1. PRODUCT NAME

ADT™ Booster. Diphtheria and Tetanus Vaccine (adsorbed) for revaccination.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Each 0.5 mL 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 hydrate 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.

3. PHARMACEUTICAL FORM

Suspension for intramuscular injection. The vaccine should appear as a suspension of white or grey particles in a colourless or light yellow liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic 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.

4.2 Dose and method of 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 revaccination after an initial primary course of vaccination.

The vaccine should be thoroughly shaken before use to ensure adequate dispersion when it is injected.

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

4.3 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.

4.4 Special warnings and precautions for use
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.

4.5 Interactions with other medicines and other forms of interaction
No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation
Use in Pregnancy (Category A)
Pregnancy category A – Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

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.

4.7 Effects on ability to drive and use machines
Not applicable.

4.8 Undesirable 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	-	-	• Anaphylactic reactions
Skin and sub-cutaneous 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

4.9 Overdose
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, contact the National Poisons Centre on 0800 POISON or 0800 764 766 for advice on overdosage management.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Tetanus toxoid, combinations with diphtheria toxoid
ATC Code: J07A M51

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.

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

Aluminium hydroxide (hydrated)
Sodium chloride
Sodium hydroxide
Water for Injections

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

ADT™ Booster should be protected from light and stored at 2˚C to 8˚C. It must not be frozen. Discard if vaccine has been frozen.

6.5 Nature and contents of container

ADT™ Booster can be supplied in a 0.5 mL 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 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.

6.6 Special precautions for disposal and other handling
The vaccine should be thoroughly shaken before use to ensure adequate dispersion when it is injected.

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

7. MEDICINE SCHEDULE
S4 Prescription Only Medicine.

8. SPONSOR

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9. DATE OF FIRST APPROVAL
10 January 2008

10 . DATE OF REVISION OF THE TEXT
28 November 2019

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Summary table of changes

Section changed	Summary of new information
4.6	Addition of the Australian pregnancy category A definition