Package leaflet: Information for the patient

Bevione 50 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 [Invented name] is and what it is used for

[Invented name] 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 could be 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).

[Invented name] is used to treat or prevent vitamin B1 deficiencies (when your body does not have enough of this vitamin) like beriberi disease and Wernicke-Korsakoff syndrome.

2. What you need to know before you use [Invented name]

Do not use [Invented name]
- 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 [Invented name].
- 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).
- Your doctor will decide how to give you [Invented name]
- 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 [Invented name]. 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.

- If the solution is given by the intravenous route, it 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 [Invented name]".

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 [Invented name].

Other medicines and [Invented name]
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 (oedeme).

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
[Invented name] 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.

[Invented name] 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 [Invented name]

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.

[Invented name] 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.

If you use more [Invented name] than you should
This product will be given to you under medical supervision. It is therefore unlikely that you will be given too much. If you think you have received too much [Invented name], contact your doctor, your pharmacist or nurse.

If you forget to use [Invented name]
This product will be given to you under medical supervision. It is therefore unlikely that you will miss a dose. 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 [Invented name] 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 national reporting system listed in Appendix V.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

Keep this medicine out of the sight and reach of children. Do not store above 30°C.

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 [Invented name] contains
The active substance is thiamine hydrochloride (vitamin B1) 50 mg/ml. Each 2 ml ampoule contains 100 mg thiamine hydrochloride. The other ingredients are sodium hydroxide and water for injections.

What [Invented name] looks like and contents of the pack
[Invented name] is a solution for injection.
Aqueous, clear, colourless or almost colourless sterile solution, free of visible particles.

[Invented name] is available in 2 ml clear glass ampoules, packaged into boxes containing 5, 10 or 100 ampoules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in 2024-10-01

Other sources of information
Detailed information on this medicine is available on the web site of {MA/Agency}

The following information is intended for healthcare professionals only:

Exact dose, duration of therapy and method of administration will depend on the patient´s clinical status and response to treatment. [Invented name] is administered via intramuscular or slow intravenous injection, preferably in divided doses, until the symptoms resolve or plateau.

For elaborated posology recommendation, please consult Summary of Product Characteristics section 4.2

THE INTRAVENIOUS INJECTION IS ADMINISTRATED SLOWLY OVER 30 MINUTES.

For intramuscular administration, use the undiluted drug solution.

The solution is to be visually inspected prior to use (also after dilution). Only clear solutions free from visible particles should be used. For single use only. Discard any unused product at the end of each operating session.

Dilution for infusion

For slow intravenous administration, the drug solution must be first diluted into 50 ml to 250 ml of 5% glucose or 0.9% sodium chloride sterile solutions. It can be administered for up to 8 hours without protection from light. The solution after dilution remains clear, colourless or almost colourless, and free of visible particles.