PATIENT INFORMATION LEAFLET

diTeBooster

Suspension for injection, pre-filled syringe. Diphtheria and tetanus vaccine (adsorbed, reduced antigen content)

STATENS SERUM INSTITUT

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5, Artillerivej
2300 Copenhagen S,
Denmark.

In this leaflet

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. Before you receive diTeBooster

You should not receive diTeBooster
- If you have known allergies to any of the ingredients in the vaccine.
- If you have experienced serious side effects following previous vaccinations.

Take special care with diTeBooster

Inform your doctor if you
- are suffering from any illness. In case of acute illness with fever the vaccination should be postponed
- 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
- have any allergies
- have experienced discomfort after previous vaccinations
- are allergic to formaldehyde. Formaldehyde is used during the manufacturing process and trace amounts may therefore be present in the vaccine.

Taking other medicine

diTeBooster can be given at the same time as other vaccines but as a separate injection.
You should inform your doctor if you are taken or have recently taken other medicines including those obtained without a prescription.

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.
Consult your doctor before being vaccinated with diTeBooster if you are pregnant.

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.

Important information about some of the ingredients of diTeBooster

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

Information 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.

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.

4. Possible side effects

Like all medicines diTeBooster 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 (between 1 and 10 out of every 10,000 patients treated).
If you observe any of the above reactions contact your doctor immediately.

Other side effects include:
Common side effects (occurs between 1 and 10 out of every 100 patients treated)
General malaise (feeling unwell) and fever (temperature of 38ºC or more). A slight redness and swelling at the site of injection.

Uncommon side effects (occurs between 1 and 10 out of every 1,000 patients treated)
Pronounced redness and swelling of 6 cm or more at the site of injection. Eczema and inflammation of the skin (dermatitis).

Rare side effects (occurs between 1 and 10 out of every 10,000 patients treated)
High fever (temperature of over 40ºC). Long lasting itching nodes (granuloma) or sterile abscess at the site of injection. Hives (urticaria).

Very rare side effects (occurs in less than 1 out of every 10,000 patients treated)
Fainting.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store diTeBooster

- Keep out of the reach and sight 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 as "EXP". The expiry date refers to the last day of that month.

6. Further 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 ingredients 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 approved in 03.08.2011

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.

13-204-02 en 10.2013