

Unofficial translation of the German package leaflet

Patient Information Leaflet: Information for users

Medyn[®] forte capsules 0.5 mg / 25 mg / 2.5 mg, hard capsules

Active substances: cyanocobalamin / pyridoxine hydrochloride / folic acid

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist 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 Medyn[®] forte capsules are and what it is used for
2. What you need to know before you take Medyn[®] forte capsules
3. How to take Medyn[®] forte capsules
4. Possible side effects
5. How to store Medyn[®] forte capsules
6. Contents of the pack and other information

1. What Medyn[®] forte capsules are and what they are used for

Medyn[®] forte capsules are a vitamin preparation.

Intended use

Confirmed cases of combined deficiency of vitamin B₆, vitamin B₁₂ and folic acid that cannot be controlled through diet alone.

2. What you need to know before you take Medyn[®] forte capsules

Do not take Medyn[®] forte capsules

- If you are hypersensitive (allergic) to cyanocobalamin, pyridoxine hydrochloride, folic acid, or any of the other ingredients of Medyn[®] forte capsules listed in section 6.
- In the event of megaloblastic anaemia as the result of isolated vitamin B₁₂ deficiency, e.g., as the result of a deficiency of intrinsic factor (anaemia) or with isolated folic acid deficiency.

Warnings and precautions

Talk to your doctor or pharmacist before taking Medyn[®] forte capsules.

Tingling and pins-and-needles in the hands and feet (signs of peripheral sensory neuropathy or paraesthesia) have been observed with the long-term use of daily doses of over 50 mg vitamin B₆ and with the short-term use of doses in the region of one gram. If you experience tingling and pins-and-needles, please contact your doctor. Your doctor will check the amount that you are taking and stop the medication, if necessary.

Other medicines and Medyn[®] forte capsules

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, cycloserine and hydralazine.

Enteral absorption of folic acid is reduced with the concomitant administration of primidone, phenytoin, phenobarbital, carbamazepine, valproate, sulfasalazine, hormonal contraceptives, and antifolate drugs, such as methotrexate, trimethoprim, pyrimethamine and triamterene.

Medyn[®] forte capsules with food and drink

No interactions with food and drink are currently known.

Pregnancy and breast-feeding

During pregnancy and breast-feeding, your daily vitamin needs should be covered by consuming a balanced diet.

This medicine is only intended for the treatment of a vitamin deficiency (due to its quantity of active substance) and must therefore only be used following careful assessment of the risk/benefit balance by your doctor. There are no systematic studies of the use of Medyn[®] forte capsules in pregnancy.

Vitamin B₆ and B₁₂ are excreted in breast milk.

Driving and using machines

No specific precautions are necessary.

3. How to take Medyn[®] forte capsules

Always take 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:

Take one hard capsule daily.

The duration of use is not restricted.

If you take more Medyn[®] forte capsules than you should

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

If you forget to take Medyn[®] forte capsules

Do not take a double dose to make up for a forgotten dose.

If you stop taking Medyn[®] forte capsules

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

Vitamin B₆:

There are no known side effects at the specified dose range for the prevention and treatment of vitamin B₆ deficiency. Daily doses above 50 mg may cause peripheral sensory neuropathy (a disease of the nerves with tingling and pins-and-needles) (see Warnings).

Folic acid:

With the administration of high doses, folic acid may occasionally cause gastrointestinal problems, sleep disorders, agitation and depression.

Vitamin B₁₂:

Acne, eczema-like and urticarial drug reactions (hives), and anaphylactic or anaphylactoid reactions (hypersensitivity reactions) have been reported very rarely.

In the extremely rare event of allergic shock, it is necessary to take the general emergency measures required for such circumstances. In other cases of mild intolerance reactions, the discontinuation of Medyn[®] forte capsules is sufficient.

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 via:

Bundesinstitut für Arzneimittel und Medizinprodukte [Federal Office for Drugs and Medical Devices]

Abt. Pharmakovigilanz [Pharmacovigilance Department]

Kurt-Georg-Kiesinger Allee 3

D-53175 Bonn

Website: www.bfarm.de

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

5. How to store Medyn[®] forte capsules

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 blister pack and 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 and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer need. These measures will help protect the environment.

6. Other information

What Medyn[®] forte capsules contain:

- The active substances are:

1 hard capsule contains:

Cyanocobalamin (Vitamin B ₁₂)	0.5 mg
Pyridoxine hydrochloride (Vitamin B ₆)	25 mg
Folic acid	2.5 mg

- The other ingredients are:

Maltodextrin; citric acid monohydrate; sodium citrate dihydrate; microcrystalline cellulose; highly dispersible silica; magnesium stearate; titanium dioxide; iron (III) oxide; sodium dodecyl sulfate; purified water; gelatine.

What Medyn[®] forte capsules look like and contents of the pack

Capsules (colours: yellow/ivory)

Blister pack with 30 and 90 hard capsules

Pharmaceutical company and manufacturer

MEDICE Arzneimittel Pütter GmbH & Co. KG

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