

ADT(TM) 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(TM) 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(TM) 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(TM) Booster is used for

ADT(TM) 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(TM) Booster is used to vaccinate children (older than or equal to 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(TM) Booster is not intended for primary immunisation against diphtheria and tetanus.

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

How ADT(TM) Booster works

ADT(TM) 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(TM) 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 are given ADT(TM) Booster

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

Do not give ADT(TM) Booster to a child under 5 years of age.

ADT(TM) Booster is not suitable for children under 5 years of age.

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

Do not use ADT(TM) 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(TM) Booster, talk to your doctor or pharmacist.

Before you or your child are given ADT(TM) Booster

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

- * ADT(TM) 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(TM) Booster during pregnancy.

How ADT(TM) Booster is given

ADT(TM) 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(TM) 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(TM) 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(TM) Booster.

All medicines, including vaccines, can have side effects. ADT(TM) 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.

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

- * reaction at the injection site such as temporary redness, tenderness or swelling
- * a small lump at the injection site; sometimes this may last for a few weeks.
- * fever, general malaise, eczema and inflammation of the skin

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(TM) 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 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(TM) Booster

ADT(TM) Booster is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store ADT(TM) 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 degrees C and 8 degrees C. DO NOT FREEZE ADT(TM) Booster.**
Freezing destroys the vaccine.

Product description

What ADT(TM) Booster looks like

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

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(TM) Booster does NOT contain:

- * lactose
- * sucrose
- * gluten
- * tartrazine or
- * any other azo dyes.
- * 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/Supplier

Manufacturer

ADT(TM) Booster is made in Denmark by:

Statens Serum Institut
5 Artillerivej
2300 Copenhagen S
Denmark

Distributor

ADT(TM) Booster is distributed in Australia by:

CSL Limited ABN 99 051 588 348
45 Poplar Road
Parkville
Victoria 3052
AUSTRALIA

ADT(TM) Booster is distributed in New Zealand by:

CSL (New Zealand) Limited
666 Great South Road
Penrose, Auckland
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ADT(TM) is a trademark of CSL Limited.