Package leaflet: Information for the user
Influvac sub-unit Tetra, suspension for injection in pre-filled syringe
Influenza vaccine (surface antigen, inactivated)
2020/2021 season

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you or your child may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you or your child are vaccinated, because it contains important information for you or 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 sub-unit Tetra is and what it is used for

Influvac sub-unit Tetra 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. Influvac sub-unit Tetra is indicated in adults and children from 6 months of age. The use of Influvac sub-unit Tetra should be based on official recommendations.

When a person is given the vaccine Influvac sub-unit Tetra, 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 run the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

Influvac sub-unit Tetra will protect you or your child against the four 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 sub-unit Tetra

To make sure that Influvac sub-unit Tetra 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 sub-unit Tetra
- If you or your child are allergic (hypersensitive) to:
  - the active substances, or
  - any of the other ingredients of Influvac sub-unit Tetra (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 or your child 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.

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 or your child 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 sub-unit Tetra may not fully protect all persons who are vaccinated.

Other medicines and Influvac sub-unit Tetra
- 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 sub-unit Tetra 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 sub-unit Tetra may be used during breast-feeding.

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

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

Influvac sub-unit Tetra 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 sub-unit Tetra

Dosage

Adults receive one 0.5 ml dose.

Use in children and adolescents
Children from 6 months to 17 years receive one 0.5 ml dose.
Children less than 9 years of age, who have not previously been 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 sub-unit Tetra 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 sub-unit Tetra 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 the trivalent influenza vaccine Influvac)
- that may lead to medical emergency with low blood pressure, rapid, shallow breathing, rapid heart rate and weak pulse, cold, clammy skin, dizziness, that may lead to collapse (shock)
- swelling most apparent in the head and the neck, including the face, lips, tongue, throat or any other part of the body and which may cause difficulty in swallowing or breathing (angioedema)

During clinical trials with Influvac sub-unit Tetra, the following side effects have been observed:

Adults and elderly:

Very common: may affect more than 1 in 10 people:
- headache [a]
- fatigue
- local reaction: vaccination site pain

[a] In elderly adults (≥ 61 years) reported as common

Common: may affect up to 1 in 10 people:
- sweating
- muscular pain (myalgia), joint pain (arthralgia)
- generally feeling unwell (malaise), shivering,
- local reactions: redness, swelling, bruising (ecchymosis), hardness (induration) around the area where the vaccine is injected.

Uncommon: may affect up to 1 in 100 people:
- fever

Children (6 months to 17 years of age):

Side effects that occurred in children 6 to 35 months of age:

Very common: may affect more than 1 in 10 people:
- drowsiness
- sweating
- appetite loss
- diarrhoea, vomiting
- irritability/fussiness
- fever
- local reactions: pain, redness

Common: may affect up to 1 in 10 people:
- local reaction: swelling, induration, ecchymosis

Side effects that occurred in children 3 - 5 years of age:

Very common: may affect more than 1 in 10 people:
- drowsiness
- appetite loss
- irritability/fussiness
- local reactions: vaccination site pain, redness, swelling, hardness (induration) around the area where the vaccine is injected

Common: may affect up to 1 in 10 people:
- sweating
- diarrhoea, vomiting
- fever
- local reaction: bruising (ecchymosis)

Side effects that occurred in children 6 - 17 years of age:

Very common: may affect more than 1 in 10 people:
- headache
- nausea, abdominal pain, diarrhoea, vomiting
- muscular pain (myalgia)
- fatigue, generally feeling unwell (malaise)
- local reactions: vaccination site pain, redness, swelling, hardness (induration) around the area where the vaccine is injected

Common: may affect 1 in 10 people:
- sweating
- joint pain (arthralgia)
- fever
- shivering
- local reaction: bruising (ecchymosis)

All age groups

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.

Next to the above side effects, the following side effects occurred occasionally during general use of the trivalent influenza vaccine Influvac:

Unknown frequency:
- 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)

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 the national reporting system(s) listed below:

UK
The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 sub-unit Tetra

Keep out of the sight and reach of children.

Do not use Influvac sub-unit Tetra 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 sub-unit Tetra 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 sub-unit Tetra contains

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

- A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like strain (A/Guangdong-Maonan/SWL1536/2019, CNIC-1909)	15 micrograms HA **
- A/Hong Kong/2671/2019 (H3N2)-like strain (A/Hong Kong/2671/2019, IVR-208)	15 micrograms HA **
- B/Washington/02/2019-like strain (B/Washington/02/2019, wild type)	15 micrograms HA **
- B/Phuket/3073/2013-like strain (B/Phuket/3073/2013, 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 2020/2021 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 sub-unit Tetra looks like and contents of the pack

Influvac sub-unit Tetra is a suspension for injection presented in pre-filled glass syringe (with or 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:

UK:
Mylan Products Limited
20 Station Close
Potters Bar
Herts
EN6 1TL, UK

Malta:
Mylan IRE Healthcare Ltd.
Unit 35/36, Grange Parade,
Baldoyle Industrial Estate,
Dublin 13, Ireland

Registration number in UK: PL 46302/0055

Registration number in MT: MA 1187/01901

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

Austria	**Influvac Tetra Injektionssuspension in einer Fertigspritze**
Belgium, France, Luxembourg	**Influvac Tetra, suspension injectable en seringue préremplie**
Bulgaria	**Инфлувак Тетра инжекционна суспензия в предварително напълнена спринцовка**
Croatia	**Influvac Tetra suspenzija za injekciju u napunjenoj štrcaljki, cjepivo protiv influence (površinski antigeni), inaktivirano**
Czech Republic	**Influvac Tetra, injekční suspense v předplněné injekční stříkačce**
Cyprus, Greece	**Influvac subunit Tetra**
Denmark, Iceland	**Influvactetra**
Estonia, Finland, Germany, Norway, Poland, Portugal, Slovakia	**Influvac Tetra**
Ireland	**Influvac Tetra, suspension for injection in pre-filled syringe**

Italy	**Influvac S Tetra sospensione iniettabile in siringhe pre-riempite**
Latvia	**Influvac Tetra suspensija injekcijām pilnšļircē**
Lithuania	**Influvac Tetra injekcinė suspensija užpildytame švirkšte**
Malta, United Kingdom	**Influvac sub-unit Tetra, suspension for injection in pre-filled syringe**
Netherlands	**Influvac Tetra, suspensie voor injectie in voorgevulde spuit 0,5 ml**
Romania	**Influvac Tetra suspensie injectabilă în seringă preumplută**
Slovenia	**Influvac Tetra suspenzija za injiciranje v napolnjeni injekcijski brizgi**
Spain	**Influvac Tetra suspensión inyectable en jeringa precargada**
Sweden	**Influvac Tetra injektionsvätska, suspension i förfylld spruta**

This leaflet was last revised in April 2021.

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.
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 sub-unit Tetra