

Medivitan[®]

iV

Patient Information Leaflet: Information for users

Medivitan[®] iV ampoules 5 mg, 1 mg, 1.05 mg solution for injection

Active substances: pyridoxine hydrochloride / cyanocobalamin hydrochloride / folic acid

Read all of this leaflet carefully before you start using this medicine because it contains important information for you. Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or medical specialist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Medivitan[®] iV ampoules are and what it is used for
2. What you need to know before you take Medivitan[®] iV ampoules
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1. What Medivitan[®] iV ampoules are and what they are used for
Medivitan[®] iV ampoules are a vitamin preparation.

Medivitan[®] iV ampoules are used to treat combined deficiency of vitamin B6, vitamin B12 and folic acid that cannot be corrected through diet alone.

2. What you need to know before you use Medivitan[®] iV ampoules

Do not use Medivitan[®] iV ampoules:

- if you are allergic to pyridoxine hydrochloride, cyanocobalamin, folic acid, or any of the other ingredients of Medivitan[®] iV ampoules 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 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[®] iV ampoules.

The injection site must be changed for each injection.

For intramuscular administration, the needle must be inserted deep and the injection given slowly.

Other medicines and Medivitan[®] iV ampoules

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[®] iV ampoules.

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

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 taking this medicine.

Driving and using machines

No specific precautions are necessary.

Medivitan[®] iV ampoules contain sodium, but less than 1 mmol (23 mg) sodium per 5 ml ready-to-use solution for injection, i.e. it is practically “sodium free”.

3. How to use Medivitan[®] iV ampoules

Always use this medicine exactly as described in this leaflet or 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[®] iV ampoules via intramuscular or intravenous route twice weekly, and continue this therapy for 4 weeks (8 injections in total).

In the event of impaired intestinal absorption, intramuscular or intravenous administration of Medivitan[®] iV ampoules is to take place a 4-week intervals.

Daily oral folic acid is to be taken between the injections.

Method of administration

For intramuscular or intravenous injection.

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

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 cyanocobalamin.

Very rarely, allergic hypersensitivity reactions (skin reactions, urticaria, shock) may occur with folic acid.

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[®] iV ampoules

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 ampoules of solutions I and II up into the syringe one after the other, and mix briefly. Medivitan[®] iV ampoules should be used immediately after mixing the solutions.

6. Contents of the pack and other information

What Medivitan[®] iV ampoules contain

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

4 ml solution for injection I contains:

Pyridoxine hydrochloride 5 mg, cyanocobalamin 1 mg

1 ml solution for injection II contains:

Folic acid 1.05 mg

- The other ingredients of solutions for injection I and II are:

Sodium chloride, sodium hydroxide, water for injection

What Medivitan[®] iV ampoules look like and contents of the pack

Solution for injection I: clear, red solution for injection in a 5 ml ampoule

Solution for injection II: clear, yellow solution for injection in a 2 ml ampoule

1 pack contains 4/8/16 of each break-seal ampoule with 4 ml solution for injection I and 1 ml solution for injection II.

Pharmaceutical company and manufacturer

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