Package leaflet: Information for the user

TRIAXIS

Suspension for injection in pre-filled syringe

Diphtheria, Tetanus, Pertussis (acellular, component) Vaccine
(adsorbed, reduced antigen(s) content)

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

- 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 for your child only. 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 TRIAXIS is and what it is used for

TRIAXIS (Tdap) is a vaccine. Vaccines are used to protect against infectious diseases. They work by causing the body to produce its own protection against the bacteria that cause the targeted diseases.

This vaccine is used to boost protection against diphtheria, tetanus and pertussis (whooping cough) in children from the age of 4 years, adolescents and adults, following a complete primary course of vaccination.

Use of TRIAXIS during pregnancy allows protection to be passed on to the child in the womb to protect her/him from whooping cough during the first few months of life.

Limitations in the protection provided

TRIAXIS will only prevent these diseases if they are caused by the bacteria targeted by the vaccine. You or your child could still get similar diseases if they are caused by other bacteria or viruses.

TRIAXIS does not contain any live bacteria or viruses and it cannot cause any of the infectious diseases against which it protects.

Remember that no vaccine can provide complete, lifelong protection in all people who are vaccinated.

2 What you need to know before TRIAXIS is given to you or your child

To make sure that TRIAXIS is suitable for you or your child, it is important to tell your doctor 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 or nurse to explain.

Do not use TRIAXIS if you or your child

- has had an allergic reaction:
  - to diphtheria, tetanus or pertussis vaccines
  - to any of the other ingredients (listed in section 6)
  - to any residual component carried over from manufacture (formaldehyde, glutaraldehyde) which may be present in trace amounts.
- has ever had a severe reaction affecting the brain within one week after a previous dose of a whooping cough vaccine
- has an acute severe febrile illness. The vaccination should be delayed until you or your child has recovered. A minor illness without fever is not usually a reason to defer vaccination. Your doctor will determine if you or your child should receive TRIAXIS.

Warnings and precautions

Tell your doctor or nurse before vaccination if you or your child has

- received a booster dose of a vaccine for diphtheria and tetanus within the last 4 weeks. In this case you or your child should not receive TRIAXIS and your doctor will decide on the basis of official recommendations when you or your child can receive a further injection.
- had a Guillain-Barré syndrome (temporary loss of movement and feeling in all or part of the body) within 6 weeks of a previous dose of a tetanus containing vaccine. Your doctor will decide if you or your child should receive TRIAXIS.
- a progressive illness affecting the brain/nerves or uncontrolled fits. Your doctor will first start treatment and vaccinate when the condition has stabilized.
- a poor or reduced immune system, due to
  - medication (e.g., steroids, chemotherapy or radiotherapy)
  - HIV infection or AIDS
  - any other illness.

  The vaccine may not protect as well as it protects people whose immune system is healthy. If possible, vaccination should be postponed until the end of such disease or treatment.
- any problems with the blood that causes easy bruising, or bleeding for a long time after minor cuts (for instance due to a blood disorder such as haemophilia or thrombocytopenia or treatment with blood thinning medicines).

Fainting can occur following, or even before, any needle injection. Therefore tell the doctor or nurse if you or your child fainted in connection with a previous injection.

Tell your doctor, pharmacist or nurse before using TRIAXIS, if you or your child have had any allergic reactions to latex. The tip caps of the prefilled syringes contain a natural rubber latex derivative which may cause an allergic reaction.

Other medicines or vaccines and TRIAXIS

Tell your doctor, nurse or pharmacist if you or your child is taking, has recently taken or might take any other medicines.

As TRIAXIS does not contain any live bacteria, it can generally be given at the same time as other vaccines or immunoglobulins, but at a different injection site. Studies have demonstrated that TRIAXIS can be used at the same time as any of the following vaccines: a hepatitis B vaccine, a poliovirus vaccine (injected or oral), an inactivated flu vaccine and a recombinant Human Papillomavirus vaccine respectively. Injections of more than one vaccine at the same time will be given in different limbs.

If you or your child is receiving medical treatment affecting you or your child's blood or immune system (such as blood thinning medicines, steroids or chemotherapy), please refer to the section "Warnings and precautions" above.

Pregnancy, breast-feeding and fertility

Tell your doctor or nurse if you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby. Your doctor will help you decide if you should receive TRIAXIS during pregnancy.

Driving and using machines

It has not been studied if the vaccine affects the ability to drive or use machines. The vaccine has no or negligible influence on the ability to drive and use machines.

3 How and when TRIAXIS is given

When you or your child will be given the vaccine

Your doctor will determine if TRIAXIS is suitable for you or your child, depending on:
- what vaccines have been given to you or your child in the past
- how many doses of similar vaccines have been given to you or your child in the past
- when the last dose of a similar vaccine was given to you or your child

Your doctor will decide how long you have to wait between vaccinations.

If you are pregnant, the doctor will help you decide if you should receive TRIAXIS during pregnancy.

Dosage and method of administration

Who will give you TRIAXIS?

TRIAXIS should be given by healthcare professionals who have been trained in the use of vaccines and at a clinic or surgery that is equipped to deal with any rare severe allergic reaction to the vaccine.

Dosage

All age groups for whom TRIAXIS is indicated will receive one injection (half a millilitre).

In case you or your child experience an injury which requires preventive action for tetanus disease, your doctor may decide to give TRIAXIS with or without tetanus immunoglobulin.

