

Package leaflet: Information for the user

Tetravac, suspension for injection Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine, adsorbed.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed only for your child. Do not pass it on to others.
- If your child gets any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tetravac is and what it is used for
2. What you need to know before Tetravac is given to your child
3. How to use Tetravac
4. Possible side effects
5. How to store Tetravac
6. Contents of the pack and other information

1. What Tetravac is and what it is used for

Tetravac is a vaccine. Vaccines are used to protect against infectious diseases.

This vaccine helps to protect your child against diphtheria, tetanus, pertussis (whooping cough) and poliomyelitis (polio).

It is given as a primary series vaccination in babies and as a booster vaccination in children who received this vaccine or a similar vaccine when they were younger.

When an injection of Tetravac is given, the body's natural defences will produce protection against these different diseases.

- Diphtheria is an infectious disease that usually first affects the throat. In the throat, the infection causes pain and swelling which can lead to suffocation. The bacteria that cause the disease also produce a toxin (poison) that can damage the heart, kidneys and nerves.
- Tetanus (often called lock jaw) is caused by the tetanus bacteria entering a deep wound. The bacteria produce a toxin (poison) that causes spasms of the muscles, leading to an inability to breathe and the possibility of suffocation.
- Pertussis (often called whooping cough) is an infection of the airways, that can occur at any age but mostly affects infants and young children. Increasingly severe coughing spells that can last for several weeks are a characteristic of the disease. Coughing spells may be followed by a whooping noise.
- Poliomyelitis (often just called polio) is caused by viruses that affect the nerves. It can lead to paralysis, or muscle weakness most commonly of the legs. Paralysis of the muscle that controls breathing and swallowing can be fatal.

Important

Tetravac will only help to prevent these diseases if they are caused by the same bacteria or viruses as those used for producing the vaccine. Your child could still get infectious diseases if they are caused by other bacteria or viruses.

2. What you need to know before Tetravac is given to your child

It is important to tell your doctor, pharmacist or nurse if any of the points below apply to your child so that they can make sure that Tetravac is suitable for your child.

Do not use Tetravac if your child:

- is allergic to:
 - the active substances of Tetravac or any of the other ingredients of Tetravac (see section 6)
 - other vaccines containing any of the substances shown in section 6
 - any vaccine which protects against whooping cough
- has a high temperature or an acute illness (e.g. temperature, sore throat, cough, cold or flu). Vaccination with Tetravac may need to be delayed until your child is better;
- has any active disease of the brain (evolving encephalopathy);
- has had a severe reaction to any vaccine which protects against whooping cough that affected the brain.

Warnings and precautions

Tell your doctor or nurse before vaccination if:

- your child is allergic (hypersensitive) to glutaraldehyde, neomycin, streptomycin and polymyxin B. This is because these substances are used during the production of Tetravac and there may be undetectable traces of these substances still in the vaccine;
- your child has problems with his or her immune system or is receiving immunosuppressive treatment. It is recommended to postpone vaccination until the end of such disease or treatment. Giving Tetravac to children who have chronic problems with their immune system (including HIV infection) is recommended but protection against infections after having the vaccine may not be as good as in children with good immunity to infections;
- your child had a temporary loss of movement and feeling (Guillain-Barré syndrome) or loss of movement, pain and numbness of the arm and the shoulder (brachial neuritis) following a previous injection with a tetanus containing vaccine. Your doctor or nurse will decide whether to give Tetravac to your child;
- your child has thrombocytopenia (low levels of platelets) or a bleeding disorder (such as haemophilia) because he or she may bleed at the injection site.
- your child has had a vaccine that protects against whooping cough in the past and any of the following occurred soon afterwards:
 - temperature of 40°C or more within 48 hours, which was not due to another identifiable cause;
 - episodes when your child goes into a shock-like state or is pale, floppy and unresponsive for a period of time or fainting (hypotonic-hyporesponsive episodes or collapse) within 48 hours of the vaccination;
 - cried persistently and inconsolably for more than 3 hours within 48 hours of the vaccination;
 - fit (convulsions), with or without fever within 3 days of the vaccination.

