

TETRAXIM

ADSORBED DIPHThERIA, TETANUS, ACeLLULAR PERTUSSIS AND INACTIVATED POLIOMYELITIS VACCINE

Please read all this package insert carefully before vaccination.

Keep this package insert until your child has completed the vaccination schedule, you may need to read it again.

You must follow the advice of your doctor or nurse carefully. If you need more information and advice, ask your doctor or nurse.

Make sure that your child completes the vaccination schedule. Otherwise, his/her protection may not be complete.

This vaccine has been prescribed personally for your child. Do not give it to anyone else.

COMPOSITION

The active ingredients are as follows:

Diphtheria toxoid	≥ 30 I.U.
Tetanus toxoid	≥ 40 I.U.
<i>Bordetella pertussis</i> antigens:	
Toxoid	25 micrograms
Filamentous haemagglutinin	25 micrograms
Inactivated poliomyelitis virus type 1	40 D.U.*†
Inactivated poliomyelitis virus type 2	8 D.U.*†
Inactivated poliomyelitis virus type 3	32 D.U.*†
for one 0.5 ml dose	

* D.U.: D antigen unit.

† or equivalent quantity of antigen determined using a suitable immunochemical method.

The other ingredients are aluminium hydroxide, phenol red-free Hanks medium, acetic acid and/or sodium hydroxide to adjust the pH between 6.8 and 7.3, formaldehyde, phenoxylethanol and water for injections.

MARKETING AUTHORIZATION HOLDER

Aventis Pasteur SA - 2, avenue Pont Pasteur - 69007 Lyon - France

1. WHAT IS TETRAXIM AND WHEN IS IT USED?

TETRAXIM is presented in the form of a suspension for injection in prefilled syringe of 0.5 ml and in vials containing 10 or 20 x 0.5 ml doses.

TETRAXIM is indicated to help protect your child against diphtheria, tetanus, pertussis and poliomyelitis in children from 2 months of age as a primary vaccination and as a booster dose during the second year of life and in children from 11 to 13 years of age.

2. INFORMATION REQUIRED BEFORE USING TETRAXIM

Do not use TETRAXIM:

- if your child suffers from convulsant or non-convulsant progressive encephalopathy (neurological disease),
- if your child has experienced a strong reaction occurring within 48 hours following a previous vaccination: fever above or equal to 40°C, persistent crying syndrome, febrile or non-febrile convulsion, hypotonus - hyporeactivity syndrome,
- if your child has experienced an allergic reaction appearing after a previous vaccination against diphtheria, tetanus, pertussis and poliomyelitis,
- if your child is allergic to the active ingredients, any of the excipients, neomycin, streptomycin and polymyxin B.

Take special precautions with TETRAXIM:

- ensure that the vaccine is not injected by the intravascular route (the needle must not enter a blood vessel) or by the intradermal route,
- vaccination should be postponed in children suffering from fever or acute disease, particularly infectious disease or progressive chronic disease,
- if your child has a history of febrile convulsions not related to a previous vaccination, it is particularly important to monitor the temperature in the 48 hours following the vaccination and administer an antipyretic treatment to reduce the fever regularly for 48 hours,

- if your child is following an immunosuppressive treatment or suffers from immune deficiency, this may induce a decrease in the immune response to the vaccine,
- if your child has experienced oedematous reactions (or swelling) of the lower limbs occurring following an injection of a vaccine containing the *Haemophilus influenzae* type b component, the diphtheria - tetanus - pertussis - poliomyelitis vaccine and conjugated *Haemophilus influenzae* type b vaccine should be administered at two separate injection sites on two different days.

List of excipients with known effect:

Formaldehyde

Use of other vaccines:

This vaccine may be administered at the same time as ROR VAX vaccine or HB-VAX DNA 5 µg/0.5 ml vaccine, but at two separate injection sites.

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

If your child is to be vaccinated with TETRAXIM and vaccines other than those mentioned above at the same time, ask your doctor or your pharmacist for more information.

Inform your doctor or your pharmacist if your child is taking or has taken any other medicinal product, even in the case of non-prescription medicinal products.

3. HOW TO USE TETRAXIM?

Posology:

The general recommended schedule includes a primary vaccination in 3 injections at one- to two-month intervals from 2 months of age, followed by a booster injection one year after the primary vaccination during the second year of life, and at 11-13 years of age, as a late booster.

Administration method:

Shake before injection, until a homogeneous cloudy, whitish suspension is obtained.

Multidose vial presentation: with a 1 ml or 0.5 ml sterile syringe, take up 0.5 ml of vaccine. For each new dose, take up 0.5 ml using a new sterile syringe equipped with a sterile needle.

Administer by the intramuscular route

The vaccine should preferably be administered in the front side of the thigh (middle third) in infants and in the deltoid region in children of 11-13 years of age.

In the event of omission of a dose of TETRAXIM

Your doctor will decide when to administer the omitted dose.

4. WHAT ARE THE POSSIBLE UNDESIRABLE EFFECTS?

Like all medicinal products, TETRAXIM is liable to have undesirable effects.

Local reactions such as pain, erythema (redness), induration may occur at the injection site within 48 hours following administration.

Systemic reactions: fever sometimes over 40°C, irritability, drowsiness, sleeping and eating disorders, diarrhoea, vomiting, inconsolable and prolonged crying. Rarer cases of urticaria, skin eruptions, febrile or non-febrile convulsions have been observed within 48 hours following administration. Hypotonus or hypotonus-hyporeactivity (low tonicity) episodes have been reported.

After the administration of TETRAXIM with a vaccine containing the *Haemophilus influenzae* type b component, oedematous reactions (swelling) of the lower limbs have been reported. These reactions are sometimes accompanied by fever, pain and crying.

If you observe undesirable effects not mentioned in this package insert, inform your doctor or your pharmacist.

5. HOW TO STORE TETRAXIM?

Keep out of the reach and sight of children.

Store at a temperature between +2°C and +8°C (in a refrigerator). Do not freeze.

Do not use TETRAXIM if you notice an abnormal colour or the presence of foreign particles.

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

The last date on which this package insert was approved is: 05/2002

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