

Medivitan[®]

iM

Patient Information Leaflet: Information for users

Medivitan[®] iM with lidocaine, solution for injection

- Pre-filled syringe
- Ampoules

Active substances: pyridoxine hydrochloride / hydroxocobalamin hydrochloride / folic acid

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Medivitan[®] iM with lidocaine is and what it is used for
Medivitan[®] iM with lidocaine is a vitamin preparation.

Intended use

Medivitan[®] iM with lidocaine is used to treat combined deficiency of vitamin B6, vitamin B12 and folic acid that cannot be corrected through diet alone.

Deficiency of vitamin B6, vitamin B12 and folic acid may occur:

- in cases of malnutrition and underfeeding, in particular in the elderly or in patients in reduced general condition (e.g., cachexia).
- in the event of impaired intestinal absorption due to atrophic gastritis or chronic inflammatory bowel disease, or following gastrointestinal resection.
- in the event of increased vitamin requirement, in particular during pregnancy and breast-feeding, in patients with cachexia or on radiotherapy or chemotherapy, in the event of elevated turnover in bone marrow due to chronic haemolysis or following heavy blood loss.
- following use of medication (e.g., antiepileptics, theophylline, thiazide diuretics, antifolate drugs, oral contraceptives) or alcohol abuse.

Deficiency of vitamin B6, vitamin B12 and folic acid may lead to:

- neurological and psychiatric disorders, neuritis
- elevated levels of homocysteine

In cases of isolated deficiency, the respective vitamin deficiency should be treated in a targeted manner. However, it is necessary to keep in mind that in this case the administration of a single vitamin via one-carbon metabolism may result in elevated turnover of both of the other vitamins. Therefore, if a vitamin deficiency cannot be ruled out with certainty in the event of corresponding symptoms, treatment with the fixed-dose combination may be attempted.

2. What you need to know before you use Medivitan[®] iM with lidocaine

Do not use Medivitan[®] iM with lidocaine

- if you are allergic to pyridoxine hydrochloride, hydroxocobalamin hydrochloride, folic acid, or any of the other ingredients of this medicine listed in section 6.
- if you have inflammatory tissue changes at the administration site.
- in the event of suspected folic acid hypersensitivity.
- if you have hypersensitivity to amide local anaesthetics.

- if you have megaloblastic anaemia as a result of isolated vitamin B12 deficiency.
- if you have isolated folic acid deficiency.

Warnings and precautions

Talk to your doctor or pharmacist before using Medivitan[®] iM with lidocaine.

The injection must be given slowly, deep into the muscle. The injection site must be changed for each injection. The ampoule with the red liquid (solution for injection I) contains lidocaine. Only for intramuscular (IM) use; do not administer intravenously (IV).

Other medicines and Medivitan[®] iM with lidocaine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Therapeutic doses of pyridoxine hydrochloride may weaken the effect of L-DOPA. There are interactions with INH, D-penicillamine and cycloserine. The effects of antifolate drugs may be reduced or abolished by Medivitan[®] iM with lidocaine. The rate of lidocaine metabolism is reduced by morphine-like analgesic drugs. Lidocaine weakens the effect of sulfonamides in the region of the administration site.

There is an increase in seizure susceptibility on anticonvulsant therapy, in particular with the use of higher doses of folic acid.

Pregnancy and breast-feeding

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 taking this medicine.

Pregnancy

Due to the lidocaine content in Medivitan[®] iM with lidocaine, you should only use this medicine during pregnancy if your doctor believes that this is absolutely necessary for you.

Breast-feeding

Lidocaine, one of the ingredients of Medivitan[®] iM with lidocaine, passes into breast milk in low quantities, but the risk of harm to the infant is unlikely.

Driving and using machines

No specific precautions are necessary.

3. How to use Medivitan[®] iM with lidocaine

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

The recommended dose is:

Inject one dose of Medivitan[®] iM with lidocaine via an intramuscular route twice weekly, and continue this therapy for 4 weeks (8 injections in total).

Method of administration

For intramuscular injection.

Please talk to your doctor or pharmacist if you feel that the effect of Medivitan[®] iM with lidocaine is too strong or too weak.

If you take more Medivitan[®] iM with lidocaine than you should

Please contact your doctor, who will inform you about what further measures are required.

If you forget to use Medivitan[®] iM with lidocaine

Do not use a double quantity to make up for a forgotten dose.

If you stop using Medivitan[®] iM with lidocaine

An untreated vitamin deficiency can have clinical consequences.

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

4. Possible side effects

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

The frequency data for side effects is based on the following categories:

- Very common: more than 1 in 10 patients treated
- Common: between 1 and 10 patients treated per 100
- Uncommon: between 1 and 10 patients treated per 1,000
- Rare: between 1 and 10 patients treated per 10,000
- Very rare: fewer than 1 in 10,000 patients treated
- Unknown: frequency cannot be estimated from the available data

Possible side effects

Acne, eczema-like and urticarial drug reactions, and anaphylactic or anaphylactoid reactions have been reported very rarely with the parenteral use of hydroxocobalamin.

Very rarely, allergic hypersensitivity reactions (skin reactions, urticaria, shock) may occur with folic acid or lidocaine. In the event of overdose, lidocaine can cause seizures and heart rhythm disorders. Localised intolerance reactions are uncommon. Folic acid may occasionally cause gastrointestinal problems at high doses.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly using the notification form for adverse drug reactions (ADRs) (<http://www.bfarm.de>). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Medivitan[®] iM with lidocaine.

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

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

Storage conditions

Do not store above 25°C.

Store in the original packaging in order to protect the contents from light.

Note about shelf-life after opening or preparation

Draw the contents of the vials of solutions I and II up into the syringe one after the other, and mix briefly. Medivitan[®] iM with lidocaine should be used immediately after mixing the solutions.

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 Medivitan[®] iM with lidocaine contains

- The active substances are pyridoxine hydrochloride, hydroxocobalamin hydrochloride and folic acid.

4 ml solution for injection I contains: Pyridoxine hydrochloride (Vitamin B6) 5 mg Hydroxocobalamin hydrochloride (Vitamin B12) 1 mg

1 ml solution for injection II contains: Sodium folinate 1.1 mg

- The other ingredients are: 4 ml solution for injection I: sodium hydroxide, lidocaine hydrochloride (anhydrous), water for injection
1 ml solution for injection II: sodium hydroxide, water for injection

What Medivitan[®] iM with lidocaine looks like and contents of the pack

Solution for injection I: clear, red liquid

Solution for injection II: clear, yellow liquid

1 pack contains 1/4/8/16/24/48 pre-filled syringes (as a dual chamber system) with safety guard, or 1/4/8/16/24/48 of each break-seal ampoule with 4 ml solution for injection I and 1 ml solution for injection II.

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