Other medicines and Tetravac

Tetravac can be given at the same time as the *Haemophilus influenzae* type b vaccine (Act-Hib).

Tetravac can be given at the same time as a measles-mumps-rubella vaccine. Your doctor or nurse will give the two injections at different injection sites and will use separate syringes for each injection.

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

If there is anything you do not understand, ask your doctor, pharmacist or nurse to explain.

Pregnancy and breast-feeding

Not applicable. This vaccine is intended for use in children only.

Tetravac contains phenylalanine

Tetravac contains phenylalanine which may be harmful to people with phenylketonuria (PKU).

Tetravac contains ethanol

Tetravac contains small amounts of ethanol (alcohol), less than 100 mg per dose.

3. How to use Tetravac

Dosage

For the vaccine to be effective

- your child will need to receive a number of doses of the vaccine at different times before he/she is 2 years old. The two different schedules for when these doses can be given are shown in the table below. Your doctor will decide which schedule your child will receive.

	Age at first dose	Age at second dose	Age at third dose	Booster
Schedule 1 (Booster needed)	2 or 3 months	3 to 5 months	4 to 7 months	12 to 24 months
Schedule 2 (No Booster needed)	3 months	5 months	12 months	No booster

Schedule 1 injections are given with an interval of 1-2 months between each of the first 3 doses.

- your child may also receive Tetravac if he/she is between 5-12 years old and has already been vaccinated with any vaccine protecting against whooping cough.

Usually a high dose diphtheria vaccine, such as Tetravac, is used to immunise children less than 12 years of age. In some countries however, children under 12 years of age may receive a low dose diphtheria vaccine.

If your child misses one dose of Tetravac

If your child misses a scheduled injection, your doctor will decide when to give the missed dose.

Method of administration

The vaccination should be given by medical or healthcare professionals who are trained in the use of vaccines and who are equipped to deal with any uncommon severe allergic reaction to the injection.

Tetravac is given as an injection into a muscle in your child's thigh or upper arm. Your doctor or nurse will avoid giving this injection into a blood vessel.

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

4. Possible side effects

Like all vaccines and medicines, Tetravac can cause side effects, although not everybody gets them.

Serious allergic reactions are always a rare possibility after receiving a vaccine.

These reactions may include difficulty in breathing, blue discolouration of the tongue or lips, low blood pressure (causing dizziness) and fainting (collapse).

Sudden signs of allergy such as swelling of the face, lips, tongue or other parts of the body (oedema, Quincke's oedema) have been reported after administration of Tetravac (their exact frequency cannot be estimated from the available data).

When these signs or symptoms occur they usually develop very quickly after the injection is given and while the person affected is still in the clinic or doctor's surgery.

If any of these symptoms occur after leaving the place where your child received the injection, you must consult a doctor IMMEDIATELY.

Very common reactions (may affect more than 1 in 10 children) are:

- Loss of appetite

- Nervousness or irritability
- Abnormal crying
- Drowsiness
- Headache
- Vomiting (being sick)
- Myalgia (muscle pain)
- Redness at the site of the injection
- Injection site pain
- Injection site swelling
- Fever of 38°C or more
- Malaise

After the primary series, the frequencies of injection site reactions tend to increase with the booster dose.

Common reactions (may affect up to 1 in 10 children) are:

- Diarrhoea
- Hardness (induration) at the site of injection
- Disturbed sleep

Uncommon reactions (may affect up to 1 in 100 children) are:

- Redness and swelling of 5 cm or more at the site of the injection
- Fever of 39°C or more
- Prolonged inconsolable crying (inconsolable crying lasting more than 3 hours)

Rare reactions (may affect up to 1 in 1000 children) are:

- High fever over 40°C

Reactions with unknown frequency (Frequency cannot be estimated from the available data) are:

