PENTAXIM

Powder and suspension for suspension for injection in prefilled syringe

DIPHTHERIA, TETANUS, PERTUSSIS (ACELLULAR, COMPONENT),
POLIOMYELITIS (INACTIVATED) VACCINE AND
HAEMOPHILUS TYPE b CONJUGATE VACCINE, ADSORBED

Read all of this leaflet carefully before you get your child vaccinated.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, if you have a doubt, ask your doctor or pharmacist.
- This medicine has been prescribed for your child only. Never pass it on to others.
- If any of side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See Section 4.

What is in this leaflet:

1. WHAT PENTAXIM IS AND WHAT IT IS USED FOR

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

When PENTAXIM is injected, the body's natural defenses develop a protection against those diseases.

PENTAXIM is indicated to help protect your child against diphtheria, tetanus, pertussis, poliomyelitis and against invasive infections due to the *Haemophilus influenzae* type b bacterium (such as meningitis, blood poisoning, etc.) PENTAXIM is indicated in children from the age of 2 months.

It does not protect against infections caused by other types of *Haemophilus influenzae* or against meningitis due to other micro-organisms.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PENTAXIM

Never use PENTAXIM:

- If your child is allergic (hypersensitive):
  - to any of the vaccine components (listed in Section 6 "What PENTAXIM contains")
  - to glutaraldehyde, neomycin, streptomycin, or polymyxin B (used during the manufacturing process and which may be present as traces).
  - to a pertussis vaccine (acellular or "whole cell"),
- If your child had an allergic reaction after a previous injection of the same vaccine or a vaccine containing the same substances,
- if your child suffers from evolving encephalopathy (cerebral lesions),
- if your child suffered from encephalopathy (cerebral lesions) within 7 days of a previous dose of a pertussis vaccine (acellular or "whole cells" pertussis),
- if your child has fever or a disease which occurred suddenly (acute disease), in this case it is preferable to postpone the vaccination.

Warning and precautions for use

- if your child has blood disorder such as a decrease in platelets (thrombocytopenia) or clotting disorders because of the risk of bleeding which may occur during intramuscular administration,
- if your child already presented with febrile convulsions, not related to a 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 experienced any of the following events after a previous administration of a vaccine (then the decision to give further doses of this pertussis-containing vaccine will be carefully evaluated):
  - Fever of 40°C or above within 48 hours of vaccination, not due to another identifiable cause.
  - Collapse or shock-like state with hypotonic-hyporesponsive episode (drop in energy) within 48 hours of vaccination.
  - Persistent, inconsolable crying lasting 3 hours or more, occurring within 48 hours of vaccination.
  - Convulsion with or without fever, occurring within 3 days of vaccination.
- if your child has or had medical issues or allergies, especially an allergic reactions following an injection of PENTAXIM,

- if your child presented Guillain-Barré syndrome (abnormal sensitivity, paralysis) or brachial neuritis (paralysis, diffuse pain in the arm and shoulder) following receipt of a prior vaccine containing tetanus toxoid (vaccine against tetanus), the decision to give any further vaccine containing tetanus toxoid should be evaluated by your doctor,
- if your child presented swelling (oedematous reactions) in lower limbs following injection of a *Haemophilus influenzae* type b-containing vaccine; the diphtheria - tetanus - pertussis – poliomyelitis vaccine and the *Haemophilus influenzae* type b conjugate vaccine should then be administered into two separate injection sites and on different days,
- If your child has poor immune defenses, or if he/she is treated with corticosteroids, cytotoxic drugs, radiotherapy or other drugs that may weaken his/her immune system: the immune response may be diminished. It is then recommended to wait until the end of the treatment or disease before vaccinating. However, vaccination is recommended in subjects with chronic immunodeficiency such as HIV infection even if the immune response may be limited.
- PENTAXIM dose not protect against invasive diseases caused by serotypes other than *Haemophilus influenzae* type b, or against meningitis of other origins..

Other medicine and PENTAXIM

In case your child should receive PENTAXIM simultaneously with other vaccines, please ask your doctor or pharmacist for more information.

Please inform your doctor or pharmacist if your child takes or has recently taken any other medicines, even those not prescribed.

3. HOW TO USE PENTAXIM

This vaccine will be administered to your child by a healthcare professional.

Posology

The schedule should be chosen in accordance with current national recommendations:

- 2 injections with an interval of two months, one at the age of 2 and, one at the age of 4 months, followed by a booster injection at the age of 11 months.

or

- 3 injections at an interval of one to two months from the age of 2 months, followed by a booster injection within the second year of life.

Method of administration

Administration should be performed into a muscle, preferably in the anterolateral side of the thigh (middle third) in infants, and in the upper arm in children.

If you forget to use PENTAXIM:

If you forgot to have your child given a dose of vaccine, tell your doctor who will decide when to administer the dose. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Serious allergic reactions

Serious allergic reactions, although very rare, may occur following vaccination, generally while the child is still present on the place where he/she was vaccinated.

If any of the symptoms listed below occurs after you have left the place where your child was vaccinated, you must contact IMMEDIATELY a doctor or the emergency services.

- Swelling of the face (face oedema), sudden swelling of the face and neck (angioedema, Quincke's oedema).
- Sudden and serious malaise with drop in blood pressure causing dizziness and loss of consciousness, accelerated heart rate associated with respiratory disorders (anaphylactic reaction and shock).

