Package leaflet: Information for the user

Tetravac, suspension for injection in prefilled syringe
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, or pharmacist or nurse.
- 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, or pharmacist or nurse. 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

Tetravac is a vaccine (DTaP-IPV vaccine) used to protect against infectious diseases.

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

It is given as a primary series vaccination in children from 2 months of age 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

- if your child has any active disease of the brain (evolving encephalopathy);
- if your child 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 has a high temperature or an acute illness (e.g. temperature, sore throat, cough, cold or flu). Vaccination may need to be delayed until your child is better.
- If your child has had a vaccine that protects against whooping cough in the past and any of the following occurred soon afterwards:
  - Fever of 40°C or more within 48 hours not due to another identifiable cause.
  - Collapse of shock-like state with hypothonic-hyporesponsible episode within 48 hours of vaccination.
  - Persistent, inconsolable crying lasting 3 hours or longer, occurring within 48 hours of vaccination.
  - Convulsions with or without fever, occurring within 3 days of 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.

- If your child already presented with febrile convulsions, not related to previous vaccine injection; in this case it is particularly important that temperature be monitored in the 48 hours following vaccination and that antipyretic treatment be regularly administered to help reduce fever, for 48 hours.

- If 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.

- If your child has immunodeficiency or is receiving a treatment that suppresses their immune defenses, as the immune response to the vaccine may be decreased. It is recommended to wait until the end of such disease or treatment before vaccination. Giving Tetravac to children who have chronic immunodeficiency (including HIV infection) is recommended but protection against infections may be limited.

- If 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.

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

Other medicines/vaccines and Tetravac

Tetravac can be given at the same time as:

- Act-HIB (*Haemophilus influenzae* type b conjugate)
- Measles-mumps-rubella, varicella-containing vaccines

- Hepatitis B vaccine,

but in separate injection sites.

In case your child should receive Tetravac simultaneously with other vaccines than those already mentioned, please ask your doctor or pharmacist for more information.

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

Pregnancy and breast-feeding
Not applicable. This vaccine is intended for use in children only.

Tetravac contains phenylalanine, ethanol and sodium
Tetravac contains 12.5 micrograms phenylalanine in each 0.5 mL dose. Phenylalanine may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Tetravac contains 2 mg of alcohol (ethanol) in each 0.5 mL dose. The small amount of alcohol in this medicine will not have any noticeable effects.

Tetravac contains less than 1 mmol (23mg) sodium per dose, that is to say essentially "sodium-free".

3. How to use Tetravac

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Posology:
The usual recommended schedule includes primary vaccination, consisting of three injections at an interval of one or two months from the age of 2 months, followed by one booster vaccination within the second year of life.
The three doses of the vaccination course can be also administered at the age of 3, 5, and 12 months, in this case there is no need for a fourth dose during the second year of life.
For both schedules, a booster dose is recommended between the ages of 4 and 13 years.

The use of this vaccine should be in accordance with official recommendations.

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 [intramuscular route (IM)] in the upper part of your child's leg or upper arm. The vaccine should never be given into a blood vessel.

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.

If you use more Tetravac than you should
Since your doctor or nurse administers Tetravac to your child, overdose is not probable. If you think that your child received too much Tetravac or the interval between two injections was too short, please tell your doctor or nurse.

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

There is a possibility that **(**with unknown frequency) serious allergic reactions occur after the administration of any vaccines. These can be the following:

- Difficulty in breathing
- Blueness of the tongue or lips
- A rash
- Swelling of the face or throat or other parts of the body
- Low blood pressure causing dizziness or collapse.

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

Other side effects

If your child experiences any of the following side effects and it gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

- Very common reactions (may affect more than 1 user in 10) are:
  - Vomiting
  - Appetite loss (feeding disturbances)
  - Drowsiness (somnolence)
  - Headache
  - Nervousness (irritability)
  - Abnormal crying
  - Muscle pain (myalgia)
  - Redness at the injection site
  - Pain at the injection site
  - Injection site swelling
  - Fever of 38°C or more
  - Malaise.

- Common reactions (may affect 1 to 10 users in 100) are:
  - Diarrhoea
  - Sleep disturbances (insomnia)
  - Hardening of the skin (induration) at the injection site.

- Uncommon (may affect 1 to 10 users in 1,000) are:
  - Prolonged inconsolable crying
  - Redness and swelling larger than 5 cm at the injection site
  - Fever of 39°C or more.

