Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

TdaPBooster, suspension for injection in pre-filled syringe.Diphtheria, tetanus and pertussis (acellular component) vaccine (adsorbed, reduced antigen content)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen content).

One dose (0.5 mL) contains:

Diphtheria Toxoid, purified[1] Not less than 2 IU
Tetanus Toxoid, purified[1] Not less than 20 IU
Pertussis Toxoid, purified[1] 20 micrograms
[1] Adsorbed on aluminium hydroxide, hydrated ($Al(OH)_3$) corresponding to 0.5 mg aluminium (Al^{3+})

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.

TdaPBooster may contain traces of formaldehyde which are used during the manufacturing process (see section 4.3).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection in pre-filled syringe.
TdaPBooster is a colourless suspension of white or grey particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

TdaPBooster is indicated for booster vaccination against diphtheria, tetanus and pertussis of individuals from the age of four years onwards (see section 4.2).
Clinical studies have been performed in children, adolescents and adults, from the age of 4 years up to 55 years of age (see section 5.1).
TdaPBooster should be used according to official recommendations.

4.2 Posology and method of administration

Posology
A single injection of one dose (0.5 mL) is recommended in all age groups.
Vaccination with TdaPBooster should be performed in accordance with official recommendations and/or local practice.
Persons with unknown status of vaccination or incomplete primary vaccination can be vaccinated. However, a booster response is only expected in persons who have been primary vaccinated or exposed to a natural infection.
In persons with tetanus prone injuries, TdaPBooster can be administered when vaccination against diphtheria and pertussis is also relevant.
Booster vaccination of adults against tetanus and diphtheria should be performed in accordance with official recommendations, generally at intervals of 10 years.
There is currently no scientific data that can form the basis for official recommendations for an optimal time interval between booster vaccinations with TdaPBooster.

Special populations

- The safety and efficacy of TdaPBooster in persons above 55 years of age have not been studied.
- 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 has been finalised (see section 4.4).

Paediatric population
Children should receive the same dosage as adults.
The safety and efficacy of TdaPBooster in children below 4 years of age have not been established (no data are available).

Method of administration
Shake before use.
A single injection of one dose (0.5 mL) should be administered intramuscularly, preferably in the deltoid region.
Do not inject intravascularly.
For persons at risk of haemorrhage following intramuscular injection, TdaPBooster can be administered subcutaneously (see section 4.4).

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 or to formaldehyde that 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.

TdaPBooster 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

TdaPBooster is not intended for primary immunisation.

TdaPBooster 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.

The necessary precautions for treatment of anaphylactic reactions should always be taken.

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

TdaPBooster 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.

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

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

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of TdaPBooster with other vaccines has not been studied. It is unlikely that co-administration will affect the immune response. When considered necessary, TdaPBooster 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 TdaPBooster.
No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
There is limited amount of data from the use of TdaPBooster in pregnant women. Animal studies are insufficient with respect to reproductive toxicity.
As with other inactivated vaccines harm to the fetus is not anticipated.
TdaPBooster should be used during pregnancy only when clearly needed and the potential benefits outweigh the potential risks to the fetus.

Breast-feeding
The effect on breast-fed infants by administration of TdaPBooster to mothers has not been studied. Risks and benefits of vaccination should be weighed before deciding whether to vaccinate a breast-feeding woman.

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

TdaPBooster 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 section 4.4).

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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation 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 via HPRA Pharmacovigilance, Website: www.hpra.ie

4.9 Overdose

Not relevant, since the vaccine is distributed in a single-dose container.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Pertussis, purified antigen, combinations with toxoids.
ATC code: J 07 AJ 52

Clinical efficacy and safety
The clinical studies with TdaPBooster have been performed in children, adolescents and adults, from 5 years up to 55 years of age.
In clinical studies with TdaPBooster, antibodies were measured one month after vaccination:

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) Monocomponent 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 TdaPBooster is the pertussis antigen in the paediatric acellular pertussis combination vaccine, for which efficacy after primary vaccination has been demonstrated in children.
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 TdaPBooster 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 TdaPBooster, the risk of non-response was higher among persons aged 40-55 years compared to younger persons.

5.2 Pharmacokinetic properties

Assessment of pharmacokinetic properties is not required for vaccines, therefore data is not available.

5.3 Preclinical safety data

A single and a repeat-dose toxicity study have been conducted in rats. No adverse effects were observed apart from moderate local reactions at the injection site. Reproductive and developmental toxicity studies have not been conducted.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium hydroxide
Water for injections

For adsorbants, see section 2.

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Store in the original package in order to protect from light.
Do not freeze.
Discard if the vaccine has been frozen.

6.5 Nature and contents of container

0.5 mL (1 dose) suspension in a pre-filled single-dose syringe (type I glass) with plunger stopper (chlorobutyl rubber).
Pack size 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.

6.6 Special precautions for disposal and other handling

Shake before use.
After thorough re-suspension, the vaccine should appear as a colourless suspension of white or grey particles.
Inspect the vaccine for extraneous particulate matter and/or discolouration before use. If these conditions exist, the product should not be administered.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

AJ Vaccines A/S
5 Artillerivej
DK-2300 Copenhagen S
Denmark

8 MARKETING AUTHORISATION NUMBER

PA2160/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th July 2013
Date of last renewal: 28th February 2018

10 DATE OF REVISION OF THE TEXT

August 2024