For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory

Abridged Prescribing Information

Adsorbed Diphtheria, tetanus, pertussis (acellular component) and Inactivated Poliomyelitis Vaccine I.P.

TETRAXIM, Whitish-turbid suspension for injection in prefilled syringe.

COMPOSITION One dose (0.5 mL) contains: Diphtheria toxoid [(1)] (≥ 30 IU), Tetanus toxoid [(1)] (≥ 40 IU*),*Bordetella pertussis* antigens: Pertussis toxoid [(1)] (25 micrograms), Filamentous haemagglutinin[(1)](25 micrograms), Poliomyelitis virus (inactivated)- (type 1 (Mahoney strain) is 40 DU[(2) (3) (4)], type 2 (MEF-1 strain) is 8 DU [(2) (3) (4)], type 3 (Saukett strain) is 32 DU [(2) (3) (4)]).

[(1)] adsorbed on aluminium 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.

* As lower confidence limit (p=0.95)

TETRAXIM may contain traces of glutaraldehyde, neomycin, streptomycin and polymyxin B.

Therapeutic indications TETRAXIM vaccine is indicated in the joint prevention of diphtheria, tetanus, pertussis and poliomyelitis:

- for primary vaccination in infants from the age of 2 months,
- for booster vaccination, one year after primary vaccination during the second year of life,
- for booster vaccination between 5 and 13 years of age, according to official recommendations.

Posology TETRAXIM must be administered according to the official recommendations in effect.

- Primary vaccination: 3 injections given at an interval of one month, i.e. according to the official schedule, at the age of 2, 3, 4 months.
- Booster vaccination: 1 injection one year after primary vaccination, i.e. usually, between 16 and 18 months.
- Booster vaccination between 5 and 13 years of age: 1 injection.

For primary vaccination and for the first booster dose, this vaccine may be administered by reconstituting the *Haemophilus influenzae* type b conjugate vaccine (Act-HIB) or administered at the same time as this vaccine, but at two separate injection sites.

Method of administration: Administer via the intramuscular route. Administration should preferably be performed in the antero-lateral side of the thigh (middle third) in infants and in the deltoid area in children.

SAFETY RELATED INFORMATION

Contraindications

- Hypersensitivity to any of the active substances of TETRAXIM, any of the excipients listed, glutaraldehyde, neomycin, streptomycin, or polymyxin B (used during the manufacturing process and which may be present as traces) and to a pertussis vaccine (acellular or whole cell).
- Life-threatening reaction after previous administration of the same vaccine or a vaccine containing the same substances.
- Vaccination must be postponed in case of febrile or acute disease.
- Evolving encephalopathy.
- Encephalopathy within 7 days of administration of a previous dose of any vaccine containing pertussis antigens (whole cell or acellular pertussis vaccines).

Warnings and precautions The immunogenicity of TETRAXIM may be reduced by immunosuppressive treatment or immunodeficiency. 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 immune response may be limited. If Guillain-Barré syndrome or brachial neuritis has occurred in subjects following receipt of prior vaccine containing tetanus toxoid, the decision to give any vaccine containing tetanus toxoid should be based on careful consideration of the potential benefits and possible risks of vaccination. Vaccination is usually justified for infants whose primary immunization schedules are incomplete (i.e. fewer than three doses administered). Do not inject via the intravascular route: make sure the needle does not penetrate a blood vessel. Do not inject via the intradermal route. As with all injectable vaccines, TETRAXIM must be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects. Vaccination must be preceded by medical history screening (especially with regard to vaccination history and any occurrence of undesirable events) and a clinical examination. The decision to give further doses of pertussis-containing vaccine should be carefully considered, a history of febrile convulsions not related to a previous vaccine injection is not a contraindication to vaccination. In this respect, it is particularly important to monitor temperature in the 48 hours following vaccination and to give antipyretic treatment regularly for 48 hours. A history of afebrile convulsions not related to a previous vaccine injection should be assessed by a specialist before deciding to vaccinate. In the event of oedematous reactions occurring in the lower limbs after injection of a *Haemophilus influenzae* type b-containing vaccine, 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. As with all injectable vaccines, appropriate medical treatment must be readily available and close supervision provided should a rare anaphylactic reaction occur following administration of the vaccine. The potential risk of apnoea and the need for respiratory monitoring for 48-72h should be considered when administering the primary immunization series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

Interaction with other medicinal products and other forms of interaction: It can be administered simultaneously with the M-M-RVAXPRO vaccine or with the HBVAXPRO vaccine, but in two separate sites. TETRAXIM vaccine can be associated or combined with the *Haemophilus influenzae* type b conjugate vaccine (Act-HIB).

Pregnancy and lactation: Not applicable.

ADVERSE REACTIONS:

Very common adverse reactions include: Loss of appetite; Nervousness, irritability. Abnormal crying, Somnolence, Headache, Vomiting, Myalgia, Injection-site erythema, Injection-site pain, Injection-site oedema, Fever ≥38°C, Malaise.

Common adverse reactions include: Insomnia, sleep disturbances, Diarrhoea, Injection-site induration.

Uncommon adverse reactions include: Prolonged Inconsolable crying, Injection-site redness and oedema ≥5 cm, Fever ≥39°C.

Rare adverse reactions include: Fever >40°C.

For full prescribing information you may contact: -

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Date of update: Dec 2021

Source : Summary of Product Characteristics dated 30 January 2015 (RA_0049573 – version 10.0)