SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Orobalin 1 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 1 mg of Cyanocobalamin.

Cyanocobalamin contains cobalt.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Orobalin is indicated for haematological, neurological and other symptoms secondary to vitamin B12 deficiency, including:

- Nutritional B12 deficiency
- Malabsorption of vitamin B12, such as due to the absence of intrinsic factor (pernicious anaemia), stomach resection or disease of the small intestine.

It is also indicated during para-aminosalicylic acid therapy, which can cause impaired B12 resorption.

4.2 Posology and method of administration

Posology

Remission treatment: Usually, 2 tablets twice daily until full remission.

Thereafter follow maintenance dose.

Maintenance treatment/prophylaxis: Normally, 1 tablet daily.

In the event that neuropathy is suspected, parenteral treatment should be used.

Method of administration

Orobalin should be taken between meals.

4.3 Contraindications

Hypersensitivity to cyanocobalamin (vitamin B12) or any of the excipients.

4.4 Special warnings and precautions for use

None

4.5 Interaction with other medicinal products and other forms of interaction

The absorption of vitamin B12 from the gastrointestinal tract can be reduced by aminoglycosides, aminosalicylic acid, anticonvulsants, biguanides, chloramphenicol, cholestyramine, potassium salts, methyldopa and gastric-acid-inhibiting agents (e.g. omeprazole and cimetidine). The clinical relevance of many of these interactions is likely to be small.

4.6 Fertility, Pregnancy and lactation

Pregnancy

There are no known risks with use during pregnancy.

Breast-feeding

Cyanocobalamin is excreted into human milk, but at therapeutic doses of Orobalin no effects on the breastfed newborns/infants are anticipated.

4.7 Effects on ability to drive and use machines

Orobalin has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Rare (≥1/10,000 to <1/1,000)

Immune system disorders: Anaphylaxis. Fever.

Skin and subcutaneous tissue disorders: Urticaria Exanthema. Exanthematous rash. Allergic reactions, including skin reactions and angioedema.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Toxicity:

Low acute toxicity.

Symptoms:

None expected, even after very high doses.

Treatment:

Should not be required.

Symptomatic treatment might be necessary, in exceptional cases.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antianemic Preparations, Vitamin B12 (cyanocobalamin and analogues).

ATC code: B03BA01

Vitamin B12 is essential in humans and is primarily active in two important enzyme reactions. The adenosylising form is the co-factor to the mitochondrial enzyme methyl malonate mutase. This reaction is significant for normal lipometabolism. The methylated form of vitamin B12 is the co-factor for methionine synthetase and therefore essential for normal cell division. Lack of methylcobalamin is also considered to underlie demyelination as seen in vitamin B12 deficiency. A disturbance of this system leads to abnormal DNA metabolism with symptoms primarily from organs with rapid cell division, such as bone marrow and mucosa. It has been shown experimentally that a lack of the methylating form is accompanied by neurological damage.

5.2 Pharmacokinetic properties

Orally administered cyanocobalamin is absorbed passively in the duodenum and small intestines even without the presence of intrinsic factor. The degree of absorption is dose-dependent and is about 1% of a dose of 1 mg or 10–12 µg after one Cyanocobalamin tablet. This dose is sufficient for the maintenance treatment of patients with pernicious anaemia and other forms of malabsorption of vitamin B12. Oral therapy with higher doses can be given initially, but in cases of manifest B12 deficiency, parenteral therapy should be preferred for faster remission and liver repletion.

5.3 Preclinical safety data

There is no relevant preclinical data for evaluation of safety beyond that already stated in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose
Mannitol
Pregelatinised starch
Magnesium stearate
Stearic acid
Hypromellose
Macrogol 400
Titanium dioxide (E 171)
Erythrosine (E 127)
Yellow Iron Oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 25^{o}C.

6.5 Nature and contents of container

The tablets are packed in Blister pack of Alu-PVC/ PVDC

Blisters: 20, 30, 60, 90 and 100 film-coated tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Northumbria Pharma Ltd.
NetPark Incubator
Thomas Wright Way
Sedgefield
County Durham
TS21 3FD
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 48259/0045

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/02/2025

10 DATE OF REVISION OF THE TEXT

20/02/2025