Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

diTeBooster, suspension for injection.
Diphtheria and tetanus vaccine (absorbed, reduced antigen content).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose	= 0.5 ml:
Diphtheria Toxoid, purified	6.25 Lf / ≥ 2 I.U.
Tetanus Toxoid, purified	6.25 Lf / ≥ 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 a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection in single-dose vials.
Colourless suspension of white/ grey particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Re-vaccination of children (≥ 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.

diTeBooster contains less than 1 mmol sodium (23 mg) per dose and is essentially "sodiumfree".

Too frequent booster vaccination will increase the risk of adverse reactions (refer to *section 4.2, Posology and method of administration* for recommendations on repeated vaccination).

4.5 Interaction 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 Fertility, 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.

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)**	**Very rare (<1/10,000)**
Nervous system disorder				Vasovagal syncope
Skin and subcutaneous tissue disorders		Eczema and dermatitis	Urticarial reactions	
General disorders and administration site conditions	Malaise Fever ≥ 38°C Redness/swelling at the injection site	Redness/swelling ≥ 6 cm at the injection site.	High fever > 40°C Granuloma or sterile abscess at the injection site.	
Immune System disorders			Hypersensitivity including anaphylactic reactions.	

4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Tetanus toxoid, combinations with diphtheria toxoid.

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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.

For adsorbents, see section 2.

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 in a refrigerator ($2^{o}C$ - $8^{o}C$).
Do not freeze

Discard if vaccine has been frozen.

6.5 Nature and contents of container

Single-dose 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 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Shake before use.
After thorough re-suspension the vaccine should appear as a colourless suspension of white or grey particles.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Statens Serum Institut
5 Artillerivej
DK-2300 Copenhagen S
Denmark.

8 MARKETING AUTHORISATION NUMBER

PA0798/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 March 2005
Date of last renewal: 9 September 2008

10 DATE OF REVISION OF THE TEXT

September 2008