Package leaflet: information for the user

Pentavac, powder and suspension for suspension for injection.
Diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated) and *Haemophilus influenzae* type b conjugate 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 Pentavac is and what it is used for

Pentavac (DTaP-IPV/Hib) is a vaccine. Vaccines are used to protect against infectious diseases.
This vaccine helps to protect your child against diphtheria, tetanus, pertussis (whooping cough), poliomyelitis (polio) and serious diseases caused by *Haemophilus influenzae* type b (often just called Hib infections).
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 Pentavac 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.
- *Haemophilus influenzae* type b infections (often just called Hib infections) are all serious and invasive infections of meninges (membranes covering the brain), lungs, throat, blood, skin, joints and bones.

Important
Pentavac 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.

Pentavac does not protect against infectious diseases caused by other types of Haemophilus influenzae or against inflammation of the outer covering of the brain (meningitis) of other origins.

2. What you need to know before Pentavac 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 Pentavac is suitable for your child.

Do not use Pentavac if your child:
- is allergic to:
  - the active substances of Pentavac or any of the other ingredients of Pentavac (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 Pentavac 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 Pentavac 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 Pentavac 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 Pentavac 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.

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 and Pentavac
Pentavac 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.

Pentavac contains phenylalanine, ethanol and sodium
Pentavac 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.
Pentavac 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.
Pentavac contains less than 1 mmol sodium per dose, that is to say essentially "sodium-free".

3. How to use Pentavac

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.

If your child misses one dose of Pentavac
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.

Pentavac 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.

Your doctor or nurse will give your child the vaccine immediately after mixing the two parts of Pentavac together.

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, Pentavac 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).

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
- Vomiting (being sick)
- Redness at the injection site
- Fever of 38°C or more
- Injection site swelling
- Injection site pain

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 the 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
- Swelling of one or both lower limbs. This may occur along with bluish discolouration 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.

Reactions with unknown frequency (frequency cannot be estimated from the available data) are:
- Fits (convulsions), with or without fever
- Episodes when your child goes into a shock-like state or is pale, floppy and unresponsive for a period of time (hypotonic hyporesponsive episodes)
- 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.

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.

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 you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects directly the national reporting system listed in Appendix V*. By reporting side effects you can help provide more

information on the safety of this medicine

5. How to store Pentavac

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

Do not use Pentavac 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 and 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 Pentavac contains

The active substances are:

One dose (0.5 ml) of reconstituted vaccine 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)	29 D-antigen units[6]
Type 2 (MEF-1)	7 D-antigen units[6]
Type 3 (Saukett)	26 D-antigen units[6]
Haemophilus influenzae type b polysaccharide conjugated to tetanus protein	10 micrograms

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 adsorbent. Adsorbents are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine.

The other ingredients are formaldehyde, phenoxyethanol, ethanol anhydrous, Medium 199 Hanks without phenol red, acetic acid glacial and/or sodium hydroxide for pH adjustment, trometamol, sucrose, concentrated hydrochloric acid for pH adjustment, 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 Pentavac looks like and contents of the pack

Pentavac, powder and suspension for suspension for injection, is available as a single dose (0.5 ml) prefilled syringe with a single dose vial of *Haemophilus influenzae* type b vaccine (freeze-dried vaccine) in the same pack.

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

The Marketing Authorisation Holder is
[To be completed nationally]

Manufacturer

The manufacturer responsible for batch release is:
Sanofi Winthrop Industrie
1541 avenue Marcel Mérieux
69280 Marcy l'Etoile
France

And/or

Sanofi Winthrop Industrie
Voie de L'Institut
Parc Industriel d'Incarville B.P 101,
27100 Val de Reuil,
France

And/or

Sanofi Aventis Zrt.
Building Dc5
Campona Utca 1
Budapest XXII, 1225
Hungary

This medicine is authorised in the Member States of the European Economic Area under the following names:

Pentavac	Belgium, Denmark, Finland, Greece, Luxemburg, Portugal, Sweden, Iceland

This leaflet was last revised in 2026-05-21.

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

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- For syringes without attached needles, the needle must be fitted firmly to the syringe, rotating it by a one quarter turn.
- Shake the pre-filled syringe containing the suspension until the contents become homogeneous.
- Inject this suspension into the vial with the powder
- Gently shake the vial until complete dissolution of the powder, achieving a whitish-turbid appearance
- Withdraw immediately the reconstituted vaccine into the syringe
- Gently shake the loaded syringe and promptly deliver the injection.
- Should the reconstituted vaccine separate into a transparent phase and gel-like phase, then remix by shaking the syringe vigorously before administration.
- The whitish cloudy aspect of the reconstituted vaccine is normal.

Pentavac should not be mixed with other medicinal products.

Pentavac 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.