

Patient Information Leaflet (PIL)

Neurorubine-Forte film-coated tablets

Vitamin B₁, vitamin B₆ and vitamin B₁₂

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Neurorubine-Forte is and what it is used for

Neurorubine-Forte contains three vitamins: vitamin B₁, vitamin B₆ and vitamin B₁₂. Each of these vitamins is essential for normal metabolic processes within the nerve cell.

Signs of deficiency may manifest as nerve inflammation and dysfunction or poor mental performance.

Neurorubine-Forte is used on medical prescription for vitamin B₁, B₆ and B₁₂ deficiency due to poor diet or alcoholism, as well as for acute and chronic nerve inflammation, nerve pain such as trigeminal neuralgia, sciatica or pain associated with shingles (herpes zoster).

2. Before you take Neurorubine-Forte

a. Do not take Neurorubine-Forte

If you are allergic to any of the ingredients, you must not take this product. Patients with psoriasis should not take Neurorubine-Forte. Neurorubine-Forte should not be used in children.

b. Take special care with

Existing acne can be made worse by Neurorubine-Forte. Skin reactions, which are signs of hypersensitivity to vitamin B₁, B₆ or B₁₂, may occur during treatment.

Further information may be obtained from your doctor or pharmacist. These persons have the detailed prescribing information at their disposal.

c. Taking other medicines

High doses of vitamin B₆ of the kind contained by Neurorubine-Forte may weaken the effect of L-dopa in Parkinson's disease.

If taken at the same time, antacids (used to treat too much stomach acid) block the absorption of vitamin B₁.

There is no known incompatibility with alcohol.

Please tell your doctor or pharmacist if you are taking or using the following medicines: isoniazid, thiosemicarbazone, 5-fluorouracil.

Please tell your doctor or pharmacist if you suffer from other illnesses, have any allergies or are taking or externally using any other medicines, including those obtained without a prescription.

d. Pregnancy and breast-feeding

Vitamins can be taken at a dose equivalent to daily requirements. If you are pregnant or breast-feeding, you should take Neurorubine-Forte only if expressly prescribed by a doctor.

Tell your doctor if you are pregnant, planning to have a baby or breast-feeding.

e. Driving and using machines

There is no known effect on the ability to drive and use machines.

3. How to take Neurorubine-Forte

Always take Neurorubine-Forte exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

The usual dose is 1 to 2 coated tablets daily.

So far there is no experience with the treatment in children. The preparation should therefore not be used in children.

Do not change the prescribed dosage yourself. If you think that the effect of the medicine is too weak or too strong, talk to your doctor or pharmacist.

If you take more Neurorubine-Forte than you should

If you take too much Neurorubine-Forte contact your doctor or your nearest hospital emergency department immediately.

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

4. Possible side effects

Like all medicines, Neurorubine-Forte can cause side effects, although not everybody gets them.

The following side effects may occur due to individual vitamins contained in Neurorubine-Forte:

- Due to vitamin B₁: sweating, skin reactions (itching, hives), weakness, restlessness, anxiety, tingling of the skin, drowsiness, headache, nausea, a "lump in the throat", bleeding in the gastrointestinal tract, rapid pulse and circulatory collapse in very rare cases (in sensitive patients);
- Vitamin B₆ and high doses of Vitamin B₁₂ can trigger or aggravate acne.

Uncommon (may affect up to 1 in 100 people)

- high doses can cause acne
- pyridoxine can trigger or aggravate acne vulgaris or acne-like rash

Rare (may affect up to 1 in 1,000 people)

- allergic reactions
- anxiety (esp. in sensitive patients)
- reversible peripheral sensory neuropathy was observed at high doses over a longer period (> 500 mg/day)
- pyridoxine can reduce therapeutic effect of levodopa in patients with Parkinson's disease, unless a decarboxylase inhibitor is given at the same time
- tachycardia
- circulatory failure (esp. in sensitive patients)

Very rare (may affect up to 1 in 10,000 people)

- angioneurotic oedema
- cyanosis and pulmonary oedema (esp. in sensitive patients)
- nausea and haemorrhages in the gastrointestinal tract (esp. in sensitive patients)
- skin reactions with pruritus and urticaria (esp. in sensitive patients)
- outbreaks of sweating
- feeling of weakness
- globus symptoms ("lump in the throat" sensation)
- inhibition of prolactin release
- agitation
- anxiety
- paraesthesia
- somnolence
- headache
- high doses can lead to an increase in serum glutamic oxaloacetic transaminase (GOT)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Neurorubine-Forte

Keep out of the reach and sight of children.

Do not store above 30 °C.

Neurorubine-Forte may be used only up to the date marked with "EXP" on the pack.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

a. What Neurorubine-Forte contains

The active substances are: Thiamine nitrate (vitamin B₁), Pyridoxine hydrochloride (vitamin B₆), Cyanocobalamin (vitamin B₁₂)

Each film coated tablets of thiamine nitrate (vitamin B₁) 200 mg, pyridoxine hydrochloride (vitamin B₆) 50 mg, cyanocobalamin (vitamin B₁₂) 1,000 µg

The other ingredients are:

Table core: Mannitol, Cellulose powdered, Cellulose microcrystalline, Methylcellulose, Starch pregelatinized, Magnesium stearate & Silica colloidal anhydrous.

Film-coating: Purified water, Hypromellose, Macrogol 6000, Talc, Titanium dioxide (E171) & Erythrosine (E 127).

b. What Neurorubine-Forte looks like and content of the pack

Neurorubine-Forte is pink, round, biconvex, film coated tablet embossed “TP” on one side.

The film coated tablets are packed in aluminum blister.

Packs of 10, 20 and 100 tablets.

Not all presentations may be marketed.

c. Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder / Manufacturer Acino Pharma AG, Liesberg, Switzerland

This leaflet was revised in October 2018

To report any side effect (s):

• **Saudi Arabia:**

- The National Pharmacovigilance and Drug Safety Center (NPC):
o Fax: +966-11-205-7662
o Call NPC at 8002490000 (free phone)
o SFDA call center: 19999
o E-mail: npc.drug@sfd.gov.sa
o Website: www.sfd.gov.sa/npc

- Acino Pharma Scientific Office:
o Phone: +966-11-4631459
o E-mail: pv@acino.swiss

• **Other GCC states**

Please contact the relevant competent authority

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.