New Zealand Data Sheet

1. PRODUCT NAME

TdaP-Booster™. Diphtheria, tetanus and pertussis (acellular mono-component) vaccine (adsorbed, reduced antigen content).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

TdaP-Booster™ is a suspension for injection in pre-filled syringe.
1 dose (0.5 mL) contains:
Diphtheria Toxoid, purified ≥ 2 IU
Tetanus Toxoid, purified ≥ 20 IU
Pertussis Toxoid, purified 20 µg
Adsorbed on Aluminium hydroxide, hydrated (0.5 mg Al)

The diphtheria and tetanus toxins are produced from cultures of *Corynebacterium diphtheriae and Clostridium tetani* and subsequently purified and detoxified. The pertussis toxin is produced from cultures of *Bordetella pertussis* and subsequently purified and detoxified.

3. PHARMACEUTICAL FORM

TdaP-Booster vaccine is a sterile suspension of white or grey particles in colourless liquid supplied in a single-dose single-dose pre-filled syringe.

4. CLINICAL PARTICULARS

The clinical studies have been performed in children, adolescents and adults, from 4 years up to 55 years of age.
In clinical studies antibodies were measured one month after vaccination with TdaP-Booster™:

Study population	**Age**	**Children 5-6 years**	**Children 10 years**	**Adolescents 14-15 years**	**Adults 18-55 years**
	Vaccination history	3 x DTaP (1) first year of life	3 x DT first year of life, aP/wP vaccination/disease	3 x DTaP(5) first year of life: 1 x TdaP(5) 4-6 years	3-4 x D, T and wP first year of life
Antigen	**Immune response**				
Tetanus	**≥ 0.1 IU/mL**	99.3 %	100 %	100 %	100 %
Diphtheria	**≥ 0.1 IU/mL**	99.3%	100 %	100 %	98.5 %
Pertussis	**Anti-PT Booster response**	97.4 %*)	N.A. **)	95.6 %***)	92.0 % ****)
	Anti-PT antibody (GMC)	223 IU/mL	N.A. **)	74.2 IU/mL	122 IU/mL

(1) Mono-component pertussis vaccine
(5) Five-component pertussis vaccine
*) ≥ 4-fold increase
**) Median anti-PT antibody concentration 16.5 to >400 IU/mL
***) ≥ 2-fold increase and ≥ 4 IU/mL
****) ≥ 4-fold increase, if <20 IU/mL before vaccination; ≥ 2-fold increase, if ≥ 20 IU/mL before

vaccination

Serological correlates of protection exist for diphtheria and tetanus. Antibody levels of at least 0.1 IU/mL are generally considered protective.

Serological correlates of protection against pertussis have not been established. The pertussis antigen contained in TdaP-Booster™ is the pertussis antigen in the paediatric acellular pertussis combination vaccine, for which efficacy after primary vaccination has been demonstrated in children.
The immunogenicity of TdaP-Booster™ is independent of the primary immunisation schedule used. This has been demonstrated in clinical trials, with boosting of individuals after different primary vaccination schedules:

Age at vaccination with Pertussis Toxoid SSI	**Primary schedule**	**Other booster doses administered**
16 months (DTaP(1)-IPV Vaccine SSI)	2, 3½, and 5 months DTaP(1)-IPV Vaccine SSI	-
6 years (TdaP-Booster™)	3, 5, 12 months DTaP(1) Vaccine SSI	-
4-6 years (DTaP(1)*)	2, 4, and 6 months DTwP	12-24 months (DTaP(1)* or DTwP)
14-15 years (TdaP-Booster™)	3, 5, and 12 months DTaP(5)	5 ½ years TdaP(5) or TdaP(5)-IPV)
Adults (TdaP-Booster™)	D, T, wP	-
10 years (TdaP-Booster™)	Various primary schedules	-

* US formulation of DTaP Vaccine SSI with the same content of Pertussis Toxoid SSI as in the EU formulation
(1) Mono-component pertussis vaccine which constitutes of Pertussis Toxoid SSI
(5) Five-component pertussis vaccine which constitutes of Pertussis Toxoid, Filamentous Haemagglutinin, Fibriae 2 and 3, and Pertactin

The expected protection against diphtheria and tetanus is at least 10 years.

