DULTAVAX

DIPHTHERIA, TETANUS AND INACTIVATED POLIOMYELITIS VACCINE, ADSORBED

Read all of this leaflet carefully before you start using this medicine.
Keep this leaflet, you may need to read it again.
If you need more information or advice, ask your physician or your pharmacist.

COMPOSITION

The active substances are:

– Diphtheria toxoid	≥ 2 I.U.
– Tetanus toxoid	≥ 20 I.U.
– Inactivated type 1 poliovirus	40 D.U.*
– Inactivated type 2 poliovirus	8 D.U.*
– Inactivated type 3 poliovirus	32 D.U.*

for 0.5 ml

* D-antigen unit

The other components are: aluminium hydroxide, phenoxyethanol, 35 per cent formaldehyde solution, acetic acid or sodium hydroxide to adjust the pH to between 6.8 and 7.0, Hanks' 199 medium, containing in particular amino acids, mineral salts, vitamins and water for injections.

MARKETING AUTORIZATION HOLDER

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

1. WHAT IS DULTAVAX AND WHAT IT IS USED FOR?

DULTAVAX is supplied as a suspension for injection in a prefilled syringe (0.5 ml).
This medicinal product is a combined VACCINE, indicated for adults as a booster of a previous vaccination for the simultaneous prevention of diphtheria, tetanus and poliomyelitis.
In exceptionnal circumstances, this vaccine may be administered as a booster of a previous vaccination to children from the age of 6 years.

2. REQUIRED INFORMATION BEFORE YOU USE DULTAVAX

Do not use DULTAVAX in the following cases:

– in the case of fever or acute disease it is preferable to postpone vaccination,
– in the case of a known allergy to one of the components of the vaccine, to neomycyn, streptomycyn, or polymyxin B (traces of these substances),
– in the case of severe allergic reactions or neurological disorders occurring after a previous injection of a diphtheria, tetanus, or inactivated poliovirus vaccine.

IN CASE OF DOUBT, IT IS ESSENTIAL TO OBTAIN THE ADVICE OF YOUR DOCTOR OR PHARMACIST.

Take special care with DULTAVAX:

– if you have received a vaccine against diphtheria or tetanus in the past 5 years,

– if you are receiving an immunosuppressive treatment or if you are immunodepressed.

Pregnancy and breast-feeding:

This vaccine is not recommended for use in pregnant women.

Breastfeeding is not a contraindication.

Ask your doctor or pharmacist for advice before taking any medicine.

Using other medicines:

This vaccine can be administered with other vaccines at two separate injection sites.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. HOW TO USE DULTAVAX

A single dose must be administered as a booster every 10 years.

This vaccine must be administered intramuscularly. The recommended injection site is the deltoid muscle.

The deep subcutaneous route may also be used.

The intradermal or intravenous routes must not be used.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DULTAVAX can have side effects.

Local reactions such as pain, induration, redness and swelling at the injection site may appear within the 48 hours following the injection and persist for one or two days, and may be accompanied by the formation of a subcutaneous nodule.

General reactions such as fever with or without a local reaction and an increase in the size of the draining lymph nodes, allergic manifestations such as itching, generalised urticaria or oedema, feeling of malaise, hypotension, muscle pain, joint pain, or headache.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING DULTAVAX

Keep out of the reach and sight of children

Store in a refrigerator (2°C - 8°C). Do not freeze.

Do not use after the expiration date stated on the carton.

This leaflet was last approved on: 06/2004