Package leaflet: Information for the user
Influvac sub-unit, suspension for injection in pre-filled syringe
Influenza vaccine (surface antigen, inactivated)
2026/2027 season

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Influvac is and what it is used for

Influvac is a vaccine for adults and children who are 6 months of age and older. This vaccine helps to protect you or your child against flu (influenza). 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, pharmacist or nurse if any of the points below apply to you or your child. If there is anything you do not understand, ask your doctor, pharmacist or nurse 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)

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)
- a bleeding problem or bruising easily

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

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.

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.

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
- Tell your doctor, pharmacist or nurse if you or your child are taking or have recently taken or might take any other vaccines or 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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

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

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

Influvac contains sodium and potassium
This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium- free’.
This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially “potassium free”.

3. How to use Influvac

Dosage

Adults receive one 0.5 ml dose.

Use in children and adolescents
Children from 6 months to 17 years of age receive one 0.5 ml dose.

Children less than 9 years of age, who have not been previously vaccinated with a seasonal influenza vaccine: a second dose should be given after an interval of at least 4 weeks.
For infants less than 6 months of age the safety and efficacy of Influvac have not been established.

Route(s) and/or method of administration

Your doctor or nurse 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, pharmacist or nurse.

4. Possible side effects

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

See your doctor straight away if you or your child experience any of the following side effects - you or your child may need urgent medical attention.

Severe allergic reactions (frequency unknown, occurred occasionally during general use of Influvac):
- 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.

During clinical trials with Influvac and/or the quadrivalent influenza vaccine Influvac Tetra, the following side effects have been observed. Their frequencies have been estimated as:

- very common (may affect more than 1 in 10 people);
- common (may affect up to 1 in 10 people);
- uncommon (may affect up to 1 in 100 people); and
- not known (adverse reactions from post-marketing experience; cannot be estimated from the available data).

Side effects	**Adults and elderly**	**Children**		
	18 years and older	**6 to 35 months**	**3 to 5 years**	**6 to 17 years**
Headache	Very common*	-	-	Very common
Drowsiness	-	Very common	Very common	-
Sweating	Common	Very common	Common	Common
Appetite loss	-	Very common	Very common	-
Nausea	-	-	-	Very common
Abdominal pain	-	-	-	Very common
Diarrhoea	-	Very common	Common	Very common
Vomiting	-	Very common	Common	Very common
Irritability/fussiness	-	Very common	Very common	-
Muscular pain (Myalgia)	Common	-	-	Very common
Joint pain (Arthralgia)	Common	-	-	Common
Fatigue	Very common	-	-	Very common
Fever	Uncommon	Very common	Common	Common

Generally feeling unwell (Malaise)	Common	-	-	Very common
Shivering	Common	-	-	Common
Vaccination site Pain	Very common	Very common	Very common	Very common
Redness	Common	Very common	Very common	Very common
Swelling	Common	Common	Very common	Very common
Hardness (Induration)	Common	Common	Very common	Very common
Bruising (Ecchymosis)	Common	Common	Common	Common
for all age groups:	Skin reactions that may spread throughout the body including itchiness of the skin (pruritus, urticaria), rash			
Not known	Blood vessel inflammation which may result in skin rashes (vasculitis) and in very rare cases in temporary kidney problems.			
(cannot be estimated from the available data)	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)			
*Common in elderly (≥ 61 years)				

For all age groups, most reactions mentioned above usually occurred within the first 3 days following vaccination, resolved spontaneously within 1 to 3 days after onset. The intensity of these reactions was generally mild.

Reporting of side effects
If you or your child 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 HPRA Pharmacovigilance, Website: www.hpra.ie
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 sight and reach 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 - 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/Missouri/11/2025 (H1N1)pdm09-like strain
  (A/Missouri/11/2025, IVR-279) 15 micrograms HA **

- A/Darwin/1454/2025 (H3N2)-like strain (A/Michigan/105/2025, SAN-049A)	15 micrograms HA **
- B/Tokyo/EIS13-175/2025-like strain (B/Tokyo/EIS13-175/2025, wild type)	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 2026/2027 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 prefilled glass syringe (with or without needle), with a plunger stopper (bromobutyl rubber) 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:

Viatris Healthcare Limited,
Damastown Industrial Park,
Mulhuddart,
Dublin 15
DUBLIN,
Ireland

Registration number:
PA23355/031/001

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.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria	Influvac Tri Injektionssuspension in einer Fertigspritze, (Influenza-Impfstoff aus inaktivierten Oberflächenantigenen)
Belgium	Influvac suspensie voor injectie in een voorgevulde spuit Griepvaccin (oppervlakte-antigenen, geïnactiveerd)
Bulgaria	Инфлувак инжекционна суспензия в предварително напълнена спринцовка Ваксина срещу грип (повърхностен антиген, инактивирана)
Croatia	Influvac suspenzija za injekciju u napunjenoj štrcaljki, cjepivo protiv influence (površinski antigen), inaktivirano

Cyprus, Malta	Influvac sub-unit, suspension for injection (influenza vaccine, surface antigen, inactivated)
Czech Republic, Denmark, Estonia, Finland, Germany, Iceland, Norway, Poland, Portugal, Slovakia, Sweden	Influvac
France	INFLUVAC, suspension injectable en seringue préremplie vaccin grippal inactivé à antigènes de surface
Greece	Influvac sub-unit
Hungary	Influvac szuszpenziós injekció előretöltött fecskendőben
Ireland	Influvac sub-unit, suspension for injection in pre-filled syringe Influenza vaccine (surface antigen, inactivated)
Italy	Influvac S
Latvia	Influvac suspensija injekcijām pilnšļircē
Lithuania	Influvac injekcinė suspensija užpildytame švirkšte
Luxembourg	Influvac suspension injectable en seringue préremplie Vaccin contre la grippe (antigènes de surface, inactivés)
Netherlands	Influvac, suspensie voor injectie in voorgevulde spuit 0,5 ml
Romania	Influvac suspensie injectabilă în seringă preumplută
Slovenia	Influvac suspenzija za injiciranje v napolnjeni injekcijski brizgi
Spain	Influvac suspensión inyectable en jeringa precargada

This leaflet was last revised in June 2026

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 the colour has changed or foreign particles are present in the suspension.

Do not mix with other medicinal products in the same syringe.
The vaccine is not to be injected directly into any blood vessel.

The preferred sites for intramuscular injection are the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate) in children 6 months through 35 months of age, or the deltoid muscle in children from 36 months of age and adults.

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

See also section 3: How to use Influvac