The duration of protection afforded by acellular pertussis vaccines is not known. Observational data indicate that protection does not substantially decline during the first 5 years of follow-up.

The degree of protection against pertussis after TdaP-Booster™ vaccination depends on, among other factors, the level of existing antibodies before vaccination. Therefore, response rates after pertussis booster vaccination depend somewhat on age and on incomplete primary vaccination. In clinical studies with TdaP-Booster™, the risk of non-response was higher among persons aged 40-55 years compared to younger persons.

4.1 Therapeutic indications

TdaP-Booster™ is indicated for booster vaccination against diphtheria, tetanus and pertussis of individuals from the age of four years onwards.

Clinical studies have been performed in children, adolescents and adults, from the age of 4 years up to 55 years of age (see **4. CLINICAL PARTICULARS** section).

TdaP-Booster™ should be used according to official recommendations.

4.2 Dose and method of administration

The dose of TdaP-Booster™ is 0.5 mL. Injections should be given by the intramuscular route, preferably in the deltoid region. Do not inject intravascularly.

For persons at risk of haemorrhage following intramuscular injection, TdaP-Booster™ can be administered subcutaneously (see **4.4 Special warnings and precautions for use**).

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

TdaP-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.
Use in one patient on one occasion only. Contains no antimicrobial preservative.

4.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients or to formaldehyde which may be present as traces.

Persons suffering from progressive neurological diseases should not be vaccinated.

Vaccination should be postponed in case of acute severe febrile illness.

TdaP-Booster™ should not be administered to subjects who have experienced an encephalopathy of unknown aetiology, occurring within 7 days following previous vaccination with pertussis-

containing vaccine. In these circumstances, pertussis vaccination should be discontinued and the vaccination course should be continued with diphtheria and tetanus vaccines.

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.

TdaP-Booster™ is not intended for primary immunisation.

TdaP-Booster™ should under no circumstances be administered intravascularly.

In immunosuppressed persons the serological response may be impaired. Vaccination of persons receiving immunosuppressive treatment can take place, but may result in an impaired serological response. If possible, vaccination should be postponed until immunosuppressive treatment is finalised.

Vaccination of persons with chronic immunodeficiency, e.g. HIV infection, is recommended even though the serological response might be impaired.

If any of the following adverse events occur in relation to immunisation with a pertussis-containing vaccine, the decision to administer additional doses of pertussis vaccine should be carefully considered:

- hypotonic-hyporesponsive episode (HHE) within 48 hours of vaccination
- fever > 40°C within 48 hours of vaccination not due to any other identified cause
- persistent, inconsolable crying lasting more than 3 hours, within 48 hours of vaccination
- convulsions with or without fever, within 3 days of vaccination

TdaP-Booster™ should be administered with caution in persons treated with anticoagulants or with coagulation disorders since bleeding may occur following intramuscular administration. In such cases, deep subcutaneous injection can be considered, although the risk of local reactions is increased.

Formaldehyde is used during the manufacturing process and trace amounts may be present in the vaccine. Caution should be taken in subjects with known hypersensitivity to formaldehyde.

The vaccine contains less than 1 mmol sodium (23 mg) per dose and is essentially free of sodium.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

4.5 Interaction with other medicines and other forms of interaction

Concomitant use of TdaP-Booster™ with other vaccines has not been studied. It is unlikely that co- administration will affect the immune response. When considered necessary, TdaP-Booster™ can be administered simultaneously, before or after other live and inactivated vaccines. The vaccines should be administered at different injection sites.

Tetanus immunoglobulin can be administered concomitantly with TdaP-Booster™.

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

There is limited amount of data from the use of TdaP-Booster™ in pregnant women. Animal studies are insufficient with respect to reproductive toxicity.

As with other inactivated vaccines harm to the fetus is not anticipated.

TdaP-Booster™ should be used during pregnancy only when clearly needed and the potential benefits outweigh the potential risks to the fetus.