- Rare reactions (may affect 1 to 10 users in 10,000) are:
  - Fever over 40°C.

- Reactions with unknown frequency (frequency cannot be estimated from the available data) are:
  - Fits (convulsions), with or without fever
  - Fainting (syncope)
  - 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. The risk appears to be dependent on the number of prior doses of acellular pertussis-containing vaccines, with a greater risk following the 4th and 5th doses.

- Swelling of the glands in the neck, armpit or groin (lymphadenopathy).

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.

Potential side effects (i.e., they have not been reported directly with Tetravac, but with other vaccines containing one or more of the antigenic constituents of Tetravac) are the following:

- 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).
- 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

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 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 Tetravac

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

Store in a refrigerator (2°C - 8°C).
Do not freeze.

Do not use this medicine after the expiry date stated on the label and the box after EXP.
The expiry date refers to the last day of that month.

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 Tetravac contains

The active substances are:

One dose (0.5 mL) contains:

Diphtheria Toxoid[1]	not less than 20 IU[2,3] (30 Lf)
Tetanus Toxoid[1]	not less than 40 IU[3, 4](10 Lf)
Bordetella pertussis antigens	
Pertussis Toxoid[1]	25 micrograms
Filamentous Haemagglutinin[1]	25 micrograms
Poliovirus (Inactivated)[5]	
Type 1 (Mahoney)[4]	29 D-antigen units[6]
Type 2 (MEF-1)[4]	7 D-antigen units[6]
Type 3 (Saukett)[4]	26 D-antigen units[6]

[1] Adsorbed on aluminium hydroxide, hydrated (0.3 milligram Al^{3+})
[2] As lower confidence limit (p= 0.95) and not less than 30 IU as mean value
[3] Or equivalent activity determined by immunogenicity evaluation
[4] As lower confidence limit (p= 0.95)
[5] Cultivated on Vero cells
[6] These antigen quantities are strictly the same as those previously expressed as 40-8-32 D-antigen units, for virus type 1, 2 and 3 respectively, when measured by another suitable immunochemical method.

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

The other ingredients are: Medium 199 Hanks without phenol red (complex mixture of amino acids including phenylalanine, mineral salts, vitamins and other substances such as glucose), formaldehyde, acetic acid glacial or sodium hydroxide for pH adjustment, phenoxyethanol, ethanol anhydrous and water for injections.

The vaccine may contain traces of glutaraldehyde, neomycin, streptomycin and polymyxin B which are used during the manufacturing process.

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

Sanofi Pasteur Europe
14 Espace Henry Vallée
69007 Lyon
France

Distributed by:
Ireland:
sanofi-aventis Ireland T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland
Tel: +353 (0) 1 4035 600

Manufacturer

The manufacturer responsible for batch release is Sanofi Pasteur at the following address.
Sanofi Pasteur, 14 Espace Henry Vallée, 69007 Lyon, France

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

Tetravac	Belgium, Denmark, Finland, Greece, Ireland, Italy, Luxemburg, Portugal, Sweden, United Kingdom (Northern Ireland), Iceland, Norway

This leaflet was last revised in January 2024.

The following information is intended for healthcare professionals only:

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

For syringes without attached needles, the separate needle must be fitted firmly to the syringe, rotating it by a one-quarter turn.

Shake before injection until a homogeneous whitish-turbid suspension is obtained.

The suspension should be visually inspected prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, discard the prefilled syringe.

Tetravac may be administered by reconstituting the Act-HIB (*Haemophilus influenzae* type b conjugate) vaccine as follows:
Shake the prefilled syringe until the contents become homogeneous and reconstitute the solution by injecting the suspension of the combined diphtheria, tetanus, acellular pertussis and poliomyelitis vaccine into the vial with the powder of the *Haemophilus* type b conjugate vaccine.

- Gently shake the vial until complete dissolution of the powder. After reconstitution, the whitish-turbid appearance of the suspension is normal.
- Withdraw immediately the reconstituted suspension into the syringe.
- The whitish cloudy suspension must be used immediately after reconstitution and shaken before injection.
- After reconstitution and withdrawing into the syringe, the separation of the suspension into a transparent phase and gel-like phase can appear.

In that case, the syringe should be again vigorously shaken before administration.

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.