

PACKAGE LEAFLET

Package leaflet: Information for the user

TdapBooster Suspension for injection in pre-filled syringe

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

Read all of this leaflet carefully before you are vaccinated because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What TdapBooster is and what it is used for
2. What you need to know before you are vaccinated with TdapBooster
3. How you are vaccinated with TdapBooster
4. Possible side effects
5. How to store TdapBooster
6. Contents of the pack and other information

If the doctor has prescribed TdapBooster for your child, please note that all information in this leaflet is directed at your child (read "your child" instead of "you").

1. What TdapBooster is and what it is used for

- TdapBooster is used to vaccinate children (4 years or older), adolescents and adults.
- TdapBooster is a vaccine that provides protection against diphtheria, tetanus and whooping cough (pertussis).
- TdapBooster stimulates the body to produce antibodies against diphtheria, tetanus and pertussis bacteria.

You will receive TdapBooster only if you already have been vaccinated against diphtheria, tetanus and pertussis.

2. What you need to know before you are vaccinated with TdapBooster

You should not be vaccinated with TdapBooster

- if you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6) or to formaldehyde that may be present in very small amount.
- if you are suffering from progressive neurological diseases.
- if you are ill with high fever, vaccination should be postponed.
- if you have experienced problems of the nervous system (encephalopathy) within 7 days after previous vaccination with a vaccine against pertussis (whooping cough) disease.

Warnings and precautions

The doctor or nurse will be extra cautious about vaccinating you with TdapBooster.

- if your immune response is weakened or you receive immunosuppressive medicine, you can still be vaccinated with TdapBooster, but your immune response may be lowered.
- if you are suffering from an illness or are receiving medical treatment that increases the risk of bleeding.
- if you have experienced one or more of the following side effects after previous pertussis vaccination:

General:

- if you have had fever, (temperature of over 40°C) within 48 hours of vaccinations not due to any other identified cause.

Children:

- if the child has had a collapse or shock-like state within 48 hours of vaccination.
- if the child has had persistent crying lasting more than 3 hours or more within 48 hours of vaccination.
- if the child has had convulsions with or without fever within 3 days of vaccination.

Other medicines and TdaPBooster

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

TdaPBooster can be given at the same time as other vaccines without reducing the effect of TdaPBooster.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before vaccinated with this vaccine.

Driving and using machines

TdaPBooster should not affect your ability to drive and use machinery.

TdaPBooster contains Sodium Chloride

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How you are vaccinated with TdaPBooster

Usually the doctor or nurse will give the vaccination by injection into a muscle (intramuscularly). It can also be given by injection under the skin if there is risk of haemorrhage.

The recommended dose is 0.5 mL for children (4 years or older), adolescents and adults.

If you need a vaccination

Ask your doctor or nurse, if you think you need a vaccination.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

Serious side effects

Very rare side effects: may affect up to 1 in 10,000 people

- Serious allergic reactions (hypersensitivity reactions within minutes to hours), e.g. skin rash, trouble breathing and fainting (anaphylactic reaction). Can be fatal.

Other side effects

Very common side effects: may affect more than 1 in 10 people

- Pain, itching, redness or swelling at the injection site.
- Headache.
- Fatigue.

Common side effects: may affect up to 1 in 10 people

- General malaise (feeling unwell), irritability and fever (temperature of 38°C or more).
- Redness and swelling 5 cm or more at the injection site.
- Pain in the muscles (myalgia).

Rare side effects: may affect up to 1 in 1,000 people

- High fever (temperature above 40°C).
- Long lasting itching nodules (granuloma) or sterile abscess at the site of injection.
- Hives (urticaria).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effect directly via

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store TdaPBooster

Keep this medicine out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C).

Store in the original package in order to protect from light.

Do not freeze.

Discard the vaccine if it has been frozen.

Do not use this medicine after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What TdaPBooster contains

- The active substances per dose are:

Diphtheria Toxoid, purified ¹	not less than 2 international units
Tetanus Toxoid, purified ¹	not less than 20 international units
Pertussis Toxoid, purified ¹	20 micrograms

¹ Adsorbed on Aluminium hydroxide, hydrated, corresponding to 0.5 mg aluminium. Aluminium is included in this vaccine as an adsorbant. Adsorbants are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine.

- The other excipients are:
Sodium chloride, sodium hydroxide and water for injections.

What TdaPBooster looks like and contents of the pack

TdaPBooster is a colourless liquid with white or grey particles after shaking.

TdaPBooster is supplied as a pre-filled syringe in pack sizes of 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.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the European Economic Area under the following names:

AT: dTaP Booster
BE: BoosterTdaP
DE: TdaP-IMMUN
DK, FI, NL, NO, SE: diTekiBooster
IE, IS: TdaPBooster
IT: Tribaccine
PL: Tdap Szczepionka

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