

PACKAGE LEAFLET: INFORMATION FOR THE USER

2018/2019 season

Influvac® sub-unit

Suspension for injection

Influenza vaccine (surface antigen, inactivated)

Read all of this leaflet carefully before you or your child are vaccinated, because it contains important information for you and your child.

- 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 you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1. WHAT INFLUVAC IS AND WHAT IT IS USED FOR

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

When a person is given the vaccine Influvac, 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 not vaccinated in the autumn, it is still sensible to be vaccinated up until the spring since you or your child runs the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

Influvac 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 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. WHAT YOU NEED TO KNOW BEFORE YOU OR YOUR CHILD USE INFLUVAC

To make sure that Influvac 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 Influvac

- If you or your child are allergic (hypersensitive) to:
 - the active substances, or
 - any of the other ingredients of Influvac (see section 6), or
 - any component that may be present in very small amounts such as eggs (ovalbumin or chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin (an antibiotic that is used to treat bacterial infections)
- If you or your child have an illness with a high temperature or acute infection, the vaccination shall be postponed until after you or your child have recovered.

Warnings and precautions

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

Fainting, feeling faint or other stress related reactions can occur following, or even before, any needle injection. Therefore tell your doctor or nurse if you have experienced this kind of reaction with a previous injection.

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

If, for any reason, you or your child have 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, Influvac may not fully protect all persons who are vaccinated.

Other medicines and Influvac

- Please tell your doctor or pharmacist if you or your child are taking or have recently taken other vaccines or any other medicines, including medicines obtained without a prescription.
- Influvac 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. Influvac may be used during breast-feeding.

Your doctor/pharmacist will be able to decide if you should receive Influvac. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

3. HOW TO USE INFLUVAC

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 in accordance with existing national recommendations.

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, Influvac 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.

In addition to the above common side effects, the following side effects have been reported since 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) and 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 and 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) and temporary swelling of the glands in the neck, armpit or groin (transient lymphadenopathy)

Reporting of side effects

If you or your child get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system(s) listed below:

UK

The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

IRELAND

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPR

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

MALTA

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE INFLUVAC

Keep out of the reach and sight of children.

Do not use Influvac after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store Influvac in a refrigerator (+ 2 °C to + 8 °C). Do not freeze.

Store the product in the original package 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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Influvac contains

The active substances are:

Influenza virus surface antigens (haemagglutinin and neuraminidase) of the following strains*:

- | | |
|--|---------------------|
| - A/Michigan/45/2015 (H1N1)pdm09-like strain
(A/Singapore/GP1908/2015, IVR-180) | 15 micrograms HA ** |
| A/Singapore/INFIMH-16-0019/2016 (H3N2)-like strain
(A/Singapore/INFIMH-16-0019/2016, NIB-104) | 15 micrograms HA ** |
| B/Colorado/06/2017-like strain (B/Victoria/2/87 lineage)
(B/Maryland/15/2016, NYMC BX-69A) | 15 micrograms HA ** |

per 0.5 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks

** haemagglutinin

This vaccine complies with the World Health Organisation (WHO) recommendation (Northern hemisphere) and EU recommendation for the 2018/2019 season.

The other ingredients are: potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, sodium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate and water for injections.

What Influvac looks like and contents of the pack

Influvac is a suspension for injection presented in a prefilled glass syringe (with / without needle) containing 0.5 ml of a colourless clear injection fluid. Each syringe can only be used once.

Pack size of 1 or 10.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Mylan Products Limited
20 Station Close
Potters Bar
Herts EN6 1TL
United Kingdom

Manufacturer:

Abbott Biologicals B.V.
Veerweg 12
NL - 8121 AA Olst
The Netherlands

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

Mylan IRE Healthcare Limited, Newenham Court, Northern Cross, Malahide Road, Dublin 17, Ireland.

Registration number in UK: PL 46302/0041

Registration number in IE: PA 2136/2/1

Registration number in MT: MA 1138/00601

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

Austria, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Iceland, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Romania, Spain, Slovakia, Slovenia, Sweden	Influvac
Belgium, Italy, Luxembourg	Influvac S
Cyprus, Greece, Ireland, Malta, United	Influvac sub-unit

This leaflet was last revised in April 2018

The following information is intended for medical or healthcare 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. Shake before use.

Inspect visually prior to administration.

Do not use the vaccine if foreign particles are present in the suspension.

Remove the needle guard / cap

Hold the syringe upright and expel the remaining air.

Do not mix with other medicinal products in the same syringe.

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

For the administration of a 0.25 ml dose from a single 0.5 ml syringe (for paediatric use only):

Push the front side of the plunger exactly to the edge of the mark so that half of the volume is eliminated; a volume of 0.25 ml of the vaccine remains in the syringe, suitable for administration.

See also section 3: HOW TO USE INFLUVAC