

Medivitan[®] iV

Patient Information Leaflet: Information for users

Medivitan[®] iV pre-filled syringe 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 pre-filled syringe is and what it is used for
2. What you need to know before you take Medivitan[®] iV pre-filled syringe
3. How to take Medivitan[®] iV pre-filled syringe
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5. How to store Medivitan[®] iV pre-filled syringe
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1. What Medivitan[®] iV pre-filled syringe is and what it is used for

Medivitan[®] iV pre-filled syringe is a vitamin preparation.

Medivitan[®] iV pre-filled syringe is 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 pre-filled syringe

Do not use Medivitan[®] iV pre-filled syringe

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

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 pre-filled syringe

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 pre-filled syringes.

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 pre-filled syringe contains 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 pre-filled syringe

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 pre-filled syringe 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 pre-filled syringe 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 pre-filled syringe is too strong or too weak.

If you have any further questions on the use of this medicine, please 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 suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report each suspected case of a side effect using the report form for adverse drug reactions (ADRs).

(<http://www.bfarm.de>)

5. How to store Medivitan[®] iV pre-filled syringe

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

Medivitan[®] iV pre-filled syringe should be used immediately after mixing the solutions.

6. Contents of the pack and other information

What Medivitan[®] iV pre-filled syringe contains

- 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 are:

Sodium chloride, sodium hydroxide, water for injection

What Medivitan[®] iV pre-filled syringe looks like and contents of the pack

In the lower chamber 1 of the pre-filled syringe: clear, red solution for injection I

In the upper chamber 2 of the pre-filled syringe: clear, yellow solution for injection II

1 pack contains 4/8/16 pre-filled syringes (as dual-chamber system) with safety needles.

Pharmaceutical company and manufacturer

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