE EFFECTS

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

During clinical trials, the following side effects have been observed. Their frequencies have been estimated as common: affects 1 to 10 users in 100:

- headache
- sweating
- muscular pain (myalgia), joint pain (arthralgia)
- fever, generally feeling unwell (malaise), shivering, fatigue
- local reactions: redness, swelling, pain, bruising (ecchymosis), hardness (induration) around the area where the vaccine is injected.

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

Next to the above common side effects, the following side effects occurred after the vaccine came on the market:

- allergic reactions:
 - leading to medical emergency with a failure of the circulatory system to maintain adequate blood flow to the different organs (shock) in rare cases,
 - swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body (angioedema) in very rare cases.
- skin reactions that may spread throughout the body including itchiness of the skin (pruritus, urticaria), rash
- blood vessel inflammation which may result in skin rashes (vasculitis) and in very rare cases in temporary kidney problems
- pain situated on the nerve route (neuralgia), anomalies in the perception of touch, pain, heat and cold (paraesthesia), fits (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)
- temporary reduction in the number of certain types of particles in the blood called platelets; a low number of these can result in excessive bruising or bleeding (transient thrombocytopenia); temporary swelling of the glands in the neck, armpit or groin (transient lymphadenopathy)

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

Reporting of side effects

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. 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 INFLEXAL V

Keep out of the reach and sight of children.

Do not use Inflexal V 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.

A vaccine that has been frozen must not be used.

Keep the pre-filled syringe in the original 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.

6. FURTHER INFORMATION

What Inflexal V contains

The active substances are: Influenza virus surface antigens (haemagglutinin and neuraminidase), virosome, of the following strains*:

A/California/7/2009 (H1N1)pdm09-derived strain used (NYMC X-181)

15 micrograms HA**

A/Victoria/361/2011 (H3N2)-like strain used (NYMC X-223) derived from A/Texas/50/2012

15 micrograms HA**

B/Massachusetts/2/2012-derived strain used (NYMC BX-51B)

15 micrograms HA**

per 0.5 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks

** haemagglutinin

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 both as carrier and adjuvant in the vaccine.

This vaccine complies with the WHO (World Health Organisation) recommendations (Northern hemisphere) and EU decision for the 2013/2014 season.

The other ingredients are:

Sodium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate, lecithin and water for injections

What Inflexal V looks like and contents of the pack

Inflexal V is a suspension for injection presented in pre-filled syringe of 0.5 ml and is sold in packs of 1 or 10 syringes.

Not all pack sizes may be marketed.

Inflexal V is a slightly opalescent liquid.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Crucell Italy S.r.l.
Via Zambelletti 25
I-20021 Baranzate (MI)
Italy

Manufacturer:

Crucell Spain S.A.
Carretera Nacional I, km 20.900
E-28700 San Sebastián de los Reyes
Madrid
Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

Member State	Name
Austria, Belgium, Germany, Denmark, Finland, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Spain, Sweden, United Kingdom	Inflexal V

This leaflet was last approved in:

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

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

The vaccine should be allowed to reach room temperature before use.

Shake before use.

Inspect visually prior to administration.

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.

Inflexal V must not be mixed with other medicinal products before use.

This vaccine is not to be injected directly into any blood vessel.

See also section 3. HOW TO USE INFLEXAL V