

Package leaflet: Information for the patient 20166841

Neurobion 100 mg/50 mg/1 mg film-coated tablets
thiamine nitrate/pyridoxine hydrochloride/cyanocobalamin

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Neurobion is and what it is used for
2. What you need to know before you take Neurobion
3. How to take Neurobion
4. Possible side effects
5. How to store Neurobion
6. Contents of the pack and other information

1. What Neurobion is and what it is used for

Neurobion is a medicine containing thiamine (vitamin B1), pyridoxine (vitamin B6) and cyanocobalamin (vitamin B12) and is for use in adults only. It can be taken to prevent the levels of these vitamins in your body becoming low or to treat a deficiency when your body does not have enough of the vitamins.

Low levels of vitamin B1, B6 or B12 may happen if:

- you do not eat enough foods containing these vitamins
- your body cannot absorb the vitamins from food you have had surgery on your stomach or intestines, and it can affect how nutrients are absorbed
- you have certain conditions such as some inflammatory diseases which can increase the amount of vitamins your body uses
- you have conditions such as kidney disease which can cause your body to remove more vitamins than normal

Low levels of vitamin B1, B6 or B12 can be more common in the elderly or in patients suffering from neurological diseases, diabetes or gastrointestinal diseases such as inflammatory bowel diseases or celiac diseases.

If you have low levels of vitamin B1, B6 or B12 you may not have any symptoms at first, however you may start to experience signs such as tiredness or tingling and numbness in the hands and feet.

You should use this medicinal product only if you know that you suffer from any of the conditions or diseases listed above (i.e. the diagnosis was confirmed by a doctor) and the treatment with this medicine was recommended to you by a doctor.

2. What you need to know before you take Neurobion

Do not take Neurobion:

- if you are allergic to vitamins B1, B6, B12 or any of the other ingredients of this medicine (listed in section 6),
- if you are aged under 18 years.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Neurobion:

- if you are suffering from megaloblastic anaemia. Vitamin B12 (cyanocobalamin) may improve folate-deficient megaloblastic anaemia. Use of Neurobion may improve this condition due to the presence of vitamin B12 (cyanocobalamin) and care should be taken that a correct diagnosis is not masked.

Stop taking the product and consult your doctor, pharmacist or nurse if you experience any new symptoms during the treatment with Neurobion.

Other medicines and Neurobion

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

- Medicines used to treat Parkinson's disease, as their effect might be reduced.
- Isoniazid, cycloserine, penicillamine, or hydralazine
- Loop diuretics (medicines to increase urine output and excretion) such as furosemide.

Neurobion with food, drink and alcohol

Alcohol reduces the absorption of vitamin B1.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

No effects of Neurobion on the ability to drive or use machines are known.

Information about some of the ingredients in this medicine

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Neurobion

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults

Take 1 tablet daily. Swallow the tablet with liquid and take the tablet with or after meals.

You must talk to a doctor if you do not feel better or if you feel worse after 30 days of treatment. Do not use this product for more than 30 days without medical advice. If you want to keep taking the tablets, speak to a doctor.

Children and adolescents

Neurobion must not be used by children and adolescents below the age of 18 years due to the high dose of vitamins B1, B6 and B12.

If you take more Neurobion than you should

If you accidentally take too much Neurobion, tell your doctor or your pharmacist, or contact your nearest hospital casualty department for further advice.

Signs of neuropathy may occur when more than 1 tablet daily is taken for 6 months or longer, e.g., increased or decreased sensation for pressure, temperature and pain in the arms, hands, feet, or legs, numbness, tingling, muscle weakness, reduced reflexes, or other neurological symptoms. In this case, stop taking the product and consult your doctor, pharmacist, or nurse.

If you forget to take Neurobion

If you forget to take Neurobion take one as soon as you remember with your next meal on the same day. Do not take a double dose to make up for a forgotten tablet.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. When taking Neurobion, the following side effects may occur with the frequency 'Not known' (frequency cannot be estimated from the available data):

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Signs of allergic reactions such as sweating, tachycardia (accelerated heartbeat), and skin reactions with itching and urticaria (nettle-rash).

Gastrointestinal complaints, such as nausea (feeling sick), vomiting (being sick), diarrhoea and abdominal pain.

Chromaturia ("reddish urine" which can appear during the first hours after taking a tablet and typically resolves soon after stopping treatment).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard, or search for MHRA Yellow card in Google Play or Apple App store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Neurobion

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 foil and outer carton after EXP. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What Neurobion contains

The active substances are thiamine nitrate, pyridoxine hydrochloride and cyanocobalamin. Each coated tablet contains 100 mg thiamine nitrate, 50 mg pyridoxine hydrochloride and 1 mg cyanocobalamin.

The other ingredients are:
 Tablet core:
 Microcrystalline cellulose, gelatin, croscarmellose sodium, hydroxypropylcellulose, magnesium stearate, silica colloidal anhydrous, sodium starch glycolate.

Clear coating:
 Poly (vinyl alcohol), talc, glycerol monocaprylocaprate, sodium laurylsulfate.

White coating:
 Hydroxypropylcellulose, polydextrose, titanium dioxide, macrogol.

Polish:
 Beeswax white, carnauba wax.

What Neurobion looks like and contents of the pack

White round biconvex, film-coated tablets. Blister packed sheets contained in a cardboard box supplied in packs of 30 tablets.

Marketing Authorisation Holder
 Procter & Gamble (Health & Beauty Care) Limited, The Heights, Brooklands, Weybridge, Surrey, KT13 0XP, United Kingdom

Manufacturer
 P&G Health Austria GmbH & Co. OG
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 9800 Spittal an der Drau
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