

Part II**Summary Of Product Characteristics****1. NAME OF THE MEDICINAL PRODUCT**

diTeBooster
Diphtheria and tetanus vaccine (adsorbed)
Suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose = 0.5 ml:

Diphtheria Toxoid, purified	6.25 Lf / \geq 2 I.U.
Tetanus Toxoid, purified	6.25 Lf / \geq 20 I.U.
Aluminium hydroxide, hydrated, corr. to aluminium content	0.5 mg

The Diphtheria and Tetanus toxins, obtained from cultures of *Corynebacterium diphtheriae* and *Clostridium tetani*, are purified and detoxified. The two toxoids are adsorbed to aluminium hydroxide. No substances of human origin are used during the vaccine manufacture.
For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Suspension for Injection.
Colourless suspension of white/grey particles

4. CLINICAL PARTICULARS**4.1. Therapeutic Indications**

Re-vaccination of children (\geq 5 years of age) 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.

4.2. Posology and method of administration

In comparison with a vaccine for primary immunisation diTeBooster contains reduced amounts of diphtheria and tetanus antigens, and the vaccine should be administered in accordance with national official recommendations regarding the use of such vaccines.

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

diTeBooster should be administered intramuscularly as a single dose of 0.5 ml.

At certain indications (for example haemorrhagic diathesis) diTebooster can be administered deep subcutaneously.

Clinical studies have shown fewer local reactions after i.m. injection than after s.c. injection.

Adults and children (> 5 years) receive the same dosage.

Repeat vaccination against diphtheria and tetanus should be performed at intervals per official recommendations (generally 10 years).

4.3. Contraindications

Serious adverse reactions following previous vaccination with the vaccine or known allergy against

any of the vaccine components or constituents.

4.4. Special warnings and precautions for use

diTeBooster is not intended for primary immunisation against diphtheria and tetanus.

Vaccination should be postponed in case of acute illness with fever.

In children and adults with compromised immune response, the serological response may be impaired.

Vaccination of children and adults receiving immunosuppressive treatment can take place, but may result in a reduced immunological response.

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.

Too frequent booster vaccination will increase the risk of adverse reactions (refer to section 4.2 for recommendations on repeated vaccination).

4.5. Interactions with other medicinal products and other forms of interaction

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

Concomitant use of diTeBooster with 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.

4.6. Pregnancy and lactation

No relevant animal data are available. In humans the data are inadequate to assess teratogenic or fetotoxic risk during pregnancy. During pregnancy the possible risk of clinical infection following exposure should be weighed against the theoretical risks of vaccination.

There is no evidence that vaccination of the breast feeding mother with diTeBooster is harmful to the infant.

4.7. Effects on ability to drive and use machines

No effect on ability to drive and use machines have been observed

4.8. Undesirable effects

In relation to the administration of diTeBooster, the most common adverse reactions are redness and swelling at the injection site and fever. The reactions most commonly start within 48 hours from the day of vaccination.

4.8. Undesirable effects (Cont/d)

Frequency of ADR Organ class	Common (>1/100 and <1/10)	Uncommon (>1/1,000 and <1/100)	Rare (>1/10,000 and <1/1,000)
Immune system disorders	-	-	<ul style="list-style-type: none"> Anaphylactoid reactions
Skin and sub-cutaneous tissue disorders	-	<ul style="list-style-type: none"> Eczema and dermatitis 	<ul style="list-style-type: none"> Urticarial reactions
General disorders and administration site conditions	<ul style="list-style-type: none"> Malaise Fever $\geq 38^{\circ}\text{C}$ Redness/swelling at the injection site 	<ul style="list-style-type: none"> Redness/swelling ≥ 6 cm at the injection site 	<ul style="list-style-type: none"> High fever $> 40^{\circ}\text{C}$ Granuloma or sterile abscess at the injection site

4.9. Overdose

Cases of overdose have not been reported.

5. PHARMACOLOGICAL PROPERTIES

5.0 Therapeutic classification

ATC-code J 07 AM 51.

5.1. Pharmacodynamic properties

Shortly after re-vaccination, antibodies are produced against both vaccine antigens. Protection against diphtheria and tetanus can be expected to last for at least 10 years.

5.2. Pharmacokinetic properties

No experience.

5.3. Preclinical safety data

The subacute and acute toxicity of the vaccine components have been investigated in animal tests. No clinical symptoms or systemic toxicity have been reported.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Per dose = 0.5 ml:

Sodium Hydroxide to pH = 7

Sodium Chloride

Water for injections

The pH of the vaccine is approximately 7.

6.2. Incompatibilities

The vaccine must not be mixed with other vaccines or medicinal products.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

Store at 2°C - 8°C. Do not freeze.

Discard if vaccine has been frozen.

6.5. Nature and contents of container

Vials (type I glass) containing 0.5 ml (1 dose)

Pack size: 1 x 0.5 ml, 5 x 0.5 ml, and 10 x 0.5 ml

Not all pack sizes may be marketed

6.6. Instructions for use and handling

Shake before use.

After thorough re-suspension the vaccine should appear as a colourless suspension of white or grey particles.

7. MARKETING AUTHORISATION HOLDER

Statens Serum Institut

5 Artillerivej

DK-2300 Copenhagen S

Denmark.

8. MARKETING AUTHORISATION NUMBER

PA 798/3/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

10. DATE OF REVISION OF THE TEXT

September 2005