

Biological Therapies Thiamine Hydrochloride 100 mg in 1 mL Injection

for Intravenous or Intramuscular Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Biological Therapies Thiamine Hydrochloride Injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of giving you Thiamine Hydrochloride Injection against the benefits they expect it will have for you.

If you have any concerns about having this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Biological Therapies Thiamine Hydrochloride Injection is used for

Thiamine is used for the prevention and treatment of vitamin B1 deficiency.

Thiamine hydrochloride is a form of Vitamin B1.

This medicine works by increasing the amount of thiamine in your body.

Vitamin B1 deficiencies:

Thiamine deficiencies may occur as

a result of a diet deficient in B vitamins, malnutrition, or changes to the gastrointestinal tract which slow or prevent the absorption of B vitamins (e.g. abdominal surgery or some diseases of the gastrointestinal tract).

A specific deficiency of vitamin B1 (thiamine) may cause the disease beriberi and cause the condition Wernicke's encephalopathy.

Extra vitamin B1 may be needed during pregnancy, with increased carbohydrate intake, increased physical activity, infection and with some diseases relating to the liver.

Your doctor may prescribe this medicine to treat vitamin B1 deficiency, to supplement vitamin B1 missing in your diet or to raise the level of Thiamine in your body.

Your doctor may decide that Thiamine Hydrochloride Injection is the best way for you to take Vitamin B1.

Malnutrition resulting from alcoholism:

Alcoholism can lead to a diet deficient in B vitamins. The normal metabolism of alcohol in your liver also requires B vitamins, especially thiamine.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is not addictive.

This medicine is only available from a medical practitioner or from a pharmacy with a prescription from a medical practitioner.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you are given Biological Therapies Thiamine Hydrochloride Injection

When you must not be given it:

You must not be given this medicine if you have an allergy to:

- **any medicine containing thiamine**
- **any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include:

- Coughing or shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash; itching or hives on the skin

You must not be given this medicine if you are taking high dose B vitamins

This medicine should not be given to you if you have high levels of B

vitamins in your body from other sources, such as high dose vitamin supplements.

This medicine must not be given to a child under 2 years.

This medicine should not be given to Children under the age of 2 years because it contains benzyl alcohol which may be harmful.

You must not be given this medicine if the solution in the vial is not clear or contains particles.

You must not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are given this medicine after the expiry date has passed, it may not work and it may be harmful to you.

If it is expired or damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given this medicine:

Tell your doctor or pharmacist if you have had an allergy to any of the ingredients listed at the end of this leaflet

Your doctor may test if you have an allergy to this medicine by injecting a small amount under your skin

Tell your doctor if you have any of the following medical conditions:

- Memory problems

Tell your doctor if you have allergies to any other medicines or any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or plan to become pregnant.

There is an increased need for some B vitamins during pregnancy. It is recommended that you and your doctor discuss your requirements during pregnancy and the possible risks and benefits of having this medicine during pregnancy.

Tell your doctor if you are breastfeeding or are intending to breastfeed.

There is an increased need for some B vitamins during breastfeeding. It is recommended that you and your doctor discuss your requirements during breastfeeding and the possible risks and benefits of having this medicine during breastfeeding.

If you have not told your doctor about any of the above, tell them before you are given Thiamine Hydrochloride Injection.

Taking Other Medicines:

Tell your doctor 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.

Some medicines and Thiamine Hydrochloride Injection may interfere with each other. These include:

- Vitamin and Mineral Supplements
- Medicines used to relax muscles
- Some antibiotic drugs such as kanamycin sulfate and streptomycin sulfate

These medicines may be affected by Thiamine Hydrochloride Injection, or affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information about medicines to be careful with, or avoid while you are being treated with this medicine.

How Biological Therapies Thiamine Hydrochloride Injection is given

Thiamine Hydrochloride Injection is given as an injection, usually into a large muscle, or it may be given

by infusion (slow injection) into a vein in your arm.

This medicine must only be given by a doctor or nurse.

