



**NEUROBION<sup>®</sup>** coated tablets

41153/SGP

Vitamins B1, B6, and B12

#### What is NEUROBION<sup>®</sup> tablet?

It is a white, round, biconvex coated tablet.

#### What is NEUROBION<sup>®</sup> tablet used for?

It is indicated for nerve pain expressed in one or more of the following symptoms: pricking/tingling sensation, numbness, muscle stiffness, muscle cramp, impaired sensation.

#### What does NEUROBION<sup>®</sup> tablet contain?

Each coated tablet contains, as active ingredients, 100 mg vitamin B1 (thiamine disulfide), 200 mg vitamin B6 (pyridoxine hydrochloride), 200 mcg vitamin B12 (cyanocobalamin).

Excipients: montan-glycol wax, acacia, povidone, methyl cellulose, magnesium stearate, purified water, calcium carbonate, glycerol, mannitol, colloidal anhydrous silica, kaolin, gelatin, titanium dioxide (E 171), sodium starch glycolate, talc, sucrose.

#### Side effects:

Symptoms	Frequency
<b>Nervous system</b> Long-term intake (> 6-12 months) of a daily dosage > 50mg vitamin B6 may cause peripheral sensory neuropathy.	Unknown: frequency cannot be estimated on the basis of the data available
<b>Gastrointestinal system</b> Gastrointestinal complaints such as nausea, vomiting, diarrhea and abdominal pain.	Unknown: frequency cannot be estimated on the basis of the data available
<b>Immune system</b> Hypersensitivity reactions such as sweating, tachycardia (rapid heartbeat) and skin reactions like itching and urticaria.	Unknown: frequency cannot be estimated on the basis of the data available
<b>Excretory system</b> Chromaturia ("reddish urine", appeared during the first 8 hours after an administration and typically resolves within 48 hours).	Unknown: frequency cannot be estimated on the basis of the data available

#### What other medicines should be avoided while taking NEUROBION<sup>®</sup> tablet?

- L-dopa: The effect of L-dopa may be reduced when vitamin B6 is administered concomitantly.
- Pyridoxine-antagonists, e.g. isoniazid (INH), cycloserine, penicillamine, hydralazine: the efficacy of vitamin B6 may be decreased.
- Loop diuretics, e.g. furosemide: In long-term use, the blood level of vitamin B1 may be reduced.

#### What should you do if you miss a dose?

- Take the missed dose as soon as you remember.
- Skip the missed dose if it is almost time for your next scheduled dose.
- Do not take extra medicine to make up the missed dose.

#### How should you keep this medicine?

- Keep out of the reach and sight of children.
- Store in a dry place, below 25 °C.
- Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.
- 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.

#### Signs and symptoms of over dosage:

- Prolonged overdose of vitamin B6 i.e. for longer than 2 months and more than 1g per day, may lead to neurotoxic effects.
- No cases of overdose with thiamine or cyanocobalamin have been described. Sensorial neuropathy and other sensorial neuropathy syndromes which can be caused by long-term administration of high doses of pyridoxine improve gradually upon vitamin discontinuation.
- If you notice any unusual symptoms of peripheral sensory neuropathy (sensation of tingling, tickling, pricking, pricking, or burning), tell your doctor immediately.

#### What to do when you have taken more than the recommended dosage:

If you (or someone else) swallow a lot of tablets at the same time, or your think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately.

#### How to take NEUROBION<sup>®</sup> tablet?

- Adults: One tablet 3 times daily.
- To be swallowed without chewing with a little liquid with or after meals.
- If symptoms persist please consult your doctor or pharmacist.

#### When should you not take NEUROBION<sup>®</sup> tablet?

- Hypersensitivity to any of the active ingredients or excipients of the product.
- Not suitable for the treatment of children due to the high content of active ingredients.

#### Effects on the ability to drive and use machines

NEUROBION<sup>®</sup> tablet has no influence on the ability to drive and use machines.

#### Pregnancy and lactation

No risks have become known associated with the use of NEUROBION<sup>®</sup> tablet during pregnancy at the recommended dosage.

Vitamin B1, B6 and B12 are secreted into human breast milk, but risks of overdose for the infant are not known. In individual cases, high doses of vitamin B6, i.e. > 600 mg daily, may inhibit the production of breast milk.

#### Long term usage

Neuropathies are described in the literature following long term intake (6-12 months) of more than 50mg mean daily dose of vitamin B6. Therefore, regular monitoring is recommended under long-term treatment.

#### When should you consult your doctor or pharmacist?

- NEUROBION<sup>®</sup> tablet contain sucrose; therefore its use is not recommended in patients with rare hereditary galactose or fructose intolerance, glucose-galactose malabsorption, Lapp lactase deficiency, or sucrase-isomaltase insufficiency
- Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, especially levodopa (for Parkinson's disease) or medicines obtained without a prescription.
- If you are pregnant particularly in the first three months, planning to become pregnant or are breast-feeding, speak to your doctor or pharmacist before taking this medicine.
- If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains sucrose.
- If symptoms persist, please consult your doctor.

