

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Betolvex 1 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains: Cyanocobalamin 1 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Appearance: pink, round, convex, film-coated tablet, 8 mm diameter, CCO embossed on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Haematological, neurological and other symptoms as a result of vitamin B₁₂ deficiency.
Malabsorption of vitamin B₁₂, for example as a result of lack of intrinsic factor (pernicious anaemia),
ventricular resection or small intestinal disease.
At aminosalicylic therapy which may impair B₁₂ resorption.

4.2 Posology and method of administration

Posology

Remission therapy: Usually 2 tablets 2 times daily until full remission. Thereafter maintenance dose. At established or suspected neuropathy treatment shall be parenteral.

Maintenance dose/prophylaxis: Usually 1 tablet daily.

Method of administration

Betolvex tablets should be taken between meals.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

No specific.

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, aminosalicic acid, antiepileptics, biguanides, chloramphenicol, cholestyramine, potassium salts, methyldopa and gastric acid inhibiting substances (for example omeprazole and cimetidine). The clinical relevance of several of these interactions is probably small.

4.6 Fertility, pregnancy and lactation

Pregnancy

No known risks during pregnancy.

Breastfeeding

Excreted in breastmilk but the risk of affecting the baby seems unlikely with therapeutic doses.

4.7 Effects on ability to drive and use machines

Betolvex has no influence on the ability to drive and use machines.

4.8 Undesirable effects

System Organ Class	Frequency	Adverse reaction
Immune system disorders	Rare ($\geq 1/10,000$, $< 1/1,000$)	Anaphylaxis. Fever
Skin and subcutaneous tissue disorders	Rare ($\geq 1/10,000$, $< 1/1,000$)	Urticaria, Exathema Eczematous 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 national reporting system listed in [Appendix V](#).

4.9 Overdose

Toxicity

Low acute toxicity.

Symptoms

Not to be expected even after very high doses.

Treatment

Should not be required (symptomatic in rare cases).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Substance for peroral B₁₂ treatment, ATC code: B03BA01

Vitamine B₁₂ is essential for humans and is active particularly in two important enzyme systems. The adenosylated form is a co-factor for the microcondrial enzyme methylmalonyl CoA-mutase. This reaction is of importance for normal fatty acid metabolism. The methylated form of vitamin B₁₂ is a co-

factor for methionine synthetase and therefore essential for normal cell proliferation. Lack of methylcobalamine is also considered to be responsible for the demyelination which is seen at B₁₂ deficiency. A disturbance in this system results in abnormal DNA-metabolism with symptoms from primary organs with fast cell proliferation such as bone marrow and mucosa. Experimentally, it has been shown that lack of the methylised form is accompanied by neurological damage.

5.2 Pharmacokinetic properties

Peroral administrated cyanocobalamin is passively absorbed in duodenum and small intestines even without the presence of intrinsic factor. The extent of absorption is dose depending and approximately 1% of one dose of 1 mg or 10-12 µg after one tablet Betolvex. This dose is sufficient for maintenance therapy of patients with pernicious anaemia and other forms of malabsorption of vitamin B₁₂. Peroral treatment with higher doses can be administrated initially but at manifest B₁₂ deficiency parenteral treatment should be preferred for a faster remission and liver depot re-fill.

5.3 Preclinical safety data

There are no preclinical data of relevance for safety evaluation other than what has already been taken into account in the summary of product characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Potato starch
Pregelatinised starch
Microcrystalline cellulose
Magnesium stearate
Stearic acid
Film coat (Opadry pink):
Hypromellose (E464)
Macrogol 400
Titanium dioxide (colouring agent E 171)
Red Iron oxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

This medicine does not require any special storage conditions.

6.5 Nature and contents of container

Bottle: 30, 60, 100 tablets
1000 tablets (for dose dispensing and hospital use only)

Blister: 50x1, 98x1 tablet (for hospital use only)

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

8. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<[To be completed nationally]>

10. DATE OF REVISION OF THE TEXT

2023-06-22