

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 (≥ 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">Anaphylactic 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">MalaiseFever $\geq 38^{\circ}\text{C}$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

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

AJ Vaccines A/S
5, Artillerivej
DK-2300 Copenhagen S
DENMARK

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

Seqirus Pty Ltd
ABN 26 160 735 035
63 Poplar Road
Parkville VIC 3052
Australia

In New Zealand:

Seqirus (NZ) Ltd
PO Box 62 590
Greenlane
Auckland 1546
New Zealand

Telephone: 0800 502 757

POISON SCHEDULE OF THE MEDICINE

S4 Prescription Only Medicine

DATE OF TGA APPROVAL

29 January 2010

DATE OF MOST RECENT AMENDMENT

13 October 2017

ADT™ is a Trademark of Seqirus UK Limited or its affiliates