

New Zealand Consumer Medicine Information

Tdap-Booster™ (*tee-dee-ay-pee boo-ster*)

Tetanus, diphtheria and pertussis (acellular mono-component) vaccine (adsorbed, reduced antigen content)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about **Tdap-Booster™**.

It does not contain all the available information.

It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you or your child (of four years or older) having **Tdap-Booster™** against the benefits they expect it will have.

If you have any concerns about this vaccine, talk to your doctor, nurse or pharmacist.

Keep this leaflet.

You might need to read it again.

What Tdap-Booster™ is used for

Tdap-Booster™ is a “combination” vaccine. It helps prevent **three** diseases, each caused by a different infection. The diseases are

- diphtheria
- tetanus *and*
- pertussis (whooping cough).

These infections are serious and can be life-threatening.

Tdap-Booster™ is used to revaccinate children (≥ 4 years of age), adolescents and adults who have previously received at least three doses of a vaccine for primary immunisation against diphtheria, tetanus and whooping cough. **Tdap-Booster™** is not intended for primary immunisation against diphtheria, tetanus and whooping cough.

Tdap-Booster™ is given as one **additional** dose (**booster** dose) with intervals according to national recommendations.

How Tdap-Booster™ works

Tdap-Booster™ works by getting your body to produce its own protection against the three types of bacteria (germs). The germs are those that cause three different and serious infections

- diphtheria
- tetanus *and*
- pertussis (whooping cough).

The vaccine does not contain live germs and cannot give you these illnesses.

After you have **Tdap-Booster™**, your body makes substances called antibodies. These antibodies fight the diphtheria, the tetanus and pertussis germs. When you come into contact with these germs, your body is usually ready to destroy them.

Most people who receive the booster dose (suitable only if in the past they have had the full primary course against diphtheria, tetanus and pertussis) will produce enough antibodies to protect against the three diseases. However, as with all vaccines, 100% protection cannot be guaranteed.

Before you are given Tdap-Booster™

When you or your child must not be given Tdap-Booster™

Do not give Tdap-Booster™ to a child under 4 years of age.

Do not use Tdap-Booster™ if

- **you or your child are allergic to the active substances, or any of the other ingredients listed at the end of this leaflet, or to formaldehyde that may be present in very small amount**
- **you are suffering from progressive neurological diseases**
- **you are ill with high fever**
- **you have experienced problems of the nervous system (ie disease of the brain) within 7 days after previous vaccination with a vaccine against pertussis (whooping cough) disease**

Do not use Tdap-Booster™ after the expiry date printed on the pack.

Do not use Tdap-Booster™ if the packaging is torn or shows signs of tampering.

If you are not sure whether you or your child should have Tdap-Booster™, talk to your doctor, nurse or pharmacist.

Before you or your child are given Tdap-Booster™

Tell your doctor if:

- **your immune response is weakened or you received immunosuppressive medicine; you can still be vaccinated with **Tdap-Booster™** but your immune response may be lowered**
- **you are suffering from an illness or are receiving medical treatment that increases the risk of bleeding**
- **you are treated with medicines which prevent formation of blood clots**
- **you have experienced one or more of the following side effects after previous pertussis vaccination:**
 - **fever (temperature >40°C) within 48 hours of vaccination not due to any other identified cause**
 - **for children:**
 - **a child has had shock-like state or being unresponsive for a long period of time within 48 hours of vaccination**
 - **persistent crying lasting more than 3 hours or more within 48 hours of vaccination**
 - **convulsion with or without fever within 3 days of vaccination**

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay vaccination until the illness has passed. A mild illness, such as a cold, is not usually a reason to delay vaccination. Vaccination is recommended for persons suffering from HIV infection.

As for all vaccines, medical supervision and treatment should be available in case there is a severe allergic reaction.

Tell your doctor or nurse if you or the person to be immunised are breastfeeding, pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of having **Tdap-Booster™** during breastfeeding or pregnancy.