How much is given:

Your doctor will decide how much Thiamine Hydrochloride Injection will need to be given and for how long it will need to be given. This is determined by many factors including your body weight and your medical condition. The usual dose of thiamine hydrochloride is 5mg to 100 mg under normal circumstances or much higher amounts in critically ill patients.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

How long to be treated with it:

Each person will respond differently to Thiamine Hydrochloride Injection.

Treatment times will differ depending on the reason for prescribing this medicine.

Your doctor will tell you how long you will need to be treated with this medicine.

If you miss an appointment:

If you miss an appointment, talk to your doctor and arrange another appointment as soon as possible.

If you are not sure what to do, contact your doctor or pharmacist as soon as possible.

If too much is given (overdose):

Your doctor or nurse should be the only person to inject Thiamine Hydrochloride Injection, so an overdose is not likely to occur.

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital if you think

that you or anyone else may have been given too much Thiamine Hydrochloride Injection. **Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

While you are being given Biological Therapies Thiamine Hydrochloride Injection

Things you must do:

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with Thiamine Hydrochloride Injection.

Tell any other doctors, dentists and pharmacists who treat you that you are being given this medicine.

If you are going to have surgery, tell the surgeon and anaesthetist that you are being treated with this medicine.

It may affect other medicines used during surgery.

If you are about to have any urine or blood tests tell your doctor that you are being treated with this medicine.

It may interfere with the results of some tests.

If you become pregnant while being treated with Thiamine Hydrochloride Injection, tell your doctor immediately.

Tell your doctor if you feel that giving Thiamine Hydrochloride Injection is not helping your condition.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do:

Do not attempt to inject this medicine yourself.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting a pharmacist.

Do not give your medicine to anyone else, even if they have the same condition as you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given or treated with Thiamine Hydrochloride Injection.

This medicine helps most people with Vitamin B1 deficiency conditions, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

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

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

- Tenderness or a hard lump around the injection site

The above list includes the more common side effects of this medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- Allergic reaction such as nausea, sweating, a feeling of warmth, tingling, weakness, tightness of the throat, pain in the chest, fast heart beat, difficulty breathing, faintness

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately, or go to Accident and Emergency Department at your nearest hospital:

- severe allergic reaction which may include sudden signs of allergy such as rash, itching or hives on the skin, or swelling of the face, lips, tongue, throat or other parts of the body.
- sneezing
- severe rash
- temporary itchiness
- blue discolouration of the skin
- bleeding
- prolonged stomach pain
- severe dizziness or drowsiness
- muscular paralysis
- low blood pressure
- prolonged nausea or vomiting
- Restlessness
- Scaling of the facial skin
- Inability to focus eyes

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

These side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell, even if it is not on this list.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

You should not experience any of them.

After being given Biological Therapies Thiamine Hydrochloride Injection

Storage

Thiamine Hydrochloride Injection is usually stored in the doctor's surgery or clinic, or at the pharmacy.

If you need to store Thiamine Hydrochloride Injection keep it in the original pack until it is time for it to be given.

If you take the vials out of the pack they may not keep well.

Keep this medicine in a cool dry place, where the temperature stays below 25°C.

Do not store Thiamine Hydrochloride Injection or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

This product is for SINGLE USE in one patient on one occasion only. It will be used once only and then it will be discarded. It must never be stored after it is opened or used for more than one person.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any vials that are left over.

Product Description

What it looks like:

Biological Therapies Thiamine Hydrochloride 100 mg in 1 mL Injection is a clear and colourless solution contained in an amber glass

vial sealed with a rubber stopper and aluminium seal with polypropylene flip-off insert. It is packed in an outer carton.

This medicine may be available in 4 pack sizes:

- 1 x 1 mL vials
- 5 x 1 mL vials.
- 6 x 1 mL vials.
- 10 x 1 mL vials.

Ingredients per vial:

Biological Therapies Thiamine Hydrochloride 100 mg in 1 mL Injection contains the following ingredients:

Active Ingredient:

Thiamine Hydrochloride 100mg

It also contains:

- Benzyl alcohol
- Disodium edetate
- Water for injections

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Biological Therapies Thiamine Hydrochloride 100 mg in 1 mL Injection is supplied and manufactured in Australia by:

Biological Therapies

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