TETRAct-HIB

(Act-HIB - D.T. COQ/D.T.P.)

ADSORBED DIPHTHERIA, TETANUS, PERTUSSIS AND CONJUGATED HAEMOPHILUS TYPE b VACCINE

COMPOSITION

Act-HIB (Powder for one vaccinating dose):

– *Haemophilus influenzae* type b polysaccharide conjugated with tetanus protein .....10 µg
– Sucrose and trometamol

D.T.COQ/D.T.P. (Suspension for injection for one vaccinating dose (0.5 ml)):

– Purified diphtheria toxoid ..... not less than 30 I.U.
– Purified tetanus toxoid ..... not less than 60 I.U.
– *Bordetella pertussis* ..... not less than 4 I.U.
– Aluminium hydroxide, thiomersal and buffer solution containing sodium chloride, dihydrate sodium hydrogen phosphate, potassium dihydrogen phosphate, acetic acid and/or sodium hydroxide and water for injections.

PHARMACEUTICAL DOSAGE FORM

Single-dose presentation: Suspension for injection obtained by reconstituting the powder from one vial of Act-HIB with one syringe or one ampoule (0.5 ml) of D.T.COQ/D.T.P.

Multidose presentation: Suspension for injection obtained by reconstituting the powder from one 10-dose vial of Act-HIB with one 10-dose vial of 0.5 ml of D.T.COQ/D.T.P.

MARKETING AUTHORIZATION HOLDER

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

INDICATIONS

This medicinal product is a VACCINE.
This combined vaccine is indicated for the joint prevention of invasive *Haemophilus influenzae* type b infections (meningitis, septicaemia, cellulitis, arthritis, epiglottitis, etc.), diphtheria, tetanus and pertussis.
TETRAct-HIB does not protect against infections due to other types of *Haemophilus influenzae* or against meningitis of other origins.

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 above or equal to 40°C, persistent crying syndrome, febrile or non-febrile convulsion, hypotonus - hyporeactivity syndrome.
– Hypersensitivity appearing after a previous vaccination against diphtheria, tetanus and pertussis.
– 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.
– In the event of œdematous reactions of the lower limbs occurring following an injection of a vaccine containing the *Haemophilus influenzae* type b component, the diphtheria - tetanus - pertussis and Act-HIB vaccines should be administered at two separate injection sites on two different days.
– An immunosuppressive treatment or immune deficiency may induce a decrease in the immune response to the vaccine.

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

PRECAUTIONS FOR USE

Tell your doctor if you or your child have any known allergies or have shown any abnormal reaction following a previous vaccination.
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 recommended to always ask your doctor or pharmacist for advice before taking a medicinal product.

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

– Thiomersal
– Sodium salts (sodium chloride, dihydrate sodium hydrogen phosphate)
– Potassium salt (potassium dihydrogen phosphate)

DOSAGE AND MODE OF ADMINISTRATION

PRIMARY VACCINATION: since two months of age, 3 injections of a unit dose of vaccine (0.5 ml) at one or two months intervall.
BOOSTER: 1 injection one year after the 3rd injection of the primary vaccination.

For a single-dose presentation:

The vaccine is administered after the Act-HIB powder contained in the vial is reconstituted with one syringe or one ampoule of D.T.COQ/D.T.P. suspension. Shake until the powder has completely dissolved without producing too much foam. The whitish cloudy appearance of the suspension after reconstitution is normal.

For a multidose presentation:

Since the D.T.COQ/D.T.P. vaccine is adsorbed, it is first of all necessary to shake the vial gently to avoid foam formation, but sufficiently to ensure that the product is mixed homogeneously.

Reconstitute the vial of Act-HIB vaccine powder with the suspension contained in the vial of D.T.COQ/D.T.P. using a sterile 10 ml syringe fitted with a sterile needle. The whitish cloudy appearance of the suspension after reconstitution is normal. This preparation is equivalent to 10 doses.

Successful reconstitution and extraction of one or more doses of vaccine from a multidose vial essentially depends on the quality of the operation. The user must, using a sterile 1 ml or 0.5 ml syringe fitted with a sterile needle, extract one individual dose (0.5 ml) from the multidose vial, on which the outer surface of the stopper has been disinfected beforehand with a disinfectant. For each new dose, extract 0.5 ml using a new sterile syringe fitted with a new sterile needle. Between the different extractions and, in any case, within not more than five minutes after the extraction, the vial should be placed 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). All reconstituted vials must be used on the same day.

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 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 WHO recommendations which may be found in UNICEF or PAHO brochures.

Given that the vaccine is adsorbed, it is preferable to administer it by the intramuscular route in order to minimize local reactions. The vaccine is preferably administered in the antero-lateral side of the thigh (middle third).

Do not inject by the intravascular route.

SIDE EFFECTS

As with any vaccination, this vaccine may, in certain subjects, induce undesirable effects of varying severity:
Pain, erythema (redness), induration and œdema (swelling) may occur within 48 hours at the injection point or 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 œdema (variety of urticaria with sudden swelling of face and neck).
Very rarely, attacks of hypotonus-hyporeactivity, persistent crying syndrome, convulsions with or without fever.
Exceptionally, acute encephalopathy (neurological disease).
Neurological disorders following vaccination tend to be attributed to the pertussis component.
Œdematous reactions of the lower limbs. These reactions are sometimes accompanied by fever, pain and crying.
This vaccine contains thiomersal as preservative and, as a consequence, allergic reactions may occur.
Report to your doctor or to your pharmacist any unwanted and disturbing effects wich might not be mentioned in this leaflet.

STORAGE

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

SPECIAL PRECAUTIONS FOR STORAGE

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

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