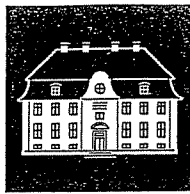


# diTeBooster

Suspension for injection



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Read all of this leaflet carefully before you/your child receive the vaccination.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- diTeBooster has been prescribed for you/your child personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

## In this leaflet

1. What diTeBooster is and what it is used for
2. Before you/your child receive a diTeBooster vaccination
3. How to use diTeBooster
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5. Storing diTeBooster

## diTeBooster composition

diTeBooster, Suspension for injection

The active ingredients in diTeBooster are purified diphtheria toxoid and purified tetanus toxoid adsorbed to aluminium hydroxide. The other ingredients are sodium hydroxide, sodium chloride, and water for injections. The vaccine contains traces of formaldehyde.

1 dose (= 0.5 ml) contains:

Purified diphtheria toxoid  $\geq 2$  International Units and purified tetanus toxoid  $\geq 20$  International Units.

Adjuvant is added in the form of aluminium hydroxide equivalent to 0.5 mg aluminium per dose. Adjuvants are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine.

## Marketing Authorisation Holder and Manufacturer

Statens Serum Institut, 5, Artillerivej, 2300 Copenhagen S, Denmark.

### 1. What diTeBooster is and what it is used for

diTeBooster is a combined diphtheria and tetanus vaccine, which is used for revaccination of children (5 years or older) and adults who have previously received primary vaccination against diphtheria and tetanus.

### 2. Before you/your child receive a diTeBooster vaccination Do not receive a diTeBooster vaccination

- If you/your child have experienced serious adverse reactions following previous vaccinations.
- If you/your child have known allergies to any of the vaccine components.

### Take special care with diTeBooster

- If you/your child are suffering from acute illness with fever vaccination should be postponed.
- Inform the doctor or nurse if you/your child are receiving treatment, which compromises the immune response or if you/your child are suffering from an illness, which increases the risk for bleeding.
- Inform the doctor if you/your child have any known allergies.
- Inform the doctor if you/your child have experienced problems at previous vaccinations.

## The following information is intended for medical and healthcare professionals only

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

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. Adults and children ( $\geq 5$  years) receive the same dose. Repeat vaccination against diphtheria and tetanus should be performed at intervals per official recommendations (generally 10 years).

diTeBooster is not intended for primary immunisation against diphtheria and tetanus.  
Vaccination of children and adults receiving immunosuppressive

## Pregnancy

There is only limited experience with the use of diTeBooster during pregnancy and breast-feeding. Consult your doctor if you are pregnant.

## Breast-feeding

Ask your doctor for advice if you are breast-feeding.

## Driving and using machines

diTeBooster is not considered to affect the ability to drive and use machinery.

## Taking other medicine

If you/your child are taking or have recently taken other medicine including over-the-counter medicine you should inform your doctor of this.

diTeBooster can be administered simultaneous with other vaccines but as a separate injection.

## 3. How to use diTeBooster

Shake before use.

Dose = 0.5 ml for children and adults.

The doctor or nurse will give the vaccination in a muscle (intramuscularly).

## 4. Possible side effects

Like all medicines diTeBooster can have side effects.

## Serious adverse reactions

- Rare side effects (occur for more than 1 in 10,000 and less than 1 in 1,000)

High fever (temperature of over 40°C) may occur.

There is a very small risk of 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 these reactions contact your doctor immediately.

## Non-serious side effects

- Common side effects (occur for more than 1 in 100 and less than 1 in 10)

General malaise and fever (temperature of 38°C or more) may occur. Redness and swelling at the injections site may occur.

- Less common side effects (occur for more than 1 in 1,000 and less than 1 in 100)

Redness and swelling (of 6 cm or more) at the injection site may occur. Eczema and inflammation of the skin (dermatitis) may occur.

- Rare side effects (occur for more than 1 in 10,000 and less than 1 in 1,000)

An enduring itching granuloma or a sterile abscess may occur at the injection site. Urticaria may occur.

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

## 5. Storing diTeBooster

diTeBooster must be kept out of reach and sight of children.

Store in a refrigerator (2°C – 8°C).

Do not freeze.

Discard the vaccine safely if it has been frozen.

Do not use diTeBooster after the expiry date stated on the label.

Last revision

02-2005

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.

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 leftover medicine and waste deriving there from must be disposed of as hazardous healthcare waste in accordance with current waste