Taking other medicines

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tdap-Booster™ can be given at the same time as other vaccines without reducing the effect of **Tdap-Booster™** at different injection sites.

Having other vaccines

Tell your doctor if you have had any vaccines in the last 4 weeks.

Your doctor will advise you if **Tdap-Booster™** is to be given with another vaccine.

Your doctor and pharmacist may have more information on medicines and vaccines to be careful with or avoid during vaccination with **Tdap-Booster™**.

How Tdap-Booster™ is given

Tdap-Booster™ is given by a trained health professional, as an injection into the muscle.

How much is given and when

One dose of 0.5 mL is given.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

If you are given too much

(overdose)

Because each **Tdap-Booster™** contains only one dose, overdosage is unlikely.

If you think you or anyone else may have been given too much of this medicine

- consult your doctor immediately or
- telephone the Poisons Information Centre (telephone 0800 POISON (0800 764 766) in New Zealand) for advice, or
- go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. Urgent medical attention may be required.

After having Tdap-Booster™

Things you must do

Keep an updated record of your vaccinations or your child's vaccinations.

Tdap-Booster™ should not normally interfere with your ability to drive or operate machinery.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you or your child feel unwell after having Tdap-Booster™.

All medicines, including vaccines, can have side effects. **Tdap-Booster™** may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment if you get some of the side effects.

Ask your doctor, nurse or pharmacist to answer any questions you have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- reaction at the injection site such as temporary redness, pain, itching or swelling
- fever, general malaise, irritability
- pain in the muscles
- headache
- tiredness
- long lasting itching nodules (granuloma) or sterile abscess at the site of injection

Allergic reaction:

As with all vaccines given by injection, there is a very small risk of a severe allergic reaction.

If any of the following happen, consult your doctor, nurse or pharmacist immediately, or go to Accident and Emergency at your nearest hospital.

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body
- shortness of breath

These are very serious side effects. If you or your child has them, you may have had a severe allergic reaction to **Tdap-Booster™**. You or your child may need urgent medical attention or hospitalisation.

This type of side effect mostly occurs within the first few hours of being given the vaccine.

Other side effects not listed above might occur in some people. Tell your doctor, nurse or pharmacist if you notice anything that is making you or your child feel unwell.

Do not be alarmed by this list of possible side effects.

You or your child may not experience any of them.

Storing Tdap-Booster™

Tdap-Booster™ is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store **Tdap-Booster™**:

- **Keep it where children cannot reach it.**
- **Keep it in the original pack until it is time for it to be given.**
- **Keep it in the refrigerator, between 2°C and 8°C. Do not freeze Tdap-Booster™. Protect from light.**

Discard the vaccine if it has been frozen.

Product description

What TdaP-Booster™ looks like

TdaP-Booster™ is supplied as a single dose (0.5 mL) in a needle-less pre-filled glass syringe. The vaccine should appear as white and grey particles suspended in a colourless fluid.

Ingredients

Active ingredients:

- Diphtheria Toxoid, purified: ≥ 2 IU
- Tetanus Toxoid, purified: ≥ 20 IU
- Pertussis Toxoid, purified: 20 μ g

Other ingredients:

- Aluminium hydroxide
- Sodium chloride
- Sodium hydroxide
- Water for injection.

TdaP-Booster™ does NOT contain:

- lactose
- sucrose
- gluten
- tartrazine *or*
- any other azo dyes
- latex
- preservatives.

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.

Manufacturer/Distributor

Manufacturer

TdaP-Booster™ is made in Denmark by:

Statens Serum Institut
5 Artillerivej
2300 Copenhagen S
Denmark

Distributor

TdaP-Booster™ is distributed in New Zealand by:

bioCSL (NZ) Ltd
P O Box 62 590
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NEW ZEALAND
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Tdap-Booster™ is a trademark of Statens Serum Institut.