

**NAME OF THE MEDICINE**

ADT™ Booster. Diphtheria and Tetanus Vaccine (adsorbed) for re-vaccination.

**DESCRIPTION**

ADT™ Booster is a suspension for intramuscular injection, containing aluminium-hydroxide-adsorbed diphtheria and tetanus toxoids.

Each 0.5mL dose contains no less than 2 International Units (IU) of purified diphtheria toxoid and no less than 20 IU of purified tetanus toxoid.

Each dose of ADT™ Booster also contains the following excipients: aluminium hydroxide (hydrated) corresponding to 0.5 mg aluminium, sodium chloride (4 mg), sodium hydroxide q.s. to pH 7, and Water for Injections.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalitis) has resulted from the administration of any vaccine product.

**PHARMACOLOGY**

Following intramuscular injection, ADT™ Booster stimulates the immune system with the effect that antibodies are formed that protect against the diseases caused by exposure to *Corynebacterium diphtheriae* and *Clostridium tetani*. Protection against diphtheria and tetanus can be expected to last for up to 10 years.

**INDICATIONS**

Vaccination of children ( $\geq 5$  years of age) and adults who have previously received at least 3 doses of a vaccine for primary immunisation against diphtheria and tetanus. ADT™ Booster is **not** intended for primary immunisation against diphtheria and tetanus.

Use of ADT™ Booster should be scheduled in accordance with official national recommendations.

**CONTRAINDICATIONS**

ADT™ Booster should not be administered to subjects who have previously experienced a serious reaction (e.g. anaphylaxis) to this vaccine or who are known to be hypersensitive to any of the vaccine components.

**PRECAUTIONS**

As with other injectable vaccines, appropriate medical treatment and supervision should always be available in the event of anaphylactic reaction. Adrenaline should always be readily available whenever the injection is given.

ADT™ Booster is not intended for primary immunisation against diphtheria and tetanus.

Vaccination should normally be postponed in persons with moderate or severe acute illness, with or without fever.

Mild common illnesses are NOT contraindications to vaccination.

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.

**Use in Pregnancy (Category A)**

No relevant animal data are available.

No increase in frequency of malformations or other direct or indirect harmful effects on the foetus have been observed.

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 ADT™ Booster is harmful to the infant.

**ADVERSE EFFECTS**

Following vaccination with ADT™ Booster, the most common adverse reactions are redness and swelling at the injection site and fever. These reactions most commonly start within 48 hours from the day of vaccination.

Systemic reactions reported for this type of vaccine include pruritis, rash, urticaria and peripheral oedema, anaphylactoid and hypersensitivity reactions, flu-like symptoms (including headache, rigors, asthenia, fatigue

and myalgia), pyrexia, nausea, vomiting and dizziness. Postvaccinal neurologic disorders have been reported following the injection of almost all biological products and the possibility of their occurrence must be considered. Such disorders have included hypoesthesia, paraesthesia and brachial radiculitis.

For the frequency of the adverse effects that have been reported for ADT™ Booster, please refer to the table below.

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"><li>Anaphylactic reactions</li></ul>
Skin and sub-cutaneous tissue disorders	-	<ul style="list-style-type: none"><li>Eczema and dermatitis</li></ul>	<ul style="list-style-type: none"><li>Urticarial reactions</li></ul>
General disorders and administration site conditions	<ul style="list-style-type: none"><li>Malaise</li><li>Fever ≥ 38°C</li><li>Redness/swelling at the injection site</li></ul>	<ul style="list-style-type: none"><li>Redness/swelling ≥ 6 cm at the injection site</li></ul>	<ul style="list-style-type: none"><li>High fever &gt; 40°C</li><li>Granuloma or sterile abscess at the injection site</li></ul>

## DOSAGE AND ADMINISTRATION

The dose of ADT™ Booster is 0.5 mL. Injections should be given by the intramuscular route.

For details of recommended vaccination schedules, including for tetanus prone wounds, refer to The Australian Immunisation Handbook of the NHMRC in Australia or the New Zealand Immunisation Handbook in New Zealand.

ADT™ Booster is recommended for re-vaccination after an initial primary course of vaccination.

The vaccine should be thoroughly shaken before use to ensure adequate dispersion when it is injected. The vaccine should appear as a suspension of white and grey particles in a colourless fluid.

ADT™ Booster is for single use in one patient only. Discard any residue.

## OVERDOSAGE

There have been no cases of overdosage reported.

In Australia, contact the Poisons Information Centre on 131 126 for advice on overdosage management.

In New Zealand, call the New Zealand Poisons Centre on 0800 POISON or 0800 764 766 for advice on overdosage management.

**PRESENTATION AND STORAGE CONDITIONS**

**ADT™ Booster can be supplied in a 0.5mL needle-less pre-filled syringe or vial (Type 1 glass). Both these presentations may not necessarily be marketed.**

Syringe and vial pack sizes: 1 x 0.5 mL and 5 x 0.5 mL.

ADT™ Booster should be stored at 2°C to 8°C. It must not be frozen. Discard if vaccine has been frozen.

ADT™ Booster does not contain preservatives or ingredients of human origin.

The tip cap of the ADT™ Booster syringe contains latex (natural rubber). The ADT™ Booster syringe barrel, plunger rod and plunger stopper do not contain latex.

The ADT™ Booster vial and vial stopper do not contain latex.

**NAME AND ADDRESS OF MANUFACTURER**

Statens Serum Institut  
Copenhagen  
DENMARK

**NAME AND ADDRESS OF SPONSOR****In Australia:**

CSL Limited ABN 99 051 588 348  
45 Poplar Road  
Parkville VIC 3052 AUSTRALIA

**In New Zealand:**

CSL Biotherapies (NZ) Ltd  
666 Great South Road  
Penrose, Auckland  
NEW ZEALAND  
Ph: 0800 502 757

**POISON SCHEDULE OF THE MEDICINE**

S4 Prescription Only Medicine

**DATE OF TGA APPROVAL**

29 January 2010

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