

## **Package leaflet: Information for the user**

### **Thiamine hydrochloride 50 mg/ml solution for injection Thiamine hydrochloride 125 mg/ml solution for injection**

Thiamine hydrochloride

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Thiamine hydrochloride solution for injection is and what it is used for
2. What you need to know before you use Thiamine hydrochloride solution for injection
3. How to use Thiamine hydrochloride solution for injection
4. Possible side effects
5. How to store Thiamine hydrochloride solution for injection
6. Contents of the pack and other information

#### **1. WHAT THIAMINE HYDROCHLORIDE SOLUTION FOR INJECTION IS AND WHAT IT IS USED FOR**

Thiamine hydrochloride solution for injection contains the active substance thiamine (vitamin B1) as thiamine hydrochloride. This is a water-soluble vitamin that belongs to a group of medicines called “vitamins B”.

Sometimes your body requires a supplement of vitamin B1. This is because your diet doesn't contain enough thiamine or you may not absorb it effectively from your diet. You may also have a special need for extra thiamine if you are excreting it quickly from your body (e.g. in your urine).

Thiamine hydrochloride solution for injection is used to treat or prevent vitamin B1 deficiencies (when your body does not have enough of this vitamin) like beriberi disease, in case of chronic alcoholism and Wernicke-Korsakoff syndrome.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE THIAMINE HYDROCHLORIDE SOLUTION FOR INJECTION**

##### **Do not use Thiamine hydrochloride solution for injection**

If you are allergic to thiamine or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Thiamine hydrochloride solution for injection.

- The solution should be injected only when thiamine is rapidly necessary (e.g. Wernicke-Korsakoff syndrome) or when the oral route is ineffective (e.g. in case of vomiting or malabsorption).
- The 50 mg/ml solution will be less painful when administered by IM route as it is much less hypertonic than the 125 mg/ml solution. Prefer the IV administration (after dilution) for the 125 mg/ml solution, especially for long-term treatment.
- Be careful if you have ever had a mild allergic reaction (sneezing or mild asthma) to any previous

administrations of thiamine. This could mean that you may have become hypersensitive, and could have a more severe allergic reaction if given Thiamine hydrochloride solution for injection. This risk increases in case of repeated doses. Your doctor must be ensured before administration of the solution that you are not allergic to thiamine. A skin test should be performed in case of doubt. Emergency medical equipment should be present for treating an eventual anaphylactic shock when injecting the solution.

- The solution should be injected SLOWLY by the intravenous route (over 30 minutes). This can reduce the risk of anaphylactic shock and reactions at the injection site.
- The solution should be injected into a vein before or simultaneously to an administration of glucose.
- If you have problems with your kidneys, your doctor will carefully monitor you.

If you use other drugs, read also the following section “Other medicines and Thiamine hydrochloride solution for injection”.

### **Having blood tests or other medical tests**

High concentrations of thiamine in the blood can affect certain medical tests. If you are having a blood test, scan or any other medical test (e.g. urinary test) tell your doctor that you are using Thiamine hydrochloride solution for injection.

### **Other medicines and Thiamine hydrochloride solution for injection**

Tell your doctor if you are using, have recently used or might use any other medicines. This includes medicines obtained without a prescription and herbal products.

Tell your doctor if you are using the following medicines because he/she may need to adjust your treatment:

- Fluorouracil, other fluoropyrimidines (e.g. capecitabine) and ifosfamide, medicines used to treat certain cancers.
- Diuretics (e.g. furosemide), medicines used for the treatment of high blood pressure (hypertension) and the excess of watery fluid collecting in the cavities and tissues of the body (oedema).

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

This medicine can be used during pregnancy and breast-feeding if necessary when benefit outweighs risk.

Your doctor will decide whether you should discontinue breastfeeding or discontinue/abstain from thiamine therapy, taking into account the benefit of breastfeeding for your child or the benefit of the treatment for you.

### **Driving and using machines**

Thiamine hydrochloride solution for injection is not expected to affect your ability to drive or operate machinery.

If you feel you may be affected, do not drive or use machines and speak to your doctor.

### **Thiamine hydrochloride solution for injection contains sodium**

This medicine contains less than 1 mmol of sodium (23 mg) per 2 ml ampoule, that is to say essentially “sodium-free”.

## **3. HOW TO USE THIAMINE HYDROCHLORIDE SOLUTION FOR INJECTION**

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The dosage, frequency of administration and duration of the treatment will be established by your doctor.

Thiamine hydrochloride solution for injection will be given to you by a healthcare professional by injection into a muscle (intramuscular route) or slowly into a vein (slow intravenous route) as directed by your doctor.

The dosage will be determined by your doctor.

For further instructions for use, see information intended for healthcare professionals at the end of the leaflet.

#### **If you use more Thiamine hydrochloride solution for injection than you should**

This product will be given to you under medical supervision. It is therefore unlikely that you will be given too much.

Nevertheless, if you used more Thiamine hydrochloride solution for injection than you should, contact your doctor, your pharmacist, the Poison Centre or the nearest hospital emergency department immediately.

#### **If you forget to use Thiamine hydrochloride solution for injection**

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, then skip the missed dose and resume your usual dosing schedule. Missing a dose shouldn't constitute a risk for your health. Do not use a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor if you have any of the following side effects:

Side effects with unknown frequency (frequency cannot be estimated from the available data):

- Allergic reactions such as breathing problems, itching (pruritus), shock and abdominal pain. Those reactions were frequently preceded by sneeze or transitory pruritus. If you experience these symptoms after your injection **tell your doctor immediately**. This may be an indication that you are sensitive to Thiamine hydrochloride solution for injection and should not be given a repeated dose.
- Pain at the injection site. A slow administration in larger veins can avoid burning sensations in the arm.
- Skin inflammation at the injection site (contact dermatitis). This can appear after injection to sensitized patients.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard), or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. HOW TO STORE THIAMINE HYDROCHLORIDE SOLUTION FOR INJECTION**

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Do not freeze.

