Package leaflet: Information for the user

IMOVAX d.T. Adult

suspension for injection in prefilled syringe

Adsorbed diphtheria and tetanus vaccine

Read all of this leaflet carefully before you start using this medicinal product, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their sign of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What IMOVAX d.T. Adult is and what it is used for

IMOVAX d.T. Adult is a vaccine. Vaccines are used to protect against infectious diseases.

This vaccine helps protect against diphtheria and tetanos in adults from 18 years.

It acts by helping your body produce it own defense (antibodies) against these diseases.

2. What you need to know before you use IMOVAX d.T. Adult

Do not use IMOVAX d.T. Adult:

- If you are allergic to any active substance or any of the other ingredients of this vaccine (listed in section 6).
- If you experienced allergic reactions or neurological disorder after a previous vaccine injection.
- If you have fever or an acute disease or chronic progressive illness, vaccination should be postponed.

IF YOU HAVE DOUBTS, IT IS IMPORTANT THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Warnings and precautions

Talk to your doctor before using IMOVAX d.T. Adult :

- If your immune system has been weakened by corticosteroids or a anticancer treatment, radiotherapy or other treatments likely to weake your immune system.
- If you are allergic or if you have already experienced an abnormal reactic during a previous vaccine administration.
- If you received diphtheria or tetanus vaccine in the previous five years.
- If you presented with Guillain-Barré syndrome (abnormal sensitivit paralysis) or brachial neuritis (paralysis, diffuse pain in arm and shoulde following receipt of prior tetanus toxoid containing vaccine (tetan vaccine), the decision to give any further vaccine containing tetanus toxo should be carefully evaluated by your doctor.

Other medicines and IMOVAX d.T. Adult

Tell your doctor or pharmacist if you are taking or have recently taken ar other medicines.

Pregnancy, breast-feeding and fertility

It is preferable not to use this vaccine during pregnancy.

If you are pregnant or breast-feeding, think you may be pregnant or a planning to have a baby, ask your doctor or pharmacist for advice befo taking this medicine.

Your doctor will decide if you should receive the vaccine.

Driving and using machines

The ability to drive and use machines following the administration of th vaccine has not been studied.

3. How to use IMOVAX d.T. Adult

Dosage

- For routine booster injections – a single dose of 0.5 ml every 10 years.
- Primary vaccination – 3 successive 0.5 ml doses at monthly intervals.
- The post-tetanus exposure prophylaxis recommendations are summarize below:

TYPE OF WOUND	PATIENT NOT IMMUNISED OR PARTIALLY IMMUNISED	PATIENT COMPLETELY IMMUNISED Time since last booster dose	
		5 to 10 years	>10 years
Minor – clean	Begin or complete vaccination: Tetanus toxoid, 1 dose of 0.5 ml	None	Tetanus toxoid: 1 dose of 0.5 ml
Major - clean or etanus-prone	In one arm: Human tetanus immunoglobulin, 250 I.U.* In the other arm: Tetanus toxoid**: 1 dose of 0.5 ml	Tetanus toxoid: 1 dose of 0.5 ml	In one arm: Human tetanus immunoglobulin, 250 I.U.* In the other arm: Tetanus toxoid**: 1 dose of 0.5 ml*
Tetanus-prone	In one arm: Human tetanus immunoglobulin, 500 I.U.*		In one arm: Human tetanus immunoglobulin, 500 I.U.*
Delayed or incomplete debridement	In the other arm: Tetanus toxoid**: 1 dose of 0.5 ml Antibiotic therapy	Tetanus toxoid: 1 dose of 0.5 ml Antibiotic therapy	In the other arm: Tetanus toxoid**: 1 dose of 0.5 ml* Antibiotic therapy

* Use different syringes, needles and injection sites.

** Complete the vaccination according to the vaccination schedule.

Route of administration

This vaccine will be administered to you in a muscle or deep under the skin by a healthcare professional.

If you forget to take IMOVAX d.T. Adult

Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine, can cause side effects, although not everybody gets them.

Swelling of lymph nodes.

Serious allergic reaction: rash, face oedema, sudden swelling of the face and neck (angioedema, Quincke's oedema) or generalised reactions: sudden and serious malaise with drop in blood pressure, increase in cardiac rhythm associated with respiratory disorders (anaphylactic reaction).

Allergic reactions:

- Rash, itching that may spread to the whole body (generalised prurit and urticaria).
- Redness on the skin (erythema), swelling (oedema).

Headache, malaise.

Decrease in blood pressure (hypotension).

- Muscle and joint pain.

Injection site reactions such as pain, rash, redness, induration or oedema occurring within 48 hours and lasting 1 or 2 days. These reactions can sometimes be accompanied with bubbles under the skin (subcutaneous nodules) and in exceptional cases with uninfected abscesses (aseptic abscesses).

- Transient fever, malaise.

The possible side effect (i.e. those which were not directly reported with IMOVAX d.T. Adult but with other vaccines containing of several constituents of IMOVAX d.T. Adult) are as follows:

- Guillain-Barré syndrome (abnormal sensitivity, paralysis) and brachial neuropathy (paralysis, diffuse pain in arm and shoulder) following receipt of prior tetanus toxoid containing vaccine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Štátny ústav pre kontrolu liečiv, Sekcia klinického skúšania liekov a farmakovigilancie, Kvetná ul. 11, SK-825 08 Bratislava 26, Tel: + 421 2 507 01 206, Fax: + 421 2 507 01 237, e-mail: neziaduce.ucinky@sukl.sk

Tlačivo na hlásenie nežiaduceho účinku je na webovej stránke www.sukl.sk v časti Lieky/Bezpečnosť liečiv. Formulár na elektronické podávanie hlásení: https://portal.sukl.sk/eskadra/

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store IMOVAX d.T. Adult

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that months.

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

Do not throw any medicines should via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What IMOVAX d.T. Adult contains

- The active substances are:

Diphtheria toxoid . . . . . ≥ 2 I.U.

Tetanus toxoid. . . . . ≥ 20 I.U.

adsorbed on hydrated aluminium hydroxide . . . . . 0.6 mg of Al for one 0.5 ml dose.

- The other ingredients are:

A buffer solution containing sodium chloride, disodium dihydrate phosphate, monopotassium phosphate and water for injections.

What IMOVAX d.T. Adult looks like and contents of the pack

This medicinal product is a suspension for injection in prefilled syringe. Box of 1 or 10.

Marketing authorisation holder and manufacturer

Sanofi Pasteur, 14 Espace Henry Vallée, 69007 LYON - FRANCE

This leaflet was last approved in January 2018.

SANOFI PASTEUR