Version 4.2, 04/2021

PACKAGE LEAFLET

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 any further questions, ask your doctor, pharmacist or nurse.
- 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.

What is in this leaflet

1. What diTeBooster is and what it is used for

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

diTeBooster stimulates the body to produce antibodies against diphtheria and tetanus.

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

The vaccine is also used to vaccinate children (5 years or older) and adults who have missing, incomplete or unknown primary vaccination against diphtheria and tetanus.

In case of deep and potentially contaminated wounds, the vaccine can also be used as prevention against tetanus and revaccination against diphtheria.

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 or your child 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 any 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

Children and adolescents
Children below 5 years of age should not be vaccinated with diTeBooster.

Other medicines and diTeBooster
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including those obtained without a prescription.
diTeBooster can be given at the same time as other vaccines but as a separate injection.

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 sodium (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).
The recommended dose is 0.5 ml for both children (5 years or older) and adults.

If you or your child have not been vaccinated previously against diphtheria and tetanus, you may be vaccinated more than once. Follow the doctor’s instructions.

If you have any 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 side effects
- 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).
  If you observe any of the above reactions contact your doctor immediately.

Other side effects include:
Very common (may affect more than 1 in 10 people)
- A slight redness and swelling at the site of injection.
- Pain and itching at the injection site.
- Headache and fatigue.

Common (may affect up to 1 in 10 people)
- General malaise (feeling unwell) and fever (temperature of 38ºC or more).
- Pronounced redness and swelling of 5 cm or more at the site of injection.

- Muscle pain.
- Dizziness
- Nausea, vomiting and diarrhoea.

Uncommon (may affect up to 1 in 100 people)
- Eczema and inflammation of the skin (dermatitis).

Rare (may affect up to 1 in 1,000 people)
- High fever (temperature of over 40ºC).
- 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.
Website: www.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 on aluminium hydroxide, hydrated, corresponding to 0.5 mg aluminium. Aluminium 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 or light yellow 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 European Economic Area under the following names:
AT, DK, EL, ES, FI, IE, NO, PT, SE: diTeBooster
DE: Td-IMMUN

This leaflet was last revised in 06-2023

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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 also used to vaccinate children (≥ 5 years) and adults who have missing, incomplete or unknown primary vaccination against diphtheria and tetanus.
In case of deep and potentially contaminated wounds, diTeBooster can also be used as prevention against tetanus and revaccination against diphtheria.

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 or light yellow 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

Persons with unknown immunisation status, missing or incomplete primary vaccination can be vaccinated with diTeBooster. More than one vaccination may be needed to require protective immunity against diphtheria and tetanus. National recommendations should be followed.
In persons with tetanus-prone injuries, diTeBooster can be administered when vaccination against diphtheria is also relevant. Tetanus immunoglobulin can be administered simultaneously in accordance with national recommendations.
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.