

Package leaflet: Information for the user
Orobalin 1 mg Film-Coated Tablets
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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Orobalin is and what it is used for

Orobalin contains Vitamin B12 and is used to prevent and treat Vitamin B12 deficiency. Vitamin B12 is a vital vitamin and it is needed for normal cell division, normal production of blood and normal neurological function. Lack of Vitamin B12 can result for example in the blood deficiency disease (pernicious anaemia) and/or symptoms of the neurological system, such as sensory disturbances. Normally Vitamin B12 is provided in small amounts from food. It is absorbed by the body through the gastric acid and a special protein (intrinsic factor) which is formed in the gastric mucous. Vitamin B12 deficiency can be developed if the vitamin cannot be absorbed normally from food by the body. Orobalin is used to treat malabsorption of Vitamin B12, this can be due to the absence of intrinsic factor, stomach surgery (stomach resection) or disease of the small intestine. It can also be used during para-aminosalicylic acid therapy, which can cause impaired B12 resorption.

2. What you need to know before you take Orobalin

Do not take Orobalin:

- if you are allergic to Cyanocobalamin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Orobalin.

Other medicines and Orobalin

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

Some medicines can reduce the effectiveness of Orobalin. These include:

- Medicines against serious infections (Aminoglycosides)
- Tuberculosis medicine (para-aminosalicylic acid)
- Antiepileptics (Anticonvulsants)
- Medicines against diabetes (biguanides such as metformin)
- Medicines against infection in the eye (Chloramphenicol)
- Medicines against high cholesterol (Colestyramine) Medicines against lack of potassium (Potassium salts)
- Medicines against high blood pressure (Methyldopa)
- Medicines against excessive stomach acid (e.g. omeprazole and cimetidine).

Orobalin with food and drink

Orobalin should be taken between meals.

Pregnancy and breast-feeding

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

No harmful effects on the foetus or breast-fed children have been identified.

Driving and using machines

Orobalin does not affect the ability to drive and use machines.

3. How to take Orobalin

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

The dose should be decided by your doctor, who will adjust it individually for you.

The usual dose for adults during maintenance treatment is 1 tablet daily. At the beginning of treatment a higher dose is often prescribed: usually, 2 tablets twice daily.

The tablets should be taken between meals.

If you take more Orobalin than you should

If you take more Orobalin than you should, you are unlikely to have any ill effects. However, if you are unsure, ask your doctor or pharmacist.

If you forget to take Orobalin

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

If you stop taking Orobalin

You should consult your doctor before you stop taking Orobalin. It is important to continue taking this medicine to treat your condition.

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.

Serious side effects

The following side effects are very serious and may require immediate treatment.

Stop taking the medicine straight away and seek urgent medical advice, if any of the following side effects occur:

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

- Swelling of face, tongue or throat
- Difficulties swallowing
- Rash and breathing difficulties

Other side effects

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

- Allergic reactions including itching and swelling, rash and hives.
- Fever.

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 via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Orobalin

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

Store below 25°C.

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 Orobalin contains

- The active substance is cyanocobalamin
- The other excipients are: Microcrystalline Cellulose, Mannitol, Pregelatinised starch, Magnesium stearate, Stearic acid, Hypromellose, Macrogol 400, Titanium dioxide (E 171), Erythrosine (E 127), Yellow Iron Oxide (E 172)

What Orobalin looks like and contents of the pack

Orobalin tablets are pink, round, convex film-coated tablets, plain on both sides with 8 mm diameter.

The tablets are available in the following blister packs: 20, 30, 60, 90 and 100 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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