PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

TETRAXIM® suspension for injection in a pre-filled syringe.

Diphtheria, tetanus, pertussis (acellular, component)

and poliomyelitis (inactivated) vaccine (adsorbed).

Preservatives:

2-phenoxyethanol – ethanol 50 % solution

- 2-phenoxyethanol 2,5 microlitres
- ethanol anhydrous 2,5 microlitres

Formaldehyde 10 micrograms

Sugar (glucose): trace amounts.

Contains sweetener: phenylalanine 12,5 micrograms.

Read all of this leaflet carefully before getting vaccinated

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, or your pharmacist, nurse or other health care provider.
- Do not share TETRAXIM with any other person.

What is in this leaflet:

6. Contents of the pack and other information.

1. What TETRAXIM is and what it is used for

TETRAXIM is indicated to help protect your child against diphtheria, tetanus, pertussis and poliomyelitis from the age of 6 weeks with primary vaccination and for booster vaccination during the second year of life and a late booster between 5 and 12 years of age, according to national official recommendations.

2. What you need to know before your child receives TETRAXIM

Do not receive TETRAXIM if your child

- Is allergic to any component of TETRAXIM, to any residue from the manufacturing process (glutaraldehyde, neomycin, streptomycin and polymyxin B) or to pertussis vaccines (acellular or whole cell pertussis) (see section 6), or if your child experienced an allergic reaction after injection of a vaccine containing the same substances.
- Suffers from evolving encephalopathy (cerebral lesions).
- Suffered from encephalopathy (cerebral lesions) within 7 days of a previous dose of a pertussis vaccine (acellular or whole cell pertussis).
- Has a fever or an acute disease (the vaccination must be postponed).

Warnings and precautions

Your health care provider will ensure correct administration of the full dose of TETRAXIM (see section 3).

Tell your doctor or health care provider before your child receives TETRAXIM:

- 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 greater than or equal to 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 three hours or longer than 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 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 influenza* type b valence, the two vaccines, diphtheria-tetanus-pertussis-poliomyelitis vaccine and the *Haemophilus influenza* type b conjugate vaccine should be administered in two separate injection sites and at two different days.
- If your child follows a treatment that suppresses his/her 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.

Fainting can occur following, or even before, any needle injection. Therefore, tell your doctor or health care provider if your child fainted with a previous injection.

Other medicines and TETRAXIM

For primary vaccination and for the first 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.
TETRAXIM used to reconstitute freeze-dried ACT-HIB® vaccine (*Haemophilus influenzae* type b) may be administered concomitantly with measles-mumps-rubellla (MMR) and varicella-containing vaccines at separate injection sites.

In case your child should receive TETRAXIM simultaneously with other vaccines than those already mentioned, please ask your doctor or pharmacist for more information.
Please inform your doctor or pharmacist if your child has recently taken any other medicines, even those not prescribed.

Pregnancy, breastfeeding and fertility

As TETRAXIM is not intended for administration to adults, data on the use of this vaccine in pregnant women are not available. Therefore, TETRAXIM is not recommended for pregnant women.
As TETRAXIM is not intended for adults, it not known whether this vaccine is excreted in human milk.
Caution must be exercised when you are a breastfeeding mother.

TETRAXIM contains phenylalanine, ethanol and sodium

TETRAXIM contains 12,5 micrograms of phenylalanine in each 0,5 mL dose. Phenylalanine may be harmful for people who have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

TETRAXIM contains 2 mg of alcohol (ethanol) in each 0,5 mL dose. The small amount of alcohol in this medicine will not have any noticeable effects.

TETRAXIM contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially sodium free.

3. How to receive TETRAXIM

Primary vaccination

Starting from 6 weeks of age, primary vaccination consists of three successive doses of 0,5 mL at an interval of one or two months, such as 6, 10 and 14 weeks or 2, 3, 4 months or 2, 4, 6 months, or 3, 4, 5 months or 3, 5, 12 months (or Expanded Programme on Immunisation).

Booster vaccination

This is the fourth dose given one year after primary vaccination within the second year of life.

Late booster

One booster injection between 5 and 12 years of age, according to national official recommendations.

Method of administration

For syringes without attached needles, 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 via the intramuscular route.

