AUSTRALIAN PRODUCT INFORMATION – ADT™ BOOSTER (DIPHTHERIA AND TETANUS TOXOIDS (ADSORBED) (DIPHTHERIA AND TETANUS VACCINE)) – SUSPENSION FOR INJECTION

1 NAME OF THE MEDICINE

Diphtheria and Tetanus toxoids (adsorbed) (Diphtheria and Tetanus Vaccine).

2 AND 3 QUALITATIVE AND QUANTITATIVE COMPOSITION AND PHARMACEUTICAL FORM

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 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.

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 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 or grey particles in a colourless or light yellow liquid.

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.

Use in the elderly

No data available.

Paediatric use

No data available.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No data available.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy – 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.

Use in lactation.

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

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (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

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

There have been no cases of overdosage reported.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

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

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

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.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

No data available.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Refer to Section 2 and 3 - Qualitative and quantitative composition and pharmaceutical form.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

ADT™ Booster should be 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 0.5mL 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 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

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

No data available.

CAS number

No data available.

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 Prescription Only Medicine.

8 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

Name and address of manufacturer:
AJ Vaccines A/S
5, Artillerivej
DK-2300 Copenhagen S
Denmark

9 DATE OF FIRST APPROVAL

29 January 2010.

10 DATE OF REVISION

13 December 2019.

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	Reformatted to align with the Form for providing the Product Information March 2018.