015 90941-0

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

ADSORBED DIPHTHERIA, TETANUS, PERTUSSIS VACCINE

COMPOSITION
Une dose vaccinante de 0,5 ml contient :

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One 0.5 ml immunizing dose contains:
– purified diphtheria toxoid (obtained by detoxification of the toxin by formaldehyde) . . . . . ≥ 30 I.U.
– purified tetanus toxoid (obtained by detoxification of the toxin by formaldehyde) . . . . . ≥ 60 I.U.
– *Bordetella pertussis* inactivated by heat in the presence of thiomersal . . . . . ≥ 4 I.U.
– aluminium hydroxide (quantity expressed in aluminium)
– thiomersal
– buffer solution (1)

(1) Buffer solution: sodium chloride, sodium hydrogen phosphate dihydrate, potassium dihydrogen phosphate, water for injections.
This vaccine is in conformity with W.H.O. specifications.

PHARMACEUTICAL DOSAGE FORM
Suspension for injection, 1 dose prefilled syringe or ampoule (0.5 ml),
10 dose vial (5 ml) or 20 dose vial (10 ml).

MARKETING AUTHORIZATION HOLDER
Aventis Pasteur SA
2, avenue Pont Pasteur, F-69007 Lyon

INDICATIONS
This combined vaccine is indicated in the prevention of diphtheria, tetanus and pertussis in infants as a first vaccination and in children as a booster.

CONTRAINDICATIONS
This medicinal product MUST NOT BE USED in the following cases:
– Convulsive or non-convulsive active encephalopathy (neurological disorder).
A 2nd or 3rd dose of D.T.COQ/D.T.P. should not be administered to a child who has presented a major reaction subsequent to a previous vaccination. In this case, the vaccination will be continued using D.T.VAX.
– Severe reaction occurring within 48 hours following a previous vaccine injection: fever ≥ 40°C, persistent crying syndrome, febrile or non-febrile convulsion, hypotonia-hyporeactivity syndrome.
– Immediate hypersensitivity reactions following a previous vaccination against diphtheria, tetanus and pertussis.
– Known allergy to one of the components of the vaccine.
If there is any doubt, it is essential to consult your doctor or your pharmacist.

CHILDREN INFECTED WITH THE HUMAN IMMUNODEFICIENCY VIRUS
Children infected with HIV, symptomatic or asymptomatic, should be immunized with the D.T.COQ/D.T.P. vaccine according to the usual schedule.

SPECIAL WARNINGS
– Do not inject by intravascular route and make sure that the needle does not enter a blood vessel.
– In the event of fever, acute illness, in particular caused by infection, or active chronic illness, it is preferable to delay vaccination.
– In the event of a history of febrile convulsions not related to a previous vaccine injection, it is particularly important to monitor temperature during the 48 hours following vaccination and to regularly administer antipyretic treatment for 48 hours.
– Immunosuppressant treatment or a state of immunodeficiency may lead to a reduction in immune response to the vaccine.
If there is any doubt, do not hesitate to consult your doctor or your pharmacist.

PRECAUTIONS FOR USE
– Due to the use of formaldehyde in the production process, it is possible that trace quantities of this substance may be found and caution should be taken when using this vaccine in subjects presenting hypersensitivity to formaldehyde.
Tell your doctor if your child has any known allergies or has 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
The D.T.COQ/D.T.P. vaccine can be administered effectively and without danger at the same time as the following vaccines: BCG, mumps, polio (OPV and IPV), hepatitis B and yellow fever.
There are no known risks of simultaneous administration of this vaccine with other common vaccines in the course of the same vaccination session, as long as a different syringe and needle are used and they are injected at a different site.

In order to avoid possible interactions between several medicinal products, any other o
ment 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 a
tor'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 vac
at one or two months intervall.
In regions where pertussis represents a major risk for infants, D.T.COQ/D.T.P. vaccin
started as soon as possible, from the age of six weeks, followed by 2 additional doses at
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 intram
to minimize local reactions. The recommended injection site is the upper external regio
tock 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 infl*
conjugated with tetanus protein vaccine (Act-HIB).
To do this, simply use it as the solvent to reconstitute the powder of the Act-HIB vaccin
Any opened multidose vial should be used within the same day.
A successful extraction operation for one or more vaccine doses from a multidose
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
sufficiently to obtain a homogeneous mixture of the contents.
Then, using a sterile syringe fitted with a sterile needle, a single dose is withdrawn from t
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
the last dose withdrawn, the vial should be replaced in a refrigerator to keep the produ
mal 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
a product packaged in a multidose vial. For this reason, the manufacturer cannot assume
ty for the product over 24 hours after the first extraction operation unless the vial has
in compliance with the manufacturer's recommendations, at a normal refrigerator tempe
Thereafter, follow the W.H.O. recommendations which may be found in UNICEF or
chures.

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 amicrobial 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-hyporeactivity, persistent crying syndrome, convulsions with or without fever.
– In exceptional cases, acute encephalophaty (neurological disorders).

– Neurological disorders following vaccination are more likely to be attributed to the pertussis valence.

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 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). Do not freeze.
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