

Package leaflet: Information for the user

diTeBooster

Suspension for injection, pre-filled syringe

Diphtheria and tetanus vaccine (adsorbed, reduced antigen content)

Read all of this leaflet carefully before you are vaccinated because it contains important information for you.

- Keep this leaflet. You may need to read it again.
 - If you have further questions, please ask your doctor or your pharmacist.
 - If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
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What is in this leaflet

1. What diTeBooster is and what it is used for
2. What you need to know before you are vaccinated with diTeBooster
3. How you are vaccinated with diTeBooster
4. Possible side effects
5. How to store diTeBooster
6. Contents of the pack and other information

1. What diTeBooster is and what it is used for

diTeBooster is a vaccine that provides protection against diphtheria and tetanus.

This booster vaccine is used to vaccinate children (5 years or older) and adults who have already received primary vaccination against diphtheria and tetanus.

2. What you need to know before you are vaccinated with diTeBooster

You should not be vaccinated with diTeBooster

- If you are allergic to the active substances or any of the other ingredients in the vaccine (listed in section 6).
- If you have experienced serious side effects following previous vaccinations.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are vaccinated with diTeBooster:

- If you are suffering from any illness. In case of acute illness with fever the vaccination should be postponed
- If you are receiving medical treatment that compromises the immune response (eg. corticosteroids) or if you are suffering from an illness that increases the risk of bleeding
- If you have any allergies
- If you have experienced discomfort after previous vaccinations
- If you are allergic to formaldehyde. Formaldehyde is used during the manufacturing process and trace amounts may therefore be present in the vaccine.

Other medicines and diTeBooster

diTeBooster can be given at the same time as other vaccines but as a separate injection.

Tell your doctor if you are taking or have recently taken or might take any other medicines including those obtained without a prescription.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before being vaccinated with diTeBooster.

Pregnancy

There is only limited experience with the use of diTeBooster during pregnancy. If you are pregnant your doctor will decide if the risk of infection with tetanus and diphtheria is greater than the possible risk to the unborn child if you are vaccinated.

Breast-feeding

There is only limited experience with the use of diTeBooster during breast-feeding, but there is no evidence of any harmful effects of the vaccine being passed through breast milk to the baby.

Driving and using machines

diTeBooster should not affect your ability to drive and use machinery.

diTeBooster contains sodium

diTeBooster contains less than 1 mmol (23 mg) per dose and is essentially “sodiumfree”

3. How you are vaccinated with diTeBooster

The doctor or nurse will give the vaccination by injection into a muscle (intramuscularly).

This booster dose is 0.5 ml for both children (5 years or older) and adults.

If you have further questions on the use of this vaccine ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Serious allergic reactions (examples of these can be trouble breathing, difficulty swallowing, itching on hands and feet, swelling around the eyes and in the face) may occur in rare cases (up to 1 in 1,000 people).

If you observe any of the above reactions contact your doctor immediately.

Other side effects include:

Common: may affect up to 1 in 10 people

General malaise (feeling unwell) and fever (temperature of 38°C or more). A slight redness and swelling at the site of injection.

Uncommon: may affect up to 1 in 100 people

Pronounced redness and swelling of 6 cm or more at the site of injection. Eczema and inflammation of the skin (dermatitis).

Rare: may affect up to 1 in 1,000 people

High fever (temperature of over 40°C). Long lasting itching nodes (granuloma) or sterile abscess at the site of injection. Hives (urticaria).

Very rare: may affect up to 1 in 10,000 people

Fainting

Reporting of side effects

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

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

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

5. How to store diTeBooster

- Keep this medicine out of the sight and reach of children.
- Store in a refrigerator (between 2°C and 8°C).
- Do not freeze.
- Discard the vaccine safely if it has been frozen.
- Do not use diTeBooster after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater. 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 diTeBooster contains

The active substances are:

1 dose (= 0.5 ml) contains at least 2 international units of purified diphtheria toxoid and at least 20 international units of purified tetanus toxoids that are adsorbed to aluminium hydroxide, hydrated, corresponding to 0.5 mg aluminium.

Aluminum is included in this vaccine as an adsorbent. Adsorbents are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine.

The other excipients are:

Sodium hydroxide, sodium chloride, and water for injections.

What diTeBooster looks like and contents of the pack

diTeBooster is a colourless liquid with white and grey particles.

Each dose is supplied as an individual pre-filled syringe.

Pack sizes syringes: 1 x 0.5 ml, 5 x 0.5 ml, 10 x 0.5 ml and 20 x 0.5 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

AT, DK, EL, ES, FI, IE, NO, PT, SE: diTeBooster
DE: Td-IMMUN

This leaflet was last revised in 11-2016

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The following information is intended for Healthcare Professionals Only

diTeBooster is used for revaccination of children (≥ 5 years) and adults who have previously received primary immunisation of at least 3 doses of diphtheria and tetanus vaccine.

diTeBooster is not intended for primary immunisation against diphtheria and tetanus. The use of diTeBooster should be in accordance with official national recommendations.

Shake before use. After thorough resuspension the vaccine should appear as a colourless suspension of white and grey particles.

The dose is 0.5 ml, which is administered intramuscularly.

Repeat vaccination against diphtheria and tetanus should be performed at intervals per official recommendations (generally 10 years). Too frequent booster vaccination will increase the risk of adverse reactions

At certain indication (for example haemorrhagic diathesis) diTeBooster can be administered deep subcutaneously. Clinical studies have shown fewer local reactions after i.m. injections than after s.c. injections.

The necessary precautions for treatment of anaphylactic reactions should always be taken.

Formaldehyde is used during the manufacturing process and trace amounts may be present in the final product. Caution should be taken in subjects with known hypersensitivity to formaldehyde.

Do not mix diTeBooster with other vaccines in the same vial or syringe.

Concomitant use of diTeBooster and other inactivated vaccines has not been studied.

It is unlikely that co-administration will result in interference with the immune responses. When considered necessary, diTeBooster can be administered simultaneously with other vaccines, at a different injection site.

Any unused product or waste material should be disposed of in accordance with local requirements.