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

PENTAXIM

Powder and suspension for suspension for injection in prefilled syringe
Warning: To be sold by retail on the prescription of the Registered Medical Practitioner

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, septicaemia, etc.) in children from the age of 2 months or according to local recommendations.
This vaccine does not protect against infections caused by other types of Haemophilus influenzae nor against meningitis due to other micro-organisms.

2. BEFORE YOU USE PENTAXIM

Never Use PENTAXIM:

- If your child is allergic to one of the vaccine's components, to any manufacturing process residues (glutaraldehyde, neomycin, streptomycin or polymyxin B) that may be present as traces, or of a pertussis vaccine (acellular or whole cells), or if your child experienced an allergic reaction to a pertussis vaccine (acellular or whole cell) or after injection of 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 celIs pertussis),

—if your child has a fever or an acute disease (the vaccination must be postponed).

Warning and precautions for use:

- make sure the vaccine is not injected by the intravascular route (the needle must not penetrate a blood vessel) nor by the intradermal route,
- if your child suffers from thrombocytopenia or clotting problems as there is a risk of bleeding during intramuscular administration,
- if your child suffers from hypersensitivity to glutaraldehyde, neomycin, streptomycin and polymyxin B, as these substances are used during the manufacturing process,
- 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 any of the following events are known to have occurred in temporal relation to receipt of vaccine (the decision to give further doses of pertussis-containing vaccine should be carefully considered):

- Fever ≥40°C 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, occurring within 48 hours of vaccination.
- Convulsions with or without fever, occurring within 3 days of vaccination.

—If your child suffers/suffered from medical problems or allergic reactions, especially allergic reactions following injection of PENTAXIM,

— if your child presented Guillain-Barre 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 oedematous reactions (or swelling) occurring in the lower limbs after injection of a vaccine containing the Haemophilus influenzae type b valence, the two vaccines, diphtheria-tetanus-pertussis-poliomyelitis vaccine and the Haemophilus influenzae type b conjugate vaccine should be administered in two separate injection sites and on two different days,

— if your child follows a treatment that suppresses her/his immune defences (with corticosteroids, cytotoxic drugs, radiotherapy or other drugs that may weaken his / her immune system) or if your child presents with immunodeficiency: in these cases the immune response to the vaccine may be decreased. It is then recommended to wait until the end of the treatment or disease before vaccinating. Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even if the antibody response may be limited.

PENTAXIM does not protect against invasive diseases caused by serotypes other than Haemophilus influenzae type b, nor against meningitis due to other micro-organisms.
Use of other medicinal products:
In case your child should receive PENTAXIM simultaneously with other vaccines than those already mentioned, please ask your doctor for more information.
Please inform your doctor if your child takes or has recently taken any other medicines, even those not prescribed.
Important information about some of the ingredients of PENTAXIM
List of excipients with recognised effect: formaldehyde
PENTAXIM, powder and suspension for suspension for injection in prefilled syringe contains phenylalanine, ethanol and sodium
PENTAXIM contains 12.5 micrograms of phenylalanine per 0.5 mL dose. Phenylalanine can be dangerous for people with phenylketonuria (PKU), a rare genetic disease characterised by the accumulation of phenylalanine, which cannot be eliminated properly.
PENTAXIM contains 2 mg of alcohol (ethanol) per 0.5 mL dose. The small amount of alcohol in this medicine will not have any noticeable effects.
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. HOW TO USE PENTAXIM

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

Posology

The usual recommended schedule includes primary vaccination, consisting of three injections at an interval of one to two months from the age of 2 months or according to local recommendations, followed by one booster injection within the second year of life.
Method of administration
For syringes without attached needles, the needle must be fitted firmly to the syringe, rotating it by a one-quarter turn.
Reconstitute the vaccine by injecting the suspension of the combined diphtheria, tetanus, acellular pertussis and poliomyelitis vaccine into the vial of the powder of the Haemophilus type b conjugate vaccine.
Shake until complete dissolution of the powder. After reconstitution, the whitish-turbid appearance of the suspension is normal.
The vaccine must be used immediately after reconstitution.
Administer by the intramuscular route.
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).

If a dose of PENTAXIM is missed:
Please inform your doctor.
If you have any further questions on the use of this medicine ask your doctor.

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 ethe 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.
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 1000 children)

· lnjection-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 1000 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 (urticaria).
- 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 the 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 vaccination.

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 after the expiry date stated on the label, the box. The expiry date refers to the last date 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 doctor 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 IU [2] [3]
Tetanus toxoid[1] ≥ 40 IU [2] [3]
Bordetella pertussis antigens:
Pertussis toxoid [1]……...25 micrograms
Filamentous haemagglutinin [1]…...25 micrograms
Poliomyelitis virus (inactivated)
Type 1 poliomyelitis virus (Mahoney strain) [4] (inactivated)……40 DU [5] [6]
Type 2 poliomyelitis virus (MEF-1 strain) [4] (inactivated)……8 DU [5] [6]
Type 3 poliomyelitis virus (Saukett strain) [4] (inactivated)……...32 DU [5] [6]
Polysaccharide of *Haemophilus influenzae* type b 10 micrograms
conjugated to the tetanus protein..... 18-30 micrograms
[1] adsorbed on aluminium hydroxide, hydrated 0.3 mg Al3+
[2] IU: International Unit
[3] Or equivalent activity determined by an immunogenicity evaluation
[4] Produced on VERO cells.
[5] DU: D antigen unit.
[6] or equivalent antigenic quantity determined by a suitable immunochemical method.
The other components are:
Suspension for injection:
- Hanks 199 medium without phenol red, acetic acid glacial and/or sodium hydroxide(for pH adjustment), formaldehyde, phenoxyethanol, Ethanol, anhydrous, water for injections.
Hanks 199 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, Concentrated hydrochloric acid for pH adjustment

What PENTAXIM looks like and contents of the pack
PENTAXIM is a powder and a suspension for injection (0.5ml in prefilled syringe with needle) or (0.5 ml in prefilled syringe without attached needle with two separate needles) - Box of 1 or 10.
The powder is white and the solvent is cloud y and whitish.
Not all presentations may be marketed.
The following information is intended for healthcare professionals 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 powder of the Haemophilus influenzae 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.

Manufactured by:
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