Other side effects

If your child experiences any of the following side effects listed below and it persists or gets serious, please contact your doctor or pharmacist.

Very common reactions (may affect more than one in 10 children)

- Loss of appetite.
- Nervousness, irritability, abnormal crying.
- Somnolence.
- Vomiting.
- Injection-site redness (erythema), fever 38°C or higher, injection-site swelling (oedema), injection-site pain.

Common reactions (may affect less than one in 10 children but more than one in 100 children)

- Diarrhoea
- Injection-site hardening (induration)

- Insomnia, sleep disorder.

Uncommon reactions (may affect less than one in 100 children but more than one in 1,000 children)

- Injection site redness and swelling (oedema) of 5 cm or more.
- Fever 39°C or higher
- Inconsolable and prolonged crying (for more than 3 hours)

Rare reactions (may affect less than one in 1,000 children but more than one in 10,000 children)

- Fever over 40°C
- Swelling in legs and feet (oedematous reactions affecting lower limbs) with a bluish discoloration of the skin (cyanosis) or redness, small transient red spots (purpura) occurring within hours of vaccination, and disappearing without treatment and without sequelae. Swelling may be accompanied with severe crying.

Reactions with a Not Known frequency (frequencies cannot be estimated because these reactions are reported very rarely)

- Convulsions with or without fever.
- Drops in energy or periods during which your child is pale, unresponsive or seems in a shock-like state (hypotony-hyporesponsiveness)
- Skin rash, redness (erythema), itching (urticarial).
- Large injection-site reactions, larger than 5 cm, including limb swelling (oedema) that may spread to the joints on both sides of the injection site. These reactions start within 24-72 hours after vaccination and may be associated with symptoms such as redness (erythema), warmth, tenderness or pain at the injection site. They resolve spontaneously within 3-5 days.

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

- Guillain – Barré syndrome (abnormal sensitivity, paralysis) and brachial neuritis (paralysis, diffuse pain in the arm and shoulder) following administration of a vaccine containing tetanus toxoid.

Additional information concerning specific populations

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 vaccinations.

Reporting of side effects

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

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

5. HOW TO STORE PENTAXIM

Keep out of the reach and sight of children.

Do not use PENTAXIM after the expiry date stated on the label, the box. The expiry date refers to the last day of that month.

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

Do not use if you notice an abnormal colour or the presence of foreign particles.

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. FURTHER INFORMATION

What PENTAXIM contains

The active substances are:

After reconstitution one dose (0.5 ml) contains:

Diphtheria toxoid[(1)] . . . . . ≥ 30 I.U.

Tetanus toxoid[(1)] . . . . . ≥ 40 I.U.

Bordetella pertussis antigens:

Pertussis toxoid[(1)] . . . . . 25 micrograms

Filamentous haemagglutinin[(1)] . . . . . 25 micrograms

Poliomyelitis virus (inactivated)

- type 1 (Mahoney strain) . . .. 40 DU[(2)(3)(4)]
- type 2 (MEF-1 strain) . . . . 8 DU[(2)(3)(4)]
- type 3 (Saukett strain) . . .. 32 DU[(2)(3(4))]

Polysaccharide of *Haemophilus influenzae* type b . . . . . 10 micrograms

conjugated to the tetanus protein . . . . . 18 - 30 micrograms

[(1)]adsorbed on aluminum hydroxide, hydrated. . . . . 0.3 mg Al^{3+}

[(2)] DU: D antigen unit.

[(3)] or equivalent antigenic quantity determined by a suitable immunochemical method.

[(4)] produced on VERO cells.

The other components are:

Suspension for injection:

- Hanks medium without phenol red, acetic acid and/or sodium hydroxide (for pH adjustment), formaldehyde, phenoxyethanol, water for injections.

Hanks medium is a complex mixture of amino acids (including phenylalanine), mineral salts, vitamins and other components (such as glucose) diluted in water for injections.

Powder:

- Saccharose, tromethamol

What PENTAXIM looks like and contents of the pack

PENTAXIM is a powder and a suspension for injection (0.5 mL in prefilled syringe with or without needle. Box of 1 or 10)

The powder is white and the solvent is cloudy and whitish.

Not all presentations may be marketed.

Marketing Authorisation Holder

SANOFI PASTEUR SA - 2 AVENUE PONT PASTEUR, 69007 LYON, FRANCE

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The following information is intended for healthcare professional only:

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

Reconstitute the vaccine by injecting the suspension of diphtheria, tetanus, acellular pertussis and poliomyelitis vaccine into the vial of the powder of the *Haemophilus influenza* type b vaccine.

Shake until the powder is completely dissolved. The turbid whitish aspect of the suspension after reconstitution is normal.

The vaccine should be administered immediately after reconstitution.

Administer via the intramuscular route (IM).

Administration should preferably be performed in the anterolateral side of the thigh (middle third) in infants and in the deltoid area in children.

This vaccine must never be injected in a blood vessel (intravascular route).

Interference with laboratory tests

Since the Hib capsular polysaccharide antigen is excreted in the urine, a positive urine test can be observed within 1 to 2 weeks following vaccination. Other tests should be performed in order to confirm Hib infection during this period.