Keep the ampoules in the outer carton in order to protect from light.

For single use only. Discard any unused product at the end of each operating session.

The solution must be used immediately after the ampoule opening.

The product can be diluted in the following infusion fluids:

- Glucose 50 mg/ml (5%).
- Sodium chloride 9 mg/ml (0.9%).

Chemical and physical in-use stability has been demonstrated for up to 8 hours at a temperature between 15 and 25°C without protection from light when the product is diluted in 50 ml and 250 ml of sodium chloride 0.9% and glucose 5%.

From a microbiological point of view, unless the method of opening/dilution precludes the risks of microbial contamination, the diluted product in an infusion fluid should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

This medicinal product must not be mixed with other medicinal products except those mentioned here above.

Do not use this medicine after the expiry date which is stated on the carton after EXP.

Do not use this medicine if you notice visible particles in the solution, if the solution is not clear or if it contains a precipitate.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Thiamine hydrochloride solution for injection contains**

- The active substance is thiamine hydrochloride (vitamin B1). Each 2 ml ampoule contains 100 mg or 250 mg thiamine hydrochloride. Each ml solution contains 50 mg or 125 mg thiamine hydrochloride.
- The other ingredients are sodium hydroxide and water for injections.

### **What Thiamine hydrochloride solution for injection looks like and contents of the pack**

Thiamine hydrochloride solution for injection is a solution for injection.

This is an aqueous, clear, colourless to slightly yellow sterile solution, free of visible particles.

Thiamine hydrochloride solution for injection is available in 2ml uncoloured glass ampoules, packaged into boxes containing 5, 10 or 100 ampoules. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Brancaster Pharma Limited  
Church House  
48 Church Street  
Reigate, Surrey  
RH2 0SN, United Kingdom

### **Manufacturer**

LABORATOIRES STEROP NV  
Scheutlaan 46-50  
1070 Brussels  
Belgium

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The following information is intended for healthcare professionals only:

## Posology

### Adults

- Beriberi:
  - Treatment: 10 mg – 20 mg by intramuscular injection or slow intravenous infusion (over 30 minutes) 3 times/day for up to 2 weeks.  
If severe life threatening form of beriberi (e.g. *shoshin* beriberi): 100 mg to 300 mg/day by slow intravenous infusion.
  - Maintenance treatment: the treatment should be continued with an adapted oral form of vitamin B1.
- Wernicke-Korsakoff syndrome associated with alcohol use disorder:
  - Prophylaxis in patients with high risk (e.g. hospitalized patients managed for alcohol withdrawal in presence of malnutrition): 250 mg by intramuscular or intravenous route 1 time/day for 3 to 5 days.
  - Treatment: 500 mg to 750 mg by intravenous route 3 times/day for at least 2 days (up to 1000 mg/dose during the first 12 hours may be used). In case of favorable response the treatment can be continued with 250 mg by intramuscular or intravenous route 1 time/day for 5 days or until there is no further improvement.
  - Maintenance treatment: the treatment should be continued with an adapted oral form of vitamin B1.

Patients with marginal thiamine status to whom glucose is being administered should receive 100 mg thiamine hydrochloride in each of the first few litres of IV fluid to avoid precipitating heart failure (see section 4.4).

### Paediatric population

There is only limited experience with therapy in children and adolescents.

#### Beriberi:

- Treatment: 10 mg to 25 mg/day by intramuscular injection or slow intravenous infusion for 2 weeks.  
IV doses of 100 mg/day or even higher may be needed in severe cases, for example 500 mg three times a day could be used.
- Maintenance treatment: the treatment should be continued with an adapted oral form of vitamin B1.

### Elderly

There are no data available in the elderly. No dose adjustment is recommended for this population. Interactions with other medicines should be considered (see sections 4.5 and 5.2).

### Renal impairment

The influence of renal impairment on the pharmacokinetics of thiamine has not been evaluated. No dose adjustment is recommended, but caution is advised when treating patients with renal impairment (see sections 4.4 and 5.2).

### Hepatic impairment

The influence of hepatic impairment on the pharmacokinetics of thiamine has not been evaluated. No dose adjustment is recommended, but caution is advised when treating patients with hepatic impairment (see section 5.2).

### Method of administration

Thiamine hydrochloride solution for injection should be administered by slow intravenous or intramuscular route.

**The injection is administered slowly over 30 minutes.**

For intramuscular administration, use the undiluted drug solution. Deep intramuscular injection must be given into a big muscular mass (upper outer quadrant of the buttock or the lateral part of the thigh). Before injection of the dose, suck up to be sure that the needle is not into a vein. If blood appears, take the needle out and inject into another site. Change the injection site in case of repeated doses.

The solution is to be visually inspected prior to use (also after dilution). Only clear solutions free from visible particles should be used.

#### Dilution for infusion

Thiamine hydrochloride solution for injection can be administered by slow intravenous injection after dilution in 50 ml to 250 ml of a 50 mg/ml glucose (5%) or a 9 mg/ml sodium chloride (0.9%) sterile solution for up to 8 hours without protection from light.

The solution after dilution remains clear, colourless to slightly yellow and free of visible particles.

From a microbiological point of view, unless the method of opening/dilution precludes the risks of microbial contamination, the diluted product in an infusion fluid should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.