TETRACOQ

ADSORBED DIPHTHERIA, TETANUS, PERTUSSIS AND INACTIVATED POLIOMYELITIS VACCINE

COMPOSITION

Each dose of 0.5 ml of vaccine contains:

– Purified diphtheria toxoid (obtained by detoxification of the toxin with formaldehyde) ..... ≥ 30 I.U.
– Purified tetanus toxoid (obtained by detoxification of the toxin with formaldehyde) ..... ≥ 60 I.U.

– *Bordetella pertussis* inactivated by heat in the presence of formaldehyde and phenoxyethanol ..... ≥ 4 I.U.
– Poliomyelitis virus type 1 inactivated with formaldehyde ..... 40 D.U.*
– Poliomyelitis virus type 2 inactivated with formaldehyde ..... 8 D.U.*
– Poliomyelitis virus type 3 inactivated with formaldehyde ..... 32 D.U.*
– Aluminium hydroxide
– Formaldehyde
– Phenoxyethanol
– Tween 80
– HANKS Medium 199**

* D antigen units

** HANKS Medium 199: complex mixture of amino acids, mineral salts, vitamins and other substances, diluted in water for injections, for which the pH is adjusted between 6.8 and 7.5 using hydrochloric acid or sodium hydroxide.

PHARMACEUTICAL DOSAGE FORM

Suspension for injection: 1 dose syringe (0.5 ml)
20 dose vial (10 ml)

MARKETING AUTHORIZATION HOLDER

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

INDICATIONS

This combined vaccine is indicated for the prevention of diphtheria, tetanus, pertussis and poliomyelitis in infants as a primary vaccination and in children as a booster dose.

CONTRAINDICATIONS

This medicinal product MUST NOT BE USED in the following cases:

– Convulsant or non-convulsant progressive encephalopathy (neurological disease).
– Strong reaction occurring within 48 hours following a previous vaccination: fever ≥ 40°C, persistent crying syndrome, febrile or non-febrile convulsion, hypotonus-hyporeactivity syndrome.
– Hypersensitivity appearing after a previous vaccination against diphtheria, tetanus, pertussis and poliomyelitis.
– Known allergy to any of the ingredients of the vaccine.

If there is any doubt, it is essential to consult your doctor or your pharmacist.

SPECIAL WARNINGS

– Do not inject by the intravascular route. Ensure that the needle does not enter a blood vessel.
– Vaccination should be postponed in those suffering from fever or acute disease, particularly infectious disease or progressive chronic disease.
– In the event of 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 regularly for 48 hours.
– An immunosuppressive treatment or immune deficiency may induce a decrease in the immune response to the vaccine.

If there is any doubt, do not hesitate to consult your doctor or your pharmacist.

PRECAUTIONS FOR USE

Use this medicinal product WITH CARE in case of:

– hypersensitivity to neomycin, streptomycin, polymyxin B and formaldehyde due to the use of these substances during production.

If there is any doubt, do not hesitate to consult your doctor or your pharmacist.
Keep out of the reach of children.

DRUG INTERACTIONS AND OTHER INTERACTIONS

There is no known contraindication to the simultaneous administration of this vaccine with other standard vaccines during the same vaccination session, provided that a different syringe and needle and a separate injection site are used.
In order to avoid possible interactions between several medicinal products, any other ongoing treatment should be systematically reported to your doctor or to your pharmacist.

PREGNANCY - BREAST FEEDING

As a general rule, during pregnancy and breast feeding, it is always recommended to ask your doctor's or pharmacist's advice before using a medicinal product.

LIST OF THE EXCIPIENTS, KNOWN TO HAVE A RECOGNISED ACTION OR EFFECT IN SOME PATIENTS

– Formaldehyde

DOSAGE

3 injections of one unit dose of vaccine (0.5 ml) at monthly intervals, i.e. according to the official schedule, one injection at the age of 2, 3 and 4 months followed by the booster dose: one injection one year after the primary vaccination at the age of 16-18 months.
In all cases, follow your doctor's prescription strictly.

MODE AND ROUTE OF ADMINISTRATION

Given the adsorbed nature of the vaccine, it is preferable to administer it by the intramuscular route in order to minimize local reactions. The recommended injection site is the supero-external gluteal region or possibly the antero-lateral side of the thigh (middle third).
Do not inject by the intravascular route.
This vaccine can be mixed in the same syringe with the monovalent *Haemophilus influenzae* type b vaccine conjugated with tetanus protein (Hib). To do this, simply use it as a solvent to reconstitute the freeze-dried Hib vaccine.
A successful extraction operation for one or more vaccine doses from a multidose vial depends essentially on the quality of the handling.
If the vaccine is an adsorbed vaccine, the vial must first of all be shaken gently, to avoid foaming, but sufficiently to obtain a homogenous mixture of the contents.
Then, using a sterile syringe fitted with a sterile needle, a single dose is withdrawn from the multidose vial, after disinfecting the outer surface of the vial stopper using a disinfectant.
For the subsequent dose(s), the same operation should be repeated.
Between the different withdrawal operations and, in any case, within not more than five minutes after the last dose withdrawn, the vial should be replaced in a refrigerator to keep the product at its normal storage temperature, i.e. between + 2°C and + 8°C (never place it in a freezer).
The manufacturer's legal liability covers the product up until its use.
The quality of the handling performed by the user to withdraw vaccine doses can affect the quality of a product packaged in a multidose vial. For this reason, the manufacturer cannot assume responsibility for the product over 24 hours after the first extraction operation unless the vial has been stored, in compliance with the manufacturer's recommendations, at a normal refrigerator temperature.
Thereafter, follow the W.H.O. recommendations which may be found in UNICEF or PAHO brochures.

SIDE EFFECTS

Like any active product, this medicinal product may in certain persons cause effects which are disturbing to a greater or lesser extent:
Pain, erythema (redness), induration and oedema (swelling) may occur within 48 hours at the injection point and persist for several days. The formation of a subcutaneous nodule, persisting for several weeks, may accompany these reactions. Rare cases of amicrobic abscesses have been reported.
Fever above 38°C, unusual crying within 24 to 48 hours following vaccination.
Allergic symptoms: rash (skin eruption), urticaria and in exceptional cases, anaphylactic shock (allergic shock) or Quincke's oedema (variety of urticaria with sudden swelling of face and neck).
Very rarely, attacks of hypotonus-hyporeactivity, persistent crying syndrome, convulsion with or without fever.
Exceptionally, acute encephalopathy (neurological disease).

Neurological disorders following vaccination tend to be attributed to the pertussis component.
Report to your doctor or to your pharmacist any unwanted and disturbing effects which might not be mentioned in this leaflet.

STORAGE

Do not exceed the expiry date stated on the external packaging.

SPECIAL PRECAUTIONS FOR STORAGE

This medicinal product should be stored at a temperature of between + 2°C and + 8°C (in a refrigerator) and protected from light. Do not freeze.

Rev. 06/2000

Aventis Pasteur

Aventis