Administration should preferably be performed in the antero-lateral side of the thigh (middle thigh) in infants and in the deltoid area in children aged between 5 and 12 years.

If your child received more TETRAXIM than they should

Cases of over dosage are not known with TETRAXIM.

If you forget to take your child to receive a dose of TETRAXIM

Your doctor will decide when to administer the missed dose.

4. Possible side effects

TETRAXIM 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 at the vaccination site.

If any of the signs or symptoms described below occur after you leave the place where your child was vaccinated, you should IMMEDIATELY contact a doctor or emergency medical 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).

Other side effects

If your child experiences any of the side effects described below, and if the sign(s)/symptom(s) persist or worsen, you should contact your doctor or pharmacist.

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

Loss of appetite, nervousness (irritability), abnormal crying, somnolence, headache, vomiting, muscle pain (myalgia), injection site redness (erythema), injection site pain, injection site swelling (oedema), fever ≥ 38 °C, malaise.

Common reactions (may affect up to 1 in 10 children):

Insomnia, sleep disorder, diarrhoea, injection site hardening (induration).

Uncommon reactions (may affect up to 1 in 100 children):

Inconsolable and prolonged crying, injection site redness and swelling (oedema) ≥ 5 cm, fever ≥ 39 °C.

Rare reactions (may affect up to 1 in 1 000 children):

Fever > 40 °C.

The following side effects have been reported during the commercial use of TETRAXIM

Blood and lymphatic disorders:

- Lymphadenopathy (swollen lymph nodes or glands).

Immune system disorders:

- Anaphylactic reactions such as facial oedema (facial swelling), Quincke's oedema (rapid swelling).

Nervous system disorders:

- Convulsions (uncontrollable movement of the body) with or without fever.
- Syncope (fainting).

Skin and subcutaneous tissue disorders:

- Allergy-like symptoms, such as various types of rash, erythema (redness of the skin) and urticaria (red eruption of the skin).

General disorders and administration site conditions:

- Large injection site reactions (> 50 mm), including extensive limb swelling from the injection site beyond one or both joints have been reported in children. These reactions start within 24 – 72 hours after vaccination, may be associated with erythema (redness of the skin), warmth, tenderness or pain at the injection site, and resolve spontaneously within 3 – 5 days. The risk appears to be dependent on the number of prior doses of acellular pertussis-containing vaccine, with a greater risk following the 4th and 5th doses.

Potential side effects

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) such as 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 you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can report side effects directly to Sanofi's Pharmacovigilance Unit at Email: za.drugsafety@sanofi.com or Tel: 011 256 3700 or

You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

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

5. How to store TETRAXIM

Keep TETRAXIM out of the reach and sight of children.

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

Store in a refrigerator between +2 °C and +8 °C.

DO NOT FREEZE. Protect from light. Keep the syringe in the blister pack until required for use.

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. Contents of the pack and other information

What TETRAXIM contains

TETRAXIM® suspension for injection.

Each 0,5 mL dose contains:

Active ingredients:

Purified diphtheria toxoid(1)	≥ 30 IU
Purified tetanus toxoid(1)	≥ 40 IU
Purified pertussis toxoid (PTxd)(1)	25 micrograms
Purified pertussis filamentous haemagglutinin (FHA)(1)	25 micrograms
Inactivated type 1 poliovirus D antigen (Mahoney)	40 units
Inactivated type 2 poliovirus D antigen (MEF1)	8 units
Inactivated type 3 poliovirus D antigen (Saukett))	32 units

(1) Adsorbed on aluminium hydroxide, hydrated (0,3 mg Al^{3+}).

The other ingredients are:

Medium 199 Hanks' without phenol red (complex mixture of amino acids including phenylalanine, mineral salts, vitamins and other components such as glucose); glacial acetic acid and/or sodium hydroxide for pH adjustment; formaldehyde, phenoxyethanol, anhydrous ethanol as preservatives; and water for injection.

What TETRAXIM looks like and contents of the pack

TETRAXIM is supplied as a whitish turbid suspension for injection in a pre-filled syringe.
Pre-filled syringe: 0,5 mL of suspension in pre-filled syringe (type 1 clear glass) with a black plunger stopper (bromobutyl or chlorobutyl) with or without a needle. The syringe is in a blister pack and packed in a carton. Pack of 1.

Holder of Certificate of Registration

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