

# Biological Therapies

## Thiamine Hydrochloride 100 mg in 1 mL Injection

### Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

#### 1. Why am I being given this medicine?

This medicine contains the active ingredient thiamine hydrochloride. It is used for the prevention and treatment of vitamin B1 deficiency. For more information, see Section [1. Why am I being given this medicine?](#) in the full CMI.

#### 2. What should I know before I am given this medicine?

Do not use if you have ever had an allergic reaction to this medicine or any of the ingredients listed at the end of the CMI. This medicine must not be given to a child under 2 years.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given this medicine?](#) in the full CMI.

#### 3. What if I am taking other medicines?

Some medicines may interfere with Thiamine Hydrochloride 100 mg in 1 mL Injection and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

#### 4. How is this medicine given to me?

This medicine is given as an injection into a vein or a muscle. This medicine must only be given by a doctor or nurse. The usual dose is 5 mg to 100 mg under normal circumstances or much higher amounts in critically ill patients. More instructions can be found in Section [4. How is this medicine given to me?](#) in the full CMI.

#### 5. What should I know while being given this medicine?

<b>Things you must do</b>	<ul style="list-style-type: none"><li>• Remind or tell any doctor, surgeon, anaesthetist, dentist or pharmacist you visit that you are being treated with Thiamine Hydrochloride Injection.</li><li>• Tell your doctor if you feel that giving this medicine is not helping your condition.</li><li>• Keep all of your doctor's appointments so that your progress can be checked.</li></ul>
<b>Things you must not do</b>	<ul style="list-style-type: none"><li>• Do not attempt to inject this medicine yourself.</li><li>• Do not take any other medicines without first telling your doctor or consulting a pharmacist.</li><li>• Do not give this medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Alcoholism can lead to a diet deficient in B vitamins. The normal metabolism of alcohol in your liver also requires B vitamins, especially thiamine.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• This medicine is usually stored in the doctor's surgery or clinic, or at the pharmacy, in a cool dry place, where the temperature stays below 25°C and children cannot reach it. Each vial is for SINGLE USE in one patient on one occasion only.</li></ul>

For more information, see Section [5. What should I know while being given this medicine?](#) in the full CMI.

#### 6. Are there any side effects?

The more common side effects of this medicine are tenderness or a hard lump around the injection site. Serious side effects comprise of allergic reactions. Very serious side effects include severe allergic reactions, 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 and inability to focus eyes. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Biological Therapies

## Thiamine Hydrochloride 100 mg in 1 mL Injection

Active ingredient(s): *Thiamine hydrochloride*

### Consumer Medicine Information (CMI)

This leaflet provides important information about using Thiamine Hydrochloride 100 mg in 1 mL Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Thiamine Hydrochloride 100 mg in 1 mL Injection.**

Where to find information in this leaflet:

- [1. Why am I being given this medicine?](#)
- [2. What should I know before I am given this medicine?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is this medicine given to me?](#)
- [5. What should I know while being given this medicine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I being given this medicine?

Thiamine Hydrochloride 100 mg in 1 mL Injection contains the active ingredient thiamine hydrochloride. Thiamine Hydrochloride 100 mg in 1 mL Injection is a form of vitamin B1.

Thiamine Hydrochloride 100 mg in 1 mL Injection is used for the prevention and treatment of vitamin B1 deficiency.

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 gastro-intestinal 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 100 mg in 1 mL 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.

### 2. What should I know before I am given this medicine?

#### **Warnings**

You must not be given this medicine if:

- You are allergic to thiamine hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction 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.**

#### **Check with your doctor if you:**

- Have any other medical conditions
- Take any medicines for any other condition
- **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.
- **Have any memory problems**
- **Have allergies to any other medicines or any other substances, such as foods, preservatives or dyes**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### **Pregnancy and breastfeeding**

##### **Check with your doctor if you are pregnant or intend 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.

##### **Talk to your doctor if you are breastfeeding or intend 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.**

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or

supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

#### **Some medicines may interfere with Thiamine Hydrochloride 100 mg in 1 mL Injection and affect how it works.**

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 100 mg in 1 mL 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.

