SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Novavita 1 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 1 mg cyanocobalamin
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.
Pink, round, biconvex tablet, diameter 8.1 mm.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Haematological, neurological and other symptoms as a result of vitamin B_{12} deficiency.
Malabsorption of vitamin B_{12}, for example as a result of lack of intrinsic factor (pernicious anaemia), ventricular resection or small intestinal disease.
At aminosalicylic therapy which may impair B_{12} 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 parenteral treatment is indicated.

Maintenance dose/prophylaxis: Usually 1 tablet daily.