Use in lactation
The effect on breast-fed infants by administration of TdaP-Booster™ to mothers has not been studied. Risks and benefits of vaccination should be weighed before deciding whether to vaccinate a breastfeeding woman.

Effects on fertility
Nothing indicates that vaccination has an effect on male and female fertility. Data from repeated dose study in rats showed no effect on reproductive organs.

4.7 Effects on ability to drive and use machines

TdaP-Booster™ has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The safety profile presented below is based on data from clinical trials in children, adolescents and adults, and from post marketing experience.

The most common adverse reactions are transient itching, redness, swelling and pain at the injection site and fever. These reactions usually occur within 48 hours after vaccination.

System organ class and frequency	Adverse reactions
Immune system disorders Very rare (<1/10,000)	Hypersensitivity, including anaphylactic reactions
Nervous system disorders Very common (≥1/10)	Headache
Skin and subcutaneous tissue disorders Rare (≥1/10,000 to <1/1,000)	Urticaria
Musculoskeletal and connective tissue disorders Common (≥1/100 to <1/10)	Myalgia

General disorders and administration site conditions	
Very common (≥1/10)	Injection site pain Injection site itching Injection site redness Injection site swelling Fatigue
Common (≥1/100 to <1/10)	Fever (≥ 38°C), irritability and malaise Injection site redness (≥ 5 cm) Injection site swelling (≥ 5 cm)
Rare (≥1/10,000 to <1/1,000)	Fever (> 40°C) Injection site granuloma Injection site abscess sterile

Anaphylactic reactions are very rarely reported. The necessary precautions for treatment of anaphylactic reactions should always be taken (See **4.4 Special warnings and precautions for use** section). Paediatric population frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

Other special populations

Adverse reactions in persons above 55 years of age or in immunosuppressed persons are not expected to exceed those observed in children, adolescents and adults.

4.9 Overdose

There have been no cases of overdosage reported.

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

Pharmacotherapeutic group: vaccine against diptheria, tetanus and pertussis (acellular mono-component) vaccine (adsorbed, reduced antigen content): ATC code: J07AJ

Following intramuscular injection, TdaP-Booster™ stimulates the immune system with the effect that antibodies are formed that protect against the diseases caused by exposure to *Corynebacterium diphtheria, Clostridium tetani* and *Bordetella pertussis*.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Each dose of TdaP-Booster™ also contains the following excipients:
aluminium hydroxide (hydrated) corresponding to 0.5 mg aluminium, sodium chloride 4.0 mg, sodium hydroxide q.s. and water for injections q.s to 0.5 mL.

6.2 Incompatibilities

In the absence of compatibility studies, TdaP-Booster™ must not be mixed with other medicinal products in the same vial or syringe.

6.3 Shelf life

36 months stored at 2ºC to 8ºC. Refrigerate. Do not freeze. Protect from light.

6.4 Special precautions for storage

Not applicable

6.5 Nature and contents of container

TdaP-Booster™ is available as 0.5 mL suspension in a pre-filled single-dose syringe (type I glass) with plunger stopper (chlorobutyl rubber).
Pack size available are 1 x 0.5 mL, 5 x 0.5 mL, 10 x 0.5 mL and 20 x 0.5 mL*.
*Not all pack sizes may be marketed.
TdaP-Booster™ syringe and syringe stopper do not contain latex.

6.6 Special precautions for disposal

No special requirements for disposal.

7. MEDICINE SCHEDULE

Prescription Only Medicine

8. SPONSOR

New Zealand:
Seqirus (NZ) Ltd
P O Box 62 590
Greenlane, Auckland 1546
NEW ZEALAND Ph: 0800 502 757

9. DATE OF FIRST APPROVAL

11 June 2015

10. DATE OF REVISION OF THE TEXT

16 August 2018

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	Data sheet reformatted as per Data Sheet Explanatory Guide v1.0 March 2017
2	Include Aluminum hydroxide (0.5mg Al)

3	Addition of appearance of product
6.3	Addition of approved 36 months shelf-life
8	Change in sponsor/s name
9	Addition of date of first approval
10	Date of revision amended to align with date of HA approval