

Tet-Tox(TM)

Tetanus Vaccine, Adsorbed

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tet-Tox(TM).

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 having Tet-Tox(TM) 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 Tet-Tox(TM) is used for

Tet-Tox(TM) is a vaccine used to help prevent a disease called tetanus. Tetanus is a serious illness which can be life threatening.

How Tet-Tox(TM) works

Primary Course:

Tet-Tox(TM) is used to vaccinate people who have not been vaccinated against tetanus before. This is called 'the primary course'.

Tet-Tox(TM) is given to

- * children over 2 months of age and
- * adults.

A total of three (3) doses is needed for the primary course. The second and third doses are given after an appropriate time interval. (See 'How Tet-Tox(TM) is given' section, later in this leaflet.)

Booster Dose:

Tet-Tox(TM) is also given as an additional dose (booster dose) about every 10 years for people who have already had the full primary course of Tet-Tox(TM).

One (1) dose is needed for the booster dose.

How Tet-Tox(TM) works

Tet-Tox(TM) works by getting your body to produce its own protection against the bacteria (germs) that cause tetanus.

The vaccine does not contain live germs and cannot give you the illness.

After you have Tet-Tox(TM), your body makes substances called antibodies. These antibodies fight the tetanus germs. When you come into contact with the tetanus bacteria, your body is usually ready to destroy them.

NOTE: Your body takes a few weeks after vaccination to develop protection against the diphtheria and tetanus germs. You need to complete the full primary course of injections to get full protection.

Most people who receive either

- * all 3 doses, which completes the full primary course, or

- * the booster dose (suitable only if in the past they have had a full primary course against tetanus), will produce enough antibodies to protect against tetanus disease.

However, as with all vaccines, 100% protection cannot be guaranteed.

Before you are given Tet-Tox(TM)

When you or your child must NOT be given Tet-Tox(TM)

Do not have Tet-Tox(TM) if you or your child currently have:

- * an acute illness, unless you or your child have an injury that might be infected with tetanus germs.

Your doctor will advise you and decide whether or not to give you or your child the vaccine.

Do not have Tet-Tox(TM) if you or your child have had any of the following after a previous dose of Tet-Tox(TM):

- * an allergic reaction
- * a disorder of the nervous system.

Do not give Tet-Tox(TM) to a child under 2 months of age.

The safety and effectiveness of Tet-Tox(TM) in children under 2 months have not been established.

Do not use Tet-Tox(TM) after the expiry date printed on the pack.

Do not use Tet-Tox(TM) 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 Tet-Tox(TM), talk to your doctor or pharmacist.

Before you or your child are given Tet-Tox(TM)

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

- * Tet-Tox(TM) or any of the ingredients listed at the end of this leaflet
- * any other medicines
- * any other substances, such as food, 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 your child have any medical conditions, especially the following:

- * low immunity due to ill-health, for example some blood disorders
- * low immunity due to treatment with medicines such as corticosteroids, antimetabolites, alkylating agents, cytotoxic drugs, or other cancer treatment (including radiation therapy)
- * any other illness.

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 Tet-Tox(TM) during pregnancy.

Having other medicines

Tell your doctor if you or your child are taking any other medicines.

Some medicines such as chloramphenicol, an antibiotic medicine, may interfere with how well Tet-Tox(TM) works.

Your doctor will advise you and decide whether or not to give you or your child the vaccine.

How Tet-Tox(TM) is given

Tet-Tox(TM) is given by a trained health professional, as an injection into muscle.

How much is given and when

One injection of Tet-Tox(TM) is 0.5 mL.

Primary Course

This is a total of 3 doses, given at intervals of 6 to 12 weeks between the first and second doses, and 6 to 12 months between the second and third doses

Booster Dose

For the booster dose, 1 dose is given every ten (10) years.

If it has been more than 20 years since a tetanus vaccine injection, then 2 doses of Tet-Tox(TM), given 4 to 6 weeks apart, will be needed.

If you or your child have an injury that might be infected with tetanus germs, 1 dose of Tet-Tox(TM) might sometimes be given.

Your doctor can advise you of what injections are needed.

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

If you miss a dose

If you or your child miss a dose of Tet-Tox(TM), talk to your doctor and arrange another visit as soon as possible.

After having Tet-Tox(TM)

Things you must do

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

Keep follow-up appointments with your doctor or clinic.

In order to make sure the vaccine has the best chance of providing protection against diphtheria and tetanus disease, it is important that:

- * you or your child have all three doses of the primary course of Tet-Tox(TM) at the appropriate time intervals
- * the booster dose is given at the appropriate time(s) after a full primary course.

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child feel unwell after having Tet-Tox(TM)

All medicines, including vaccines, can have side effects. Tet-Tox(TM) 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.

Allergic reaction:

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

Mostly allergic reactions occur within the first few hours of being given the vaccine.

If any of the following happen, tell your doctor 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
- * headache and high temperature associated with hallucination, confusion, paralysis of part or all of the body and disturbances of behaviour, speech and eye movements.

These are very serious side effects. If you or your child have them, you might have had a severe reaction to Tet-Tox(TM). You or your child need urgent medical attention or hospitalisation.

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 Tet-Tox(TM)

Tet-Tox(TM) is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Tet-Tox(TM).

- * **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 Tet-Tox(TM).**
Freezing destroys the vaccine.

Product description

What Tet-Tox(TM) looks like

Tet-Tox(TM) is supplied as a single dose (0.5 mL) in a glass container. It is a whitish, cloudy liquid.

Ingredients

Active ingredients:

- * Tetanus Toxoid: at least 40 IU.

Other ingredients:

- * Aluminium phosphate
- * Sodium chloride
- * Sodium phosphate - monobasic
- * Sodium phosphate - dibasic dodecahydrate
- * Thiomersal (preservative)
- * Water for injection.

Tet-Tox(TM) does NOT contain:

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

Manufacturer/Distributor/Supplier

Tet-Tox(TM) is made in Australia by:

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

Distributor

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

Tet-Tox(TM) is distributed in New Zealand by:

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