

Unofficial translation of the German package leaflet

Patient Information Leaflet: Information for users

Neuro-Medivitan[®], film-coated tablets

Active substances: thiamine chloride hydrochloride / pyridoxine hydrochloride

For use in adults.

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

Always use 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 Neuro-Medivitan[®] is and what it is used for
2. What you need to know before you take Neuro-Medivitan[®]
3. How to take Neuro-Medivitan[®]
4. Possible side effects
5. How to store Neuro-Medivitan[®]
6. Contents of the pack and other information

1. What Neuro-Medivitan[®] is and what it is used for

Neuro-Medivitan[®] is a vitamin preparation.

Intended use

Systemic neurological disorders due to proven deficiency of vitamins B1 and B6.

2. What you need to know before you take Neuro-Medivitan[®]

Do not take Neuro-Medivitan[®]:

- If you are hypersensitive (allergic) to thiamine chloride hydrochloride, pyridoxine hydrochloride, or any of the other ingredients of Neuro-Medivitan[®] listed in section 6.

Warnings and precautions

Talk to your doctor or pharmacist before taking Neuro-Medivitan[®].

Children

Other medicines and Neuro-Medivitan[®]

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

Therapeutic doses of vitamin B6 may weaken the effect of L-DOPA. There are further interactions with INH, D-penicillamine and cycloserine.

Neuro-Medivitan[®] with food and drink

No interactions with food and drink are currently known.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, this medicine is only meaningful for the treatment of proven vitamin B1 and B6 deficiency, due to the quantity of the active substances. Therefore, you must only take Neuro-Medivitan[®] following careful assessment of the risk/benefit balance by your doctor. During pregnancy and breast-feeding, the recommended daily intake of vitamin B1 is 1.4-1.6 mg, and the recommended daily intake of vitamin B6 is 2.4-2.6 mg. The safety of taking more than the recommended daily dose is currently not proven.

Vitamin B1 and vitamin B6 are excreted in breast milk. High doses of vitamin B6 may inhibit milk production.

Driving and using machines

No specific precautions are necessary.

Neuro-Medivitan[®] contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking Neuro-Medivitan[®].

3. How to take Neuro-Medivitan[®]

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:

1 film-coated tablet 3x daily.

Method and duration of administration

Neuro-Medivitan[®] is to be swallowed whole with some liquid after meals.

After a period of 4 weeks at most, your doctor should decide whether the administration of vitamin B6 and vitamin B1 at the high concentrations in this tablet is still indicated. If necessary, you should switch to a preparation with lower active substance strengths, in order to reduce the risk of neuropathy associated with vitamin B6.

If you take more Neuro-Medivitan[®] than you should

Neuro-Medivitan[®] should only be taken in the recommended dosage.

If signs of peripheral sensory neuropathy develop (abnormal sensation, mainly in the hands and feet), the dosage is to be reviewed and the medicine discontinued, if necessary (see section 4 "Side effects").

In the event of overdose, please contact your doctor if you experience problems.

If you forget to take Neuro-Medivitan[®]

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

If you stop taking Neuro-Medivitan[®]

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 classification of side effects is based on the following frequencies:

- 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

Excess perspiration, tachycardia (racing heart), and skin reactions with itching and hives have been reported very rarely following the administration of vitamin B1.

With long-term overdose of vitamin B6 (longer than 2 months at a dose of more than 1 g/day), nerve-damaging effects may occur.

The long-term use (longer than 6-12 months) of daily doses of more than 50 mg vitamin B6 may cause peripheral sensory neuropathy (abnormal sensation, mainly in the hands and feet).

In the extremely rare event of allergic shock, it is necessary to take the general measures required for such circumstances. In other cases of mild intolerance reactions, the discontinuation of Neuro-Medivitan[®] 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 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 Neuro-Medivitan[®]

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.

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. Contents of the pack and other information

What Neuro-Medivitan[®] contains:

- The active substances are:

1 film-coated tablet contains:

Thiamine chloride hydrochloride (Vitamin B1)	100 mg
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Pyridoxine hydrochloride (Vitamin B6)	100 mg
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- The other ingredients are:

Lactose monohydrate, povidone K30, crospovidone, macrogol 6000, magnesium stearate, polyvinyl alcohol, macrogol 4000, talc, titanium dioxide, iron(III) oxide, iron(II, III) oxide, hydrated iron(III) oxide-hydroxide

What Neuro-Medivitan[®] looks like and contents of the pack

Brown, round film-coated tablets

Blister pack with 50 and 100 film-coated tablets

Pharmaceutical company and manufacturer

MEDICE Arzneimittel Pütter GmbH & Co. KG

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