

D.T.COQ/D.T.P.

VACCIN DIPHTÉRIQUE, TÉTANIQUE COQUELUCHEUX ADSORBÉ

COMPOSITION

Une dose vaccinante de 0,5 ml contient :

- anatoxine diphtérique purifiée (obtenue par détoxification de la toxine par le formaldéhyde) ≥ 30 U.I.
- anatoxine tétanique purifiée (obtenue par détoxification de la toxine par le formaldéhyde) ≥ 60 U.I.
- *Bordetella pertussis* inactivée par la chaleur en présence de mercurothiolate sodique ≥ 4 U.I.
- hydroxyde d'aluminium (quantité exprimée en aluminium)
- mercurothiolate sodique
- solution tampon ⁽¹⁾

(1) Solution tampon : chlorure de sodium, hydrogénophosphate de sodium dihydraté, dihydrogéo-phosphate de potassium, eau pour préparations injectables.

Ce vaccin est conforme aux normes de l'O.M.S.

FORME PHARMACEUTIQUE

Suspension injectable, seringue pré-remplie ou ampoule 1 dose (0,5 ml),
flacon 10 doses (5 ml) ou 20 doses (10 ml).

TITULAIRE DE L'AUTORISATION DE MISE SUR LE MARCHÉ

Aventis Pasteur SA
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INDICATIONS

Ce vaccin combiné est indiqué dans la prévention de la diphtérie, du tétanos et de la coqueluche chez le nourrisson en primo-vaccination et chez l'enfant en dose de rappel.

CONTRE-INDICATIONS

- Ce médicament **NE DOIT PAS ÊTRE UTILISÉ** dans les cas suivants :
- Encéphalopathie évolutive convulsivante ou non (affection neurologique).
 - Une deuxième ou troisième dose de D.T.COQ/D.T.P. ne doit pas être administrée à un enfant ayant présenté une réaction importante lors d'une injection précédente. Dans ce cas, on poursuivra la vaccination à l'aide du D.T.VAX.
 - Forte réaction survenue dans les 48 heures suivant une injection vaccinale antérieure : fièvre ≥ 40°C, syndrome du cri persistant, convulsion fébrile ou non fébrile, syndrome d'hypotonie-hyperactivité.
 - Hypersensibilité apparue lors d'une vaccination antérieure contre la diphtérie, le tétanos et la coqueluche.
 - Allergie connue à l'un des composants du vaccin.

En cas de doute, il est indispensable de demander l'avis de votre médecin ou de votre pharmacien.

ENFANTS INFECTÉS PAR LE VIRUS

DE L'IMMUNODÉFICIENCE HUMAINE

Les enfants infectés par le VIH, symptomatiques ou asymptomatiques, doivent être immunisés par le vaccin D.T.COQ/D.T.P. selon le schéma habituel.

MISES EN GARDE SPECIALES

- **Ne pas injecter** par voie intravasculaire : s'assurer que l'aiguille ne pénètre pas dans un vaisseau sanguin.
- En cas de fièvre, maladie aiguë, notamment infectieuse, ou de maladie chronique en période évolutive, il est préférable de différer la vaccination.

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 EXCIPIENTS WHICH MUST BE KNOWN

- Sodium salts (thiomersal, sodium hydrogen phosphate dihydrate).
- Potassium salt (potassium dihydrogen phosphate).

DOSAGE

Always strictly follow your doctor's prescription.

PRIMARY VACCINATION : since two months of age, 3 injections of a unit dose of vaccine (0.5 ml) at one or two months interval.

In regions where pertussis represents a major risk for infants, D.T.COQ/D.T.P. vaccination can be started as soon as possible, from the age of six weeks, followed by 2 additional doses at the 10th and 14th weeks.

BOOSTER : 1 injection one year after the 3rd injection of the primary vaccination.

MODE AND ROUTE OF ADMINISTRATION

Shake gently until a homogeneous whitish cloudy suspension is obtained.

Given the adsorbed nature of the vaccine, it is preferable to administer it by the intramuscular route to minimize local reactions. The recommended injection site is the upper external region of the buttock or, possibly, the antero-lateral region of the thigh (middle third).

Do not inject by the intravascular route.

This vaccine may be mixed in the same syringe as the monovalent anti-Haemophilus influenzae type b conjugated with tetanus protein vaccine (Act-HIB).

To do this, simply use it as the solvent to reconstitute the powder of the Act-HIB vaccine.

Any opened multidose vial should be used within the same day.

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 (hardness) or edema (swelling) may be observed in the 48 hours following vaccination and may last several days. Formation of a subcutaneous nodule lasting for several weeks may accompany these reactions. Rare cases of microbial abscesses have been reported.
- Fever of more than 38°C, unusual crying in the 24 to 48 hours following vaccination.
- Allergic signs: skin rash, urticaria (hives) and, in exceptional cases, anaphylactic (allergic) shock or angioedema (type of urticaria with sudden swelling of the face and neck).
- Very rarely, episodes of hypotonia-hyperactivity, persistent crying syndrome, convulsions with or without fever.
- In exceptional cases, acute encephalopathy (neurological disorders).

NIÑOS INFECTADOS POR EL VIRUS

DE LA INMUNODEFICIENCIA HUMANA

Los niños infectados por el VIH, sintomático o no, deberán ser inmunizados con la vacuna D.T.COQ/D.T.P. de acuerdo con la política sanitaria correspondiente.

ADVERTENCIAS ESPECIALES

- **No inyectar** por vía intravascular : asegurarse de que la aguja no penetre en un vaso sanguíneo.
- En caso de fiebre, enfermedad aguda, especialmente infecciosa, o enfermedad crónica en período evolutivo es preferible retrasar la vacunación.

- En caso de antecedentes de convulsiones febriles no ligadas a una inyección vacunal anterior, es especialmente importante vigilar la temperatura durante las 48 horas siguientes a la vacunación y administrar regularmente un tratamiento antipirético durante 48 horas.

- Un tratamiento inmunosupresor o un estado de inmunodeficiencia pueden inducir una disminución de la respuesta inmunitaria a la vacuna.

En caso de duda, es indispensable consultar con su médico o con su farmacéutico.