PACKAGE LEAFLET: INFORMATION FOR THE USER

VITAMINE B1 STEROP 100mg/2ml
VITAMINE B1 STEROP 250mg/2ml
Solution for injection

Thiamine hydrochloride

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet
1. What Vitamine B1 Sterop is and what it is used for
2. What you need to know before you use Vitamine B1 Sterop
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1. WHAT VITAMINE B1 STEROP IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: Vitamin of group B.

Indicated for:
Treatment of the acknowledged lacks in vitamin B1 (= thiamin), as
- Beri-beri, due to a lack of vitamin B1 in the food intake and whose clinical signs include ocular symptoms, a bad motor coordination (ataxia), oedema, acute cardiac insufficiency and a damage to the peripheric nervous system (peripheric neuropathy);
- Wernicke-Korsakoff encephalopathy which is a serious sign of lack in vitamin B1. It can be induced by several conditions interfering with the passage of vitamin B1 brought by the food into the blood.
Most of the time, it appears in case of chronic alcoholism, but can also be caused by:
- prolonged vomiting due to pregnancy,
- malabsorption syndrome (= trouble of the passage of vitamin B1 brought by food into the blood),
- parenteral feeding without vitamin B1 supplementation,
- mental anorexia (= loss of appetite, from mental origin),
- inflammation of a part of the small intestine (regional enteritis),
- dialysis (= process to purify the blood, in order to extract the toxic waste in case of severe renal insufficiency),
- thyrotoxicosis (= excess of thyroidian hormones with one or more of the following symptoms: abnormal increase in volume of the thyroid gland (= goiter), protruding eye out of its orbit (= exophtalmus) and infiltration of the skin, nonpitting, usually localized on the front of the tibia and characterised by nodules and hard plaques, raised, sometimes rose or orange (= pretibial myxoedema),
- treatment by nitroglycerin high IV doses,
- gastroplasty (= surgery of the stomach).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE VITAMINE B1 STEROP

**Do not use Vitamine B1 Sterop**

- If you are allergic (hypersensitive) to vitamin B1 or any of the other ingredients components (listed in section 6).
- If the solution is not limpid.

**Take special care with Vitamine B1 Sterop**

- Allergic reactions leading to a shock have been reported following vitamin B1 injection. Those reactions are uncommon and unexpected. Nevertheless, their risk increases in case of repeated doses. The doctor must be ensured that you are not allergic to vitamin B1 before the injection. An intra-dermal test dose can be given in case of doubt.

  In any case, the emergency medical equipment useful for treating allergic (anaphylactic) shocks must be easily available.

  In case of intravenous injection, this must be done in a slow way (at least 10 minutes).

- Toxic reactions have been reported following a 50 mg vitamin B1 injection, and at least one sudden death has been reported after a 100 mg vitamin B1 intravenous injection.

- Vitamin B1 may increase the effect of drugs of the neuromuscular blocking group (that is to say which block the transmission of the nervous commands to the muscles).

- Vitamine B1 Sterop does not contain any antimicrobial preservative; therefore it is not able to avoid the growth of microorganisms. Before administration, the drug solution will be withdrawn from the ampoule in order to avoid any microbial contamination, in a sterile syringe, immediately after the opening of the ampoule. The withdrawn or prepared drug solution will be used immediately. This drug solution and any syringe containing this drug are destined for single and individual use. Any unused remaining solution will be destroyed according to Good Clinical Practices.

- When Vitamine B1 Sterop is administered by intravenous route, in a general way, it exists a risk of irritation or destruction of the cells (necrosis) at the injection site or an risk of inflammation of the vein after a blood clot formation (thrombophlebitis), in case of too quick administration or injection of a too important volume of solution. This blood clot can block totally or partially the bloodstream into the concerned vein.

  In order to reduce the risk of thrombophlebitis, it is recommended to change the site of injection every 24 hours.

If you take already other drugs, read also the section “Using other medicines”.
Please consult your doctor if one of the warnings mentioned above is applied for you, or if it was in the past.

**Using other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Vitamin B1 can increase the effect of drugs of the neuromuscular blocking group (that is to say which block the transmission of nervous commands to the muscles).

The vitamin B1 intake can influence the results of some urinary tests notably the theophylline quantity determination in serum. Ask your doctor.
Incompatibilities:
Vitamin B1 is not stable in neutral or alkaline medium. It is not compatible with carbonates, citrates, barbiturates, acetates and ferric sulphate. Vitamin B1 is also not compatible with oxidant and reducing substances, iodides, mercury chloride or copper ions.
In any case, because of lack of compatibility studies, Vitamine B1 Sterop cannot be mixed with other drugs.

Vitamine B1 Sterop with food and drink
Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

In case of need, vitamin B1 can be used during pregnancy and breast-feeding, without any risk for the foetus and for the breast-fed newborn.

Driving and using machines
No effect known at this time.

3. HOW TO USE VITAMINE B1 STEROP
Always use Vitamine B1 Sterop exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Vitamine B1 Sterop is to be given by intramuscular or slow intravenous way.

The recommended doses in the treatment of insufficiencies (deficiencies) in vitamin B1 are the following:

Adults: 5 to 100 mg Vitamine B1 Sterop 3 times a day by an intramuscular or slow intravenous way during a few days. This treatment will be then followed by a maintenance dose of 2,5 to 5 mg vitamin B1 a day by oral way.

In case of Wernicke encephalopathy, the recommended starting dose is usually 100 mg vitamin B1 by intravenous way. This dose is followed by an intravenous or intramuscular dose of 50 to 100 mg per day, and this until you have again a regular and balanced feeding.

