

ADT™ Booster

(ay-dee-tee boo-ster)

Diphtheria and Tetanus Vaccine, Adsorbed

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about **ADT™ Booster**.

It does not contain all the available information.

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

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you or your child (of five years or older) having **ADT™ 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 ADT™ Booster is used for

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

- diphtheria *and*
- tetanus.

Both of these infections are serious and can be life-threatening.

ADT™ Booster is used to vaccinate children (≥ 5 years of age) and adults who have previously received at least three doses of a vaccine for primary immunisation against diphtheria and tetanus.

ADT™ Booster is not intended for primary immunisation against diphtheria and tetanus.

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

How ADT™ Booster works

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

- diphtheria *and*
- tetanus.

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

After you have **ADT™ Booster**, your body makes substances called antibodies. These antibodies fight both the diphtheria and the tetanus 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 and tetanus) will produce enough antibodies to protect against both the diphtheria and tetanus diseases. However, as with all vaccines, 100% protection cannot be guaranteed.

Before you or your child are given ADT™ Booster

When you or your child must NOT be given ADT™ Booster

Do not give ADT™ Booster to a child under 5 years of age. **ADT™ Booster** is not suitable for children under 5 years of age.

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

Do not use ADT™ Booster if the packaging is torn, shows signs of tampering, or does not look quite right.

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

Before you or your child are given ADT™ Booster

Tell your doctor if you or your child have allergies to:

- **ADT™ Booster, Tetanus Vaccine, Diphtheria Vaccine** or any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes.

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

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

Your doctor will discuss the possible risks and benefits of having **ADT™ Booster** during pregnancy.

How ADT™ Booster is given

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

How much is given and when

For the **booster dose**, one dose of 0.5 mL is given.

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

If you are given too much (overdose)

Because each **ADT™ 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 13 11 26 in Australia or 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 ADT™ Booster

Things you must do

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

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child feel unwell after having ADT™ Booster.

All medicines, including vaccines, can have side effects. **ADT™ 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 or pharmacist to answer any questions you have.

Serious side effects:

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 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
- collapse.

These are very serious side effects. If you or your child have them, you may have had a severe allergic reaction to **ADT™ 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.

High Fever

A temperature of over 40°C can occur rarely.

Non-serious side effects:

Very common (may affect more than 1 in 10 people)

- reaction at the injection site such as temporary redness, pain, itching or swelling.
- headache and fatigue

Common (may affect up to 1 in 10 people)

- general malaise (feeling unwell) and fever (temperature of 38°C or more)
- pronounced redness and swelling of 5 cm or more at the site of injection
- muscle pain
- dizziness
- nausea, vomiting and diarrhoea

Uncommon (may affect up to 1 in 100 people)

- eczema and inflammation of the skin (dermatitis)

Rare (may affect up to 1 in 1,000 people)

- a small lump at the injection site; sometimes this may last for a few weeks
- hives (urticaria)

Very rare (may affect up to 1 in 10,000 people)

- fainting or feeling faint.

Other side effects not listed above might occur in some people. Tell your doctor 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 ADT™ Booster

ADT™ Booster is usually stored in the doctor's surgery or clinic, or at

the pharmacy. However, if you need to store **ADT™ Booster**:

- **Keep it where children cannot reach it.**
- **Keep it in the original pack until it is time for it to be injected.**
- **Keep it in the refrigerator, between 2°C and 8°C. DO NOT FREEZE ADT™ Booster.**

Freezing destroys the vaccine.

Product description

What ADT™ Booster looks like

ADT™ Booster is supplied as a single dose (0.5 mL) in a needleless pre-filled glass syringe or vial. The vaccine should appear as a suspension of white or grey particles in a colourless or light yellow liquid.

Ingredients

Active ingredients:

- Diphtheria Toxoid: at least 2 International Units (IU)
- Tetanus Toxoid: at least 20 IU.

Other ingredients:

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

ADT™ Booster does NOT contain:

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

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.

The manufacture of this product includes exposure to cattle derived materials. There is no evidence that variant Creutzfeldt-Jakob disease, a brain condition linked to the consumption of cattle with "mad cow disease" has resulted from the administration of any vaccine product.

Manufacturer/Distributor/Supplier

Manufacturer

ADT™ Booster is made in Denmark by:

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

Sponsor

ADT™ Booster is distributed in Australia by:

Seqirus Pty Ltd
ABN: 26 160 735 035
63 Poplar Road
Parkville VIC 3052
Australia
Telephone: 1800 642 865
www.seqirus.com.au

ADT™ Booster is distributed in New Zealand by:

Seqirus (NZ) Ltd
PO Box 62 590
Greenlane,
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