

Sopalamin-3B[®]

Vitamin B1+B6+B12 (250+125+0,25) mg



NAME CONTENT: SOPALAMIN-3B film coated tabs (250+125+0,25) mg per tab
COMPOSITION: Active ingredients: Vitamin B1 250mg, Vitamin B6 125mg, Vitamin B12 0,25mg.

Excipients: Outer tablet: Cellulose microcrystalline, Ethyl cellulose CP45, Magnesium stearate. Inner tablet: Mannitol, Cellulose microcrystalline, Polyvidone, Magnesium stearate. Coating: Macrogol 20.000, Methocel E5 HPMC, Titanium dioxide E171, CI 77891

PHARMACEUTICAL FORM: Film coated tabs

DESCRIPTION PACKAGING: Paper box containing 30 tabs in blisters

THERAPEUTICAL CATEGORY: Combination of vitamins (A11DB)

MARKETING AUTHORISATION HOLDER / MANUFACTURER:

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To which class of drugs do Sopalamin-3B coated tablets belong and what effect do they have?

Sopalamin-3B coated tablets contain a combination of vitamins B1, B6 and B12 which are of particular importance. Like all other vitamins, they are essential nutrients which the body cannot produce by itself. The efficacy of the combined vitamins B1, B6 and B12 contained in Sopalamin-3B coated tablets is superior to that of the individual vitamins alone. The effect of B vitamins in diseases of the nervous system involves compensation of accompanying vitamin B deficiencies and stimulation of natural healing processes in the nervous tissue.

At the same time, the analgesic effects of the vitamin B complex affect favorably the therapeutic result.

INDICATIONS

In which conditions are Sopalamin-3B coated tablets indicated?

For the supportive treatment of neuritis and noninflammatory diseases of the nerves, e.g.

- Pain and / or paralysis in the facial nerves (trigeminal neuralgia, facial paresis)
- Ischialgia
- Pain in the area of the intercostal nerves, cervical vertebral column, shoulders and arms and pain of the lumbar vertebral column
- States of irritation due to diseases of the vertebral column.

CONTRAINDICATIONS

When you must not take Sopalamin-3B coated tablets?

Sopalamin-3B coated tablets must not be taken in known hypersensitivity to any of the drug ingredients.

Pregnancy and nursing period: No adverse effects during pregnancy have so far been reported after intake of vitamins B1, B6 and B12 in the recommended dosage. No studies are available on possible accumulation of the vitamins in breast milk beyond the normal range. In the individual case, the doctors will decide whether Sopalamin-3B coated tablets should be taken during pregnancy or during the nursing period.

PRECAUTIONS FOR USE AND SPECIAL WARNINGS.

Which precautions must be observed when taking Sopalamin-3B coated tablets?

You should inform your doctor immediately of any signs of side effects or in the case of pregnancy.

SPECIAL WARNINGS: 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 pharmacists are experts in medicine, its benefits and risks.
- Do not interrupt by yourself the prescribed period of treatment.
- Do not repeat the same prescription without consulting your doctor.

Keep medication out of the reach of children

INTERACTIONS

May Sopalamin-3B coated tablets be taken simultaneously with other medications?

If taken simultaneously with L-Dopa (drug against Parkinson's disease) Sopalamin-3B coated tablets can reduce the Dopa effect.

DOSAGE AND MODE OF ADMINISTRATION

How should you use Sopalamin-3B coated tablets?

Please keep strictly to the dosage prescribed by your doctor.

Generally: 4-6 tablets daily. The coated tablets should be taken whole with some liquid after meals.

OVERDOSAGE

No overdosage symptoms are to be expected in the recommended dosage.

After prolonged intake of considerably higher doses, the following complaints may occur:

Vitamin B6: Nerve lesions with motosensorial disturbances, spasms and in individual cases, changes in the blood count as well as inflammatory skin reactions after doses of more than 2g daily (equivalent to 10 Sopalamin-3B coated tablets) have been described.

Vitamin B12: Allergic reactions, eczematous skin changes and a benign form of acne after high doses have been observed in rare cases.

If you have forgotten to take Sopalamin-3B coated tablets you must not make up for it by doubling the next dose. Simply take the next dose at the usual time.

ADVERSE REACTIONS

Which adverse reactions can Sopalamin-3B coated tablets have?

There have been very rare reports of hypersensitivity reactions (e.g. skin rashes, reddening, vesicle formation) after administration of vitamin B1 but also of vitamin B12. Please consult your doctor or pharmacist if you are concerned about this or any other side effect, or if you experience other complaints.

EXPIRATION DATE AND NOTES ON STORAGE

How should you store Sopalamin-3B coated tablets?

Store at temperatures between 15-30°C

Do not use this drug after the stated expiration date.

You will find the expiration date printed on the external packaging and on the blister strip.

LAST INSTRUCTION LEAFLET REVISION DATE: November 2009

This product should be administered only after doctor's prescription