

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

### **Thiamine Hydrochloride 50 mg/ml solution for injection**

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

#### **1. What Thiamine Hydrochloride is and what it is used for**

The active substance in Thiamine Hydrochloride is Vitamin B<sub>1</sub> in the form of thiamine hydrochloride. Thiamine Hydrochloride is used to treat conditions where there is a deficiency of Vitamin B<sub>1</sub> e.g., malabsorption, anorexia, or alcohol addiction.

#### **2. What you need to know before you use Thiamine Hydrochloride**

##### **Do not use Thiamine Hydrochloride:**

- if you are allergic to thiamine hydrochloride 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. Especially if you have ever had a mild allergic reaction to any previous injections of vitamin B<sub>1</sub> (thiamine). This could mean that you may have become hypersensitive and could have a more severe allergic reaction if given Thiamine Hydrochloride.

##### **Other medicines and Thiamine Hydrochloride**

Tell your doctor if you are using, have recently used or might use any other medicines.

Remember to tell your doctor if you use any of the following medicines:

- Medicines containing furosemide (diuretics), since furosemide may lower your thiamine levels.
- Medicines containing thiamine antagonists such as thiosemicarbazones, fluoropyrimidines, and ifosfamide, since they may neutralise the effect of thiamine.

##### **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 for advice before taking this medicine.

##### **Driving and using machines**

Thiamine Hydrochloride is not expected to affect your ability to drive or operate machinery.

### **3. How to use Thiamine Hydrochloride**

The exact dose you will be given will be decided by your doctor who will monitor your condition and determine what treatment you need. If you feel that you have been given an inappropriate dose or if you would like more information about Thiamine Hydrochloride, speak to your doctor.

#### **If you use more Thiamine Hydrochloride than you should**

This product will be given to you under medical supervision. It is therefore unlikely that you will be given too much. However, if you feel unwell, you should tell your doctor immediately.

#### **If you stop using Thiamine Hydrochloride**

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

### **4. Possible side effects**

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

Not known: frequency cannot be estimated from the available data: local irritation at injection site, skin rash, itching, heavy blood pressure decrease, breathlessness.

#### **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**

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

Store in original package in order to protect from light.

Do not store above 25 °C. Do not freeze. Use immediately after dilution.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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 contains**

- The active substance is thiamine hydrochloride
- The other ingredients are water for injections, disodium phosphate dodecahydrate, thiomalic acid, sodium hydroxide (for pH adjustment)

#### **What Thiamine Hydrochloride looks like and contents of the pack**

Colourless glass ampoules (type I): 6 x 5 ml, 10 x 5 ml Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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