

Package leaflet: Information for the user
Influenza vaccine Tetra MYL, 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 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.

What is in this leaflet

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1. What Influenza vaccine Tetra MYL is and what it is used for

Influenza vaccine Tetra MYL 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. Influenza vaccine Tetra MYL is indicated in adults and children from 3 years of age. The use of Influenza vaccine Tetra MYL should be based on official recommendations.

When a person is given the vaccine Influenza vaccine Tetra MYL, 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.

Influenza vaccine Tetra MYL 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 Influenza vaccine Tetra MYL

To make sure that Influenza vaccine Tetra MYL 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 Influenza vaccine Tetra MYL

- If you or your child are allergic (hypersensitive) to:
 - the active substances, or
 - any of the other ingredients of Influenza vaccine Tetra MYL (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 problems 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, Influenza vaccine Tetra MYL may not fully protect all persons who are vaccinated.

Other medicines and Influenza vaccine Tetra MYL

- Tell your doctor or pharmacist 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.
- Influenza vaccine Tetra MYL 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. Influenza vaccine Tetra MYL may be used during breast-feeding.

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

Driving and using machines

Influenza vaccine Tetra MYL has no or negligible influence on the ability to drive or use machines.

Influenza vaccine Tetra MYL 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 Influenza vaccine Tetra MYL

Dosage

Adults receive one 0.5 ml dose.

Use in children and adolescents

Children from 3 – 17 years receive one 0.5 ml dose.

Children from 3 – 8 years, 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 children less than 3 years of age, the safety and efficacy of Influenza vaccine Tetra MYL have not been established.

Route(s) and/or method 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, Influenza vaccine Tetra MYL 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)

- 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 Influenza vaccine Tetra MYL, the following side effects have been observed:

Adults and elderly:

Very common: affects more than 1 in 10 people:

- headache ^a
- fatigue
- local reaction: vaccination site pain

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

Common: affects 1 to 10 people in 100:

- 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: affects between 1 in 1,000 and 1 in 100 people:

- fever

Children (3 - 17 years of age):

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

Very common: affects more than 1 in 10 people:

- irritability
- drowsiness
- appetite loss
- local reactions: vaccination site pain, redness, swelling, hardness (induration) around the area where the vaccine is injected

Common: affects 1 to 10 people in 100:

- sweating
- diarrhoea/vomiting
- fever
- local reaction: bruising (ecchymosis)

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

Very common: affects more than 1 in 10 people:

- headache
- gastrointestinal symptoms
- 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: affects 1 to 10 people in 100:

- sweating
- joint pain (arthralgia)
- fever
- shivering
- local reaction: bruising (ecchymosis)

For all age groups, most reactions 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:

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 or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Influenza vaccine Tetra MYL

Keep out of the sight and reach of children.

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

Store Influenza vaccine Tetra MYL 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 Influenza vaccine Tetra MYL 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 Influenza vaccine Tetra MYL looks like and contents of the pack

Influenza vaccine Tetra MYL 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:

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

Registration number:

PL 46302/0056

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	FluVaccinol Subunit Tetra Injektionssuspension in einer Fertigspritze
Germany	Xanaflu Tetra
The Netherlands	Batrevac Tetra, suspensie voor injectie in voorgevulde spuit 0,5ml
United Kingdom	Influenza vaccine Tetra MYL, suspension for injection in prefilled syringe

This leaflet was last revised in May 2020.

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.

See also section 3: How to use Influenza vaccine Tetra MYL