#### **Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Thiamine Hydrochloride 100 mg in 1 mL Injection.**

### **4. How is this medicine given to me?**

Thiamine Hydrochloride 100 mg in 1 mL 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 100 mg in 1 mL 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 5 mg 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 is the treatment time with this medicine**

Each person will respond differently to Thiamine Hydrochloride 100 mg in 1 mL Injection.

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

Your doctor will let you know 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 of this medicine is given

Your doctor or nurse should be the only person to inject Thiamine Hydrochloride 100 mg in 1 mL Injection, so an overdose is unlikely to occur.

If you think that you or anyone else may have been given too much Thiamine Hydrochloride 100 mg in 1 mL Injection you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while being given this medicine?

### Things you must do

- **If you 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.

- **Remind any other doctor, dentist or pharmacist you visit that you are being given Thiamine Hydrochloride 100 mg in 1 mL Injection.**

### 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.**

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Thiamine Hydrochloride 100 mg in 1 mL Injection affects you.**

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

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

### Looking after your medicine

Thiamine Hydrochloride 100 mg in 1 mL Injection is usually stored in the doctor's surgery or clinic, or at the pharmacy.

**If you need to store Thiamine Hydrochloride 100 mg in 1 mL 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.

Store it in a cool dry place, where the temperature stays below 25°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.** A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

### When to discard your medicine

**Each vial 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.**

## Getting rid of any unwanted medicine

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.

Do not use this medicine after the expiry date.

## 6. Are there any 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.** You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>Tenderness or a hard lump around the injection site</li></ul>	<b>Speak to your doctor, nurse or pharmacist if you have any of these less serious side effects and they worry you.</b>

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

### Serious side effects

Serious side effects	What to do
Allergic reactions such as nausea, sweating, a feeling of warmth, tingling, weakness, tightness of the throat, pain in the chest, fast heart beat, difficulty breathing, faintness	<b>Speak to your doctor if you have any of these serious side effects.</b>

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

Very serious side effects	What to do
<ul style="list-style-type: none"><li>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</li><li>Sneezing</li><li>Severe rash</li><li>Temporary itchiness</li><li>Blue discolouration of the skin</li><li>Bleeding</li><li>Prolonged stomach pain</li><li>Severe dizziness or drowsiness</li><li>Muscular Paralysis</li><li>Low blood pressure</li><li>Prolonged nausea or vomiting</li><li>Restlessness</li><li>Scaling of the Facial skin</li><li>Inability to focus</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

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

These side effects are rare.

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell, even if 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.**

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.



### What Thiamine Hydrochloride 100 mg in 1 mL Injection contains

<b>Active ingredient (main ingredient)</b>	Thiamine hydrochloride
<b>Other ingredients (inactive ingredients)</b>	Benzyl alcohol Disodium edetate Water for injections

**Do not take this medicine if you are allergic to any of these ingredients.**

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

Vial stopper is not made with natural rubber latex.

### What Thiamine Hydrochloride 100 mg in 1 mL Injection looks like

Thiamine Hydrochloride 100 mg in 1 mL Injection is a clear and colourless solution contained in an amber glass vial sealed with a grey chlorobutyl rubber stopper and aluminium seal with red polypropylene flip-off insert. It is packed in an outer carton.

Australian Registration Number: AUST R 218622

This medicine may be available in 4 pack sizes:

1 x 1 mL vial

5 x 1 mL vials

6 x 1 mL vials

10 x 1 mL vials

### Who distributes Thiamine Hydrochloride 100 mg in 1 mL Injection

#### Biological Therapies

A Division of Orthomolecular Medisearch

Laboratories Pty Ltd

5 / 20 – 30 Malcolm Road, Braeside VIC 3195

Australia

Tel: + 61 3 9587 3948

Fax: +61 3 9587 1720

Website: [www.biologicaltherapies.com.au](http://www.biologicaltherapies.com.au)

Email: [biol@biol.com.au](mailto:biol@biol.com.au)

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