D.T. VAX

ADSORBED DIPHTHERIA TOXOID AND TETANUS TOXOID VACCINE

Please read all this package insert carefully before using this medicinal product.
Keep this package insert, you may need to read it again.
If you have other questions, ask your doctor or your pharmacist.

COMPOSITION

The **active ingredients** are purified diphtheria toxoid (≥ 30 I.U. for one 0.5 ml dose), and purified tetanus toxoid (≥ 40 I.U. for one 0.5 ml dose).

The **other ingredients** are aluminium hydroxide, thiomersal, buffer solution containing sodium chloride, disodium phosphate dihydrate and monopotassium phosphate, and water for injection.

This vaccine is in conformity with W.H.O. specifications.

MARKETING AUTHORIZATION HOLDER

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1. WHAT IS D.T.VAX AND WHEN IS IT USED?

D.T.VAX is a suspension for injection in:
– single-dose prefilled syringes or ampoules (0.5 ml), or
– 10-dose (5 ml) or 20-dose (10 ml) vials.

This combined vaccine is an anti-infectious medicinal product, indicated for the joint prevention of diphtheria and tetanus particularly in the event of a contraindication to a combination vaccine containing a pertussis component:
– in newborns as a primary vaccination
– in children as a vaccination booster

CHILDREN INFECTED WITH THE HUMAN IMMUNODEFICIENCY VIRUS:

According to W.H.O. recommendations, children infected with HIV, symptomatic or asymptomatic, should be immunized with the D.T.VAX vaccine according to the usual schedule.

2. INFORMATION REQUIRED BEFORE USING D.T.VAX

Do not use D.T.VAX in the following cases:
– if you or your child are allergic to any of the ingredients of the vaccine, or
– if you or your child have experienced allergic reactions or a neurological disorder following a previous injection of vaccine.

For further details, you should ask your doctor or your pharmacist.

Take special precautions with D.T.VAX:

Inform your doctor:
– if you or your child are suffering from a febrile disease, acute infection or a progressive attack of chronic disease (it is preferable to postpone the vaccination),
– if you or your child are suffering from immunodepression or following an immunosuppressive treatment,
– if you or your child are allergic or if you have already experienced an abnormal reaction following a previous administration of vaccine,
– if you or your child have received a diphtheria or tetanus vaccine in the last 5 years.

Pregnancy and lactation:

It is preferable not to use this vaccine during pregnancy.
If you discover that you are pregnant, consult your doctor who is the only person capable of assessing the need to continue the treatment.
Ask your doctor or your pharmacist for advice before taking any medicinal product.

List of excipients with a known effect:

Thiomersal, potassium.

Drug interactions:

The D.T.VAX vaccine can be administered simultaneously without danger and effectively with any other vaccine in the expanded vaccination programme.

Inform your doctor or your pharmacist if you are taking or have recently taken any other medicinal product, even in the case of non-prescription medicinal products.

3. HOW TO USE D.T.VAX?

Posology:
• Three successive, 0.5 ml doses at 1- or 2-month intervals. A fourth dose is administered one year after the third injection (first booster dose).
• A single booster dose is indicated every 5 to 10 years.

Administration method:

Shake before injection, until a homogeneous suspension is obtained.

It is preferable to administer the vaccine intramuscularly, so as to minimize local reactions.

The deep subcutaneous route may also be used.

Do not use the intradermal route.

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.

4. WHAT ARE THE POSSIBLE UNDESIRABLE EFFECTS?

Like all medicinal products, D.T.VAX is liable to have undesirable effects.
– Local reactions: pain, redness, induration, swelling at the injection site may occur, persist for one or two days, and be accompanied by the formation of a subcutaneous nodule.
– Systemic reactions: fever might be associated with a local reaction and an increase in lymph node size, allergic symptoms such as generalized itching, urticaria or swelling; dizziness; hypotension; muscle pains; joint pains; headaches.

This vaccine contains the preservative thiomersal and, as a result, may cause allergic reactions.

If you notice undesirable effects not mentioned in this package insert, inform your doctor or pharmacist.

5. HOW TO STORE D.T.VAX?

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

Keep out of the sight and reach of children.

Do not use after the expiry date marked on the box.

The last date on which this package insert was approved: 12/2000.

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Aventis