

PENTAXIM® Abbreviated Prescribing Information (Version V02-20)

1. NAME AND PRESENTATION: PENTAXIM is diphtheria, tetanus, pertussis (acellular component), poliomyelitis (inactivated) vaccine and *Haemophilus* type B conjugated vaccine, adsorbed presented as powder and suspension for injection in 0.5 ml prefilled syringe.

2. THERAPEUTIC INDICATIONS: Protection children from the age of 2 months against diphtheria, tetanus, pertussis, poliomyelitis and against invasive infections due to the *Haemophilus influenzae* type b bacterium.

3. POSOLOGY AND METHOD OF ADMINISTRATION: Administer via intramuscular route, preferably in the anterolateral side of the thigh (middle third) in infants, and in the upper arm in children. Do not inject via intravascular route. For dosage and schedule, please see full prescribing information.

4. CONTRA-INDICATIONS: Allergic to any of the vaccine components, glutaraldehyde, neomycin, streptomycin or polymyxin B. Allergic reaction after injection of the same vaccine or a vaccine containing the same substances. Suffering from evolving encephalopathy or encephalopathy within 7 days of a previous dose of a pertussis vaccine. In case of fever or acute diseases, it is preferable to postpone the vaccination.

5. SPECIAL WARNINGS AND PRECAUTIONS FOR USE: The risk of bleeding may occur in children with blood disorder. If children presented with febrile convulsions, not related to a previous vaccine injection, temperature should be monitored in the 48 hours following vaccination and antipyretic treatment should be regularly administered for 48 hours. The decision to give further doses of pertussis-containing vaccine will be carefully evaluated if children experienced any of following events within 48 hours of previous vaccination: fever of 40°C or above, collapse or shock-like state with hypotonic-hyporesponsive episode, inconsolable crying lasting 3 hours, or convulsion with or without fever occurring within 3 days of vaccination. The decision to give any further vaccine containing tetanus toxoid should be evaluated, if Guillain-Barré syndrome or brachial neuritis has occurred following receipt of prior vaccine containing tetanus toxoid. The diphtheria-tetanus-pertussis-poliomyelitis vaccine and the *Haemophilus influenzae* type b conjugate vaccine should be administered in two separate injection sites and on different days if children presented swelling in lower limbs following injection of a *Haemophilus influenzae* type b-containing vaccine. It is recommended to postpone vaccination until the end of immunosuppressive treatment or immunodeficiency.

6. DRUG INTERACTIONS: To be considered when combination use with other vaccines.

7. PREGNANCY AND LACTATION: Not applicable. Vaccine is intended for children.

8. UNDESIRABLE EFFECTS: *Very common:* loss of appetite, nervousness, irritability, abnormal crying, somnolence, vomiting, injection-site redness, fever $\geq 38^{\circ}\text{C}$, injection-site swelling or pain
Common: diarrhoea, injection-site induration, insomnia, sleep disorder. For uncommon, rare and very rare side effects, see full prescribing information.

9. OVERDOSAGE: No data available.

10. PHARMACODYNAMIC PROPERTIES: Bacterial and viral vaccines, combined (ATC Code: J07CA06)

For more information, please see full prescribing information.