- Fits (convulsions), with or without fever
- Fainting
- Rash, redness and itchiness of the skin (erythema, urticaria)
- Large reactions at the injection site (larger than 5 cm), including extensive limb swelling from the injection site beyond one or both joints. These reactions start within 24-72 hours after vaccination, may be associated with redness, warmth, tenderness or pain at the injection site, and get better within 3-5 days without the need for treatment.
- Swelling of the glands in the neck, armpit or groin (lymphadenopathy)

Other reactions seen with vaccines containing the same active substances as this vaccine include:

- Temporary loss of movement or feeling (Guillain-Barré syndrome) and loss of movement, pain and numbness (brachial neuritis) of the arm and the shoulder.
- Episodes when your child goes into a shock-like state or is pale, floppy and unresponsive for a period of time (hypotonic hyporesponsive episodes).

Other reaction which can occur when Tetravac is administered at same time as a separate

Haemophilus influenzae type b vaccine:

- Swelling of one or both lower limbs. This may occur along with bluish discoloration of the skin (cyanosis), redness, small areas of bleeding under the skin (transient purpura) and severe crying. If this reaction occurs, it does so mainly after first (primary) injections and is seen within the first few hours following vaccination. All symptoms will disappear completely within 24 hours without the need for treatment.

In babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination.

Reporting of side effects in Ireland

If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST

Pharmacovigilance Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.ie

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

Reporting of side effects in the UK

If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. 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.

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

5. How to store Tetravac

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

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

Store in a refrigerator (2°C - 8°C). Do not freeze. If frozen discard the vaccine.

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

6. Contents of the pack and other information

What Tetravac contains

Each 0.5 ml dose of reconstituted vaccine contains the following:

The active substances are:

Purified diphtheria toxoid	not less than 30 I.U.*
Purified tetanus toxoid	not less than 40 I.U.*
Purified pertussis toxoid (PTxd)	25 micrograms
Purified filamentous haemagglutinin (FHA)	25 micrograms
Inactivated type 1 poliovirus	D antigen**: 40 units
Inactivated type 2 poliovirus	D antigen**: 8 units
Inactivated type 3 poliovirus	D antigen**: 32 units

*I.U.: International Unit

****Quantity of antigen in the vaccine**

The adjuvant is:

Aluminium hydroxide (expressed as Al³⁺) 0.30 milligram

The other ingredients are formaldehyde, phenoxyethanol, ethanol, Medium 199 in water for injection. Medium 199 is a complex mixture of amino acids (including phenylalanine), mineral salts, vitamins and other components (such as glucose) diluted in water for injection.

What Tetravac looks like and contents of the pack

Tetravac, suspension for injection, is available as a single dose (0.5 ml) prefilled syringe.

Pack sizes of 1 or 10 without needle, with attached needle, with 1 separate needle or with 2 separate needles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder - UK

Sanofi Pasteur Europe
2 Avenue Pont Pasteur
69007 Lyon
France

Marketing Authorisation Holder - Ireland

Sanofi Pasteur Europe
2 Avenue Pont Pasteur
69007 Lyon
France

Manufacturer

The manufacturer responsible for batch release is Sanofi Pasteur S.A. at the following address.
Sanofi Pasteur S.A., 2 avenue Pont Pasteur, 69007 Lyon, France

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

Tetravac	Austria, Belgium, Denmark, Finland, Germany, Greece, Ireland, Italy, Luxemburg, Portugal, Sweden, United Kingdom, Iceland, Norway
Tetravac-Acellulaire	France

This leaflet was last revised in

The following information is intended for medical or healthcare professionals only:

Instructions for use - Tetravac, suspension for injection
Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine, adsorbed.

Shake the pre-filled syringe so that the contents become homogeneous. Tetravac should not be mixed with other medicinal products.

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

Tetravac must be administered intramuscularly. The recommended injection sites are the antero-lateral aspect of the upper thigh in infants and the deltoid muscle in older children.

The intradermal or intravenous routes must not be used. Do not administer by intravascular injection: ensure that the needle does not penetrate a blood vessel.