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Vitamins B1, B6, and B12

#### 适应症:

本品适用于治疗具有下列一个或多个症状的神经疼痛: 刺痛/麻刺感, 麻木, 肌肉僵硬, 肌肉痉挛, 感觉减退。

#### 成分:

每粒药片含以下有效成分: 100毫克维生素B1 (二硫化硫胺)、200毫克维生素B6 (盐酸吡哆醇)、200微克维生素B12 (氰钴胺)。  
其他成分: montan-glycol wax, acacia, povidone, methyl cellulose, magnesium stearate, purified water, calcium carbonate, glycerol, mannitol, colloidal anhydrous silica, kaolin, gelatin, titanium dioxide (E 171), sodium starch glycolate, talc, sucrose。

#### 副作用:

症状	发生频率
<b>神经系统</b> 以每天>50mg的剂量长期服用 (>6-12个月) 维生素B6 可能会引起周围感觉神经病变。	未知: 发生频率无法根据现有数据进行估计。
<b>胃肠系统</b> 胃肠疾病, 例如恶心、呕吐、腹泻、腹痛。	未知: 发生频率无法根据现有数据进行估计。
<b>免疫系统</b> 超敏反应, 例如出汗、心动过速 (心跳加快); 皮肤反应, 例如瘙痒、荨麻疹。	未知: 发生频率无法根据现有数据进行估计。
<b>排泄系统</b> Chromaturia (“尿液偏红”, 在服用后8小时内出现, 通常在48小时内消退)。	未知: 发生频率无法根据现有数据进行估计。

#### 不宜与NEUROBION®片同用的药物:

同时服用维他命B6, L-dopa的疗效可能减低。  
维他命B6 – 拮抗剂 (pyridoxine - antagonists), 例如isoniazid (INH), cycloserine, penicillamine, hydralazine: 可能会减低维他命B6的疗效。  
亨氏环利尿剂 (loop diuretics), 如furosemide: 长期的使用可能会减低血液中的维他命B1。

#### 如果漏服药物, 怎么办?

想起后尽快将漏服的药物补上。如果这时已接近您下次预定服药的时间, 请跳过漏服的药物。不要通过额外服药弥补漏服的药物。

#### 如何保存药物?

请将本药保存在儿童不易触及和视线之外的地方。阴凉干燥处保存 (不超过25°C)。如本药过期, 请勿使用。失效日期是指相应月份的最后一天。药物不应丢进污水或家庭垃圾。请咨询药师如何处理多余药物以保护环境。

#### 用药过量的体征及症状:

长期过量服用维他命B6会导致神经毒性, 例如每天服用超过1克, 长达2个月以上。若发现周围神经病变的任何异常症状 (麻刺、瘙痒、刺痛、刺痛或烧灼等感觉), 应立即告诉您的医生。没有案例显示维他命B1及B12用药过量。长期服用高剂量维他命B6造成的感觉神经病变和其他感觉神经病变综合症可在停止服用后逐渐改善。

#### 用法用量:

成人剂量: 一日3次, 一次1片。饭中或饭后少量水吞服即可, 无需咀嚼。如果症状持续存在, 请咨询您的医生或药师。

#### 禁忌:

对任何一种产品成分敏感禁用。**NEUROBION®**片有效成分含量高, 不适合用于治疗儿童。

#### 如果服药量超过建议剂量, 怎么办:

如果您 (或其他人) 在同一时间吞下大量药片, 或者您认为孩子可能吞服过一定剂量的药物, 请联系离您最近医院的急诊科或者立即告诉您的医生。

#### 对驾驶和使用机器能力的影响

**NEUROBION®**片对驾驶和使用机器的能力没有影响。

#### 妊娠和哺乳

没有迹象显示在怀孕期服用所推荐的剂量**NEUROBION®**会有危险。维他命B1, B6, B12 分泌到人乳中, 但无证据在婴儿造成药物过量的危险。在成人, 高剂量的维他命B6, 如每天600毫克可能抑制人乳的产生。

#### 长期服用

资料显示长期服用 (6-12个月)超过每日平均50mg维生素B6 可引起神经病变。因此, 建议长期使用者必须定期检测。

#### 何时应咨询您的医生或药师?

**NEUROBION®**片含有蔗糖; 因此不推荐患有罕见遗传性半乳糖或果糖不耐受, 葡萄糖 - 半乳糖吸收不良, Lapp乳糖酶缺乏或蔗糖酶 - 异麦芽糖酶不足者服用。  
如果您正在服用或最近服用过其他药物, 特别是左旋多巴 (用于治疗帕金森病) 或非处方药物, 请告诉您的医生或药师。  
如果您目前怀孕 (特别是在第一个三月期间)、准备怀孕或者正在哺乳, 请在服用此药物前咨询您的医生或药师。  
如果您曾被告知对有些糖不耐受, 请在服用此药物前联系您的医生, 因为它包含蔗糖。  
如果症状持续存在, 请咨询您的医生。

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