PENTAXIM

ADSORBED DIPHTHERIA, TETANUS, ACELLULAR PERTUSSIS, INACTIVATED POLIOMYELITIS VACCINE AND CONJUGATE *HAEMOPHILUS INFLUENZAE* TYPE b 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.
Bordetella pertussis 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.*†
Haemophilus influenzae type b polysaccharide conjugated with tetanus protein	10 micrograms
	for one 0.5 ml dose after reconstitution

* D.U.: D antigen unit.
† or equivalent quantity of antigen determined using a suitable immunochemical method.
The other ingredients are sucrose, trometamol, aluminium hydroxide, phenol red-free Hanks medium, formaldehyde, phenoxyethanol and water for injections.

MARKETING AUTHORIZATION HOLDER

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

1. WHAT IS PENTAXIM AND WHEN IS IT USED?

PENTAXIM is presented in the form of a powder and suspension for injection in 0.5 ml pre-filled syringes in boxes of 1 or 20.
PENTAXIM is indicated to help protect your child against diphtheria, tetanus, pertussis, poliomyelitis and against invasive infections caused by the *Haemophilus influenzae* type b bacterium (meningitis, blood infection, etc.) in children from 2 months of age.
It does not protect against infections due to other types of *Haemophilus influenzae* or against meningitis caused by other micro-organisms.

2. INFORMATION REQUIRED BEFORE USING PENTAXIM

Do not use PENTAXIM:

– 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, poliomyelitis and *Haemophilus influenzae* type b infections,
– if your child is allergic to the active ingredients, any of the excipients, neomycin, streptomycin and polymixin B.

Take special precautions with PENTAXIM:
– 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 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 and conjugated *Haemophilus influenzae* type b vaccines should be administered at two separate injection sites on two different days,
– 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.

List of excipients with known effects:
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 sites.
If your child is to be vaccinated with PENTAXIM 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 PENTAXIM?

Posology:
The general recommended schedule includes a primary vaccination in 3 injections one or two month interval from 2 months of age, followed by a booster injection during the second year of life.

Administration method:
Reconstitute the vaccine by injecting the combined diphtheria, tetanus, acellular pertussis and poliomyelitis vaccine suspension into the vial of *Haemophilus influenzae* type b conjugate vaccine powder.
Shake until the powder has completely dissolved. The cloudy whitish appearance of the suspension after reconstitution is normal.
The vaccine must be administered immediately after reconstitution.
Administer by the intramuscular route.
The vaccine should preferably be administered in the front side of the thigh (middle third).

In the event of omission of a dose of PENTAXIM:
Please inform your doctor.

4. WHAT ARE THE POSSIBLE UNDESIRABLE EFFECTS?

Like all medicinal products, PENTAXIM 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, 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 episodes have been reported.
After the administration of vaccines 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 PENTAXIM?

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 PENTAXIM 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