TRIAXIS can be used for repeat vaccination. Your doctor will give you advice on repeat vaccination.

Method of administration

Your doctor or nurse will give you the vaccine into a muscle in the upper outer part of the arm (deltoid muscle).

Your doctor or nurse will **not** give you the vaccine into a blood vessel, into the buttocks or under the skin. In case of blood clotting disorders they may decide to inject under the skin, although this might result in more local side effects, including a small lump under the skin.

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

4 Possible side effects

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

Serious allergic reactions

If any of these symptoms occur after leaving the place where you or your child received the injection, you must consult a doctor IMMEDIATELY:
- difficulty in breathing
- blueness of the tongue or lips
- a rash
- swelling of the face or throat
- low blood pressure causing dizziness or collapse

When these signs or symptoms occur they usually develop very quickly after the injection is given and while you or your child is still in the clinic or doctor's surgery. Serious allergic reactions are a very rare possibility (may affect up to 1 in 10,000 people) after receiving any vaccine.

Other side effects

The following side effects were observed during clinical studies carried out in specific age groups.

In children aged 4 to 6 years

Very common (may affect more than 1 in 10 people):
- decreased appetite
- headache
- diarrhoea
- tiredness
- pain
- redness
- swelling in the area where the vaccine was injected.

Common (may affect up to 1 in 10 people):
- nausea
- vomiting
- rash
- aching (all over the body) or muscular weakness
- aching or swollen joints
- fever
- chills
- underarm lymph node disorder.

In adolescents aged 11 to 17 years

Very common (may affect more than 1 in 10 people):
- headache
- diarrhoea
- nausea
- aching (all over the body) or muscular weakness
- aching or swollen joints
- tiredness/weakness
- feeling unwell
- chills
- pain,
- redness and swelling in the area where the vaccine was injected.

Common (may affect up to 1 in 10 people):
- vomiting
- rash
- fever
- underarm lymph node disorder

In adults aged 18 to 64 years

Very common (may affect more than 1 in 10 people):
- headache
- diarrhoea
- aching (all over the body) or muscular weakness
- tiredness/weakness
- feeling unwell
- pain,
- redness and swelling in the area where the vaccine was injected.

Common (may affect up to 1 in 10 people):
- nausea
- vomiting
- rash
- aching or swollen joints
- fever
- chills
- underarm lymph node disorder

The following additional adverse events have been reported in the various recommended age groups during the commercial use of TRIAXIS. The frequency of these adverse events cannot be precisely calculated, as it would be based on voluntary reporting in relation to the estimated number of vaccinated persons.
- Allergic / serious allergic reactions (how you can recognize such a reaction, you can find in the beginning of section 4), ‘pins and needles’ or numbness, paralysis of part or all the body (Guillain-Barré syndrome), inflammation of the nerves in the arm (brachial neuritis), loss of function in the nerve that supplies the facial muscles (facial palsy), fits (convulsions), fainting, inflammation of the spinal cord (myelitis), inflammation of the muscular part of the heart (myocarditis), itching, hives,

inflammation of a muscle (myositis), extensive limb swelling associated with redness, warmth, tenderness or pain in the area where the vaccine was injected, bruising, abscess or a small lump in the area where the vaccine was injected.

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 Health Products Regulatory Authority (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 TRIAXIS

Keep this medicine out of the sight and reach of children.

TRIAXIS must not be used after the expiry date which is stated on the label after "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze. Discard the vaccine if it has been frozen.

Keep the syringe in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What TRIAXIS contains

The active substances in each dose (0.5 mL) of vaccine are:

Diphtheria Toxoid	not less than 2 International Units (2 Lf)
Tetanus Toxoid	not less than 20 International Units (5 Lf)
Pertussis Antigens:	
Pertussis Toxoid	2.5 micrograms
Filamentous Haemagglutinin	5 micrograms
Pertactin	3 micrograms
Fimbriae Types 2 and 3	5 micrograms
Adsorbed on Aluminium Phosphate	1.5 mg (0.33 mg Al^{3+})

Aluminium phosphate is included in this vaccine as an adjuvant. Adjuvants are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine.

The other ingredients are: phenoxyethanol, water for injections

What TRIAXIS looks like and contents of the pack

TRIAXIS is presented as a suspension for injection in pre-filled syringe (0.5 mL):

- without needle – pack size of 1 or 10
- with 1 or 2 separate needles – pack size of 1 or 10

Not all pack sizes may be marketed.

The normal appearance of the vaccine is a cloudy white suspension, which may sediment during storage. After shaking well it is a uniformly white liquid.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Sanofi Pasteur Europe
14 Espace Henry Vallée
69007 Lyon
France

The manufacturer responsible for batch release is:
Sanofi Pasteur
14 Espace Henry Vallée
69007 Lyon
France

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

Austria,Germany:	Covaxis
Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Norway, Portugal, Spain, Sweden, The Netherlands:	Triaxis
Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia, Slovenia, United Kingdom (Northern Ireland):	Adacel

This leaflet was last revised in April 2023.

The following information is intended for healthcare professionals only:

Instructions for use

In the absence of compatibility studies, TRIAXIS must not be mixed with other medicinal products.

Parenteral biological products should be inspected visually for extraneous particulate matter and/or discolouration prior to administration. If these conditions exist, the product should not be administered.

The needle should be pushed firmly on to the end of the pre-filled syringe and rotated through 90 degrees.

Needles should not be recapped.