Doses of 100 to 200 mg vitamin B1 per day during 3 days have been recommended for emergency treatment of this encephalopathy. In certain cases, doses up to 1000 mg have been needed during the first 12 hours.

Children: 10 to 25 mg Vitamine B1 Sterop a day by intramuscular or slow intravenous way.

As vitamin B1 plays an important role in the normal metabolism of glucides (=sugars), if a glucose administration by bolus (that is to say high doses in short periods of time) or by infusion is requested in case of an underlying vitamin B1 deficiency, it is recommended to administer vitamin B1 before or simultaneously glucose.

Administration way:
Vitamin B1 will be administrated by (slow) intravenous or intramuscular way only if it is strictly necessary (otherwise the oral way is as much as possible preferred).
In case of (slow) intravenous administration, the drug solution must be first diluted into an adequate sterile solution, such as glucose 5% or sodium chloride 0.9%. The injection must be done slowly, in 10 minutes.

For intramuscular administration, use the undiluted drug. Avoid the intravascular injection. Deep intramuscular administration must be done 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 in a vein. If blood appears, take the needle out and inject into another site. Change the injection site in case of repeated doses.

Note for the auxiliary nursing staff:
- Before administration, the drug solution will be withdrawn according to the rules of Good Clinical Practices, in order to avoid any microbial contamination, in a sterile syringe, immediately after the opening of the ampoule. The withdrawn drug solution will be used immediately. Any unused remaining solution will be destroyed according to rules of Good Clinical Practices.
- In case of infusion, the drug solution and the kit for infusion have to be maintained in aseptic conditions during the whole duration of the infusion, in accordance with the Good Clinical Practices. Any drug solution, prepared and intended for parenteral use, must be used within 24 hours.
- At the end of the infusion, any rest of unused drug solution and any kit for infusion containing this solution will be eliminated according to current regulation.
- In a general way, a risk of irritation or destruction of the cells (necrosis) exists at the injection site, or a risk of venous inflammation resulting from the formation of a blood clot (thrombophlebitis), in case of a too quick administration, or an injection of a too important volume of solution. The blood clot can block completely or partially the blood stream into the affected vein. In order to reduce the risk of thrombophlebitis, it is recommended to change the injection site every 24 hours.
- In case of administration of an important volume of fluid, check regularly the ionic balance.

If you use more Vitamine B1 Sterop than you should
If you used too much Vitamine B1 Sterop, contact immediately your doctor, your pharmacist or the Poison center (070/245.245).

Toxic reactions have been reported after the injection of 50mg vitamin B1, and at least one case of sudden death has been reported after the intravenous injection of 100 mg. The oral taken of a dose several times higher than the therapeutic dose has not shown any toxic effect.

If you forget to use Vitamine B1 Sterop
Take the dose as soon as possible. If it is nearly time for the following dose, then wait till this time and pass the forgotten dose. In general, missing a dose shouldn’t constitute a risk for your health. Do not take a double dose to make up for a forgotten dose.

If you stop using Vitamine B1 Sterop
At the end of the treatment, it can be stopped without any particular disposition. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.
4. POSSIBLE SIDE EFFECTS
Like all medicines, Vitamine B1 Sterop can cause side effects, although not everybody gets them.

Pain at the injection site:
Fast intravenous administration of 100 mg vitamin B1 has been associated with an immediate burn in the arm bringing the venous access during a few seconds to a few minutes. This reaction can be avoided by a slow administration in larger veins.

Contact dermatitis:
An exposure to vitamin B1 at the workplace can provoke a skin inflammation (contact dermatitis), which can reappear after an oral or parenteral vitamin B1 administration (i.e. directly in the body through the skin, without passing by the digestive absorption) to people sensitized.

Allergic reactions:
Severe allergic reactions, with respiratory depression, itching (pruritus), shock and abdominal pain, have been reported with an equivalent frequency (less than 0.1%) whatever the administration ways, generally after repeated injections of high doses, from 25 to 100 mg vitamin B1, at intervals of more than 7 days. Those reactions were frequently preceeded by sneeze or transitory pruritus.
Considering this risk of severe allergic reactions, it is recommended to keep parenteral administration (i.e. directly in the body through the skin, without passing by the digestive absorption) vitamin B1 administration to the absolutely essential cases, and in these cases to have all the medical emergency equipment to treat those reactions.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE VITAMINE B1 STEROP
Keep out of the reach and sight of children.
Keep the ampoules in the outer carton in order to protect from light.
This medicinal product does not require any special temperature storage conditions.

Expire date:
Do not use Vitamine B1 Sterop after the expiry date which is stated on the carton after the mention EXP. The expiry date refers to the last day of that month.

Do not use Vitamine B1 Sterop if you notice particles into ampoules.

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. FURTHER INFORMATION

What Vitamine B1 Sterop contains
- The active substance is thiamine (or vitamin B1). It is present under the form of thiamine hydrochloride 100 mg or 250 mg into 2 ml.
- The other ingredients are sodium hydroxide and water for injection.

What Vitamine B1 Sterop looks like and contents of the pack
Solution for injection for intramuscular (IM) or for slow intravenous (IV) use.
Type I uncoloured glass 2 ml ampoule, packaged into cartons of 3, 10 and 100 ampoules.
Marketing Authorisation Holder and Manufacturer
Laboratoires STEROP - Avenue de Scheut 46-50 - 1070 Brussels - Belgium.

This leaflet was last approved in 10/2010.

Dispensation status : On medical prescription.

Marketing autorisation :
VITAMINE B1 STEROP 100mg/2ml: BE271695
VITAMINE B1 STEROP 250mg/2ml: BE271704