Registration No. : 2C 30/47 (N)

Importer / Manufacturer: Sanofi Pasteur Ltd.**,** Thailand/ Sanofi Pasteur S.A., France

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT : TETRAXIM

(Diphtheria, Tetanus, Pertussis (Acellular, Component)**,** Poliomyelitis (Inactivated) Vaccine (Adsorbed**)**

2. QUALITATIVE AND QUANTITATIVE 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
Type 1 poliomyelitis virus (inactivated) . . . . . 40 DU(2)(3)
Type 2 poliomyelitis virus (inactivated). . . . . 8 DU(2)(3)
Type 3 poliomyelitis virus (inactivated). . . . . 32 DU(2)(3)
(1) adsorbed on aluminum hydroxide, dihydrate . . . . . .0.3 mg Al3+
(2) DU : D antigen unit.
(3) or equivalent antigenic quantity determined by a suitable immunochemical method.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TETRAXIM is indicated to help protect your child against diphtheria, tetanus, pertussis and poliomyelitis from the age of 2 months with primary vaccination and for booster vaccination during the second year of life and between 5 and 13 years of age, according to national official recommendations.

4.2 Posology and method of administration

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, followed by one booster injection one year after primary vaccination within the second year of life, and another one between 5 and 13 years of age, according to national official recommendations.

For syringes without attached needle, the separate needle must be fitted firmly to the syringe, rotating it by a one-quarter turn.
Shake before injection until a homogeneous whitish-turbid suspension is obtained.

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 aged between 5 and 13 years.

If you forget to take a dose of TETRAXIM:
Your doctor will decide when to administer the missing dose.

4.3 Contraindication

Do not use TETRAXIM:
– if your child is allergic to one of the vaccine's components, to any residues from the manufacturing process (glutaraldehyde, neomycin, streptomycin and polymyxin B) or to pertussis vaccines (acellular or whole cells pertussis), or if your child experienced an allergic reaction 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 cells pertussis),
– If your child has a fever or an acute disease (the vaccination must be postponed).

4.4 Special warnings and precautions for use

Take special care with TETRAXIM:
– 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 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 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.
- Convulsion 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 TETRAXIM,
– 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 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 conjugated 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 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.

Important information about some of the ingredients of TETRAXIM
List of excipients with recognised effect: formaldehyde

4.5 Interaction with other medical products and forms of interaction

For primary vaccination and for the 1st booster dose, TETRAXIM may be administered by reconstituting the *Haemophilus influenzae* type b conjugate vaccine (Act-HIB), or administered simultaneously with it in two separate injection sites.
In case your child should receive TETRAXIM simultaneously with other vaccines other than those already mentioned, please ask your doctor or your pharmacist for more information.
Please inform your doctor or pharmacist if your child has recently taken any other medicines, even those not prescribed.

4.6 Pregnancy and lactation

4.7 Effects on the ability to drive and use machines

4.8 Undesirable effects

Like all medicines, TETRAXIM can cause side effects, although not everybody gets them.
The most common reactions are: irritability, local reactions at the injection site such as redness and induration greater than 2 cm. These signs and symptoms usually occur within 48 hours following the vaccination and may continue for 48 – 72 hours. They resolve spontaneously without requiring specific treatment.
In clinical studies, hypotonic-hyporesponsive episodes (hypotonic episodes, drop in energy, hyporesponsiveness, decreased mental awareness) have been reported after administration of pertussis-containing vaccines; they have not been reported with TETRAXIM.

The following side effects have been reported:
• Fever sometimes above 40°C.
• Erythema, induration, pain at the injection site; redness and oedema (swelling) ≥ 5 cm at the injection site.
• Oedema (swelling) > 5 cm that may spread over the entire limb where the vaccine has been administered. This reaction occurs within 24 – 72 hours after vaccination and resolves spontaneously within 3 – 5 days. The risk appears to be dependent on the number of prior doses of acellular pertussis-containing vaccines, with a greater risk following the 4th and 5th doses.
• Diarrhoea; vomiting.
• Loss of appetite.
• Somnolence; convulsion with or without fever.
• Loss of consciousness (syncope)
• Nervousness, irritability; insomnia, sleep disturbances; abnormal crying, prolonged inconsolable crying.

• Allergy-like symptoms, such as skin eruptions, erythema, and urticaria, face oedema, sudden face or neck swelling (angioedema, Quincke's oedema) or generalized reactions: sudden and serious malaise with drop in blood pressure, accelerated heart rhythm associated with respiratory disorders and digestive disorders (anaphylactic reaction).
Furthermore, oedema reactions (swelling) affecting the lower limbs have been reported when TETRAXIM is administered with *Haemophilus influenzae* type b containing vaccines.
These reactions are sometimes accompanied by fever, pain and crying. They are not accompanied by cardio-respiratory signs.
Potential side effects (i.e. they have not been reported directly with TETRAXIM, but with other vaccines containing one or more of the antigenic constituents of TETRAXIM) 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.
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.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

4.9 Overdose

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hanks medium without phenol red (a complex mixture of amino acids including phenylalanine, mineral salts, vitamins and other components such as glucose), acetic acid and/or sodium hydroxide for pH adjustment, formaldehyde, phenoxyethanol and water for injections.

6.2 Incompatibilities

6.3 Shelf life

3 years

6.4 Special precautions for storage

Keep out of the reach and sight of children.
Store in a refrigerator (2°C - 8°C). Do not freeze.

6.5 Nature and contents of container

TETRAXIM is a suspension for injection (0.5 ml in prefilled syringe with needle) or (0.5 ml in refilled syringe without attached needle, with two separate needles) – Box of 1 or 10.

6.6 Special precautions for disposal and other handling

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.
Do not use after the expiry date stated on the label, the box.

7. MARKETING AUTHORISATION HOLDER

Sanofi Pasteur Ltd., Bangkok, Thailand

8. MARKETING AUTHORISATION NUMBER(S)

2C 30/47(N)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30 September 2004

10. DATE OF REVISION OF THE TEXT

March 2011
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(The above information is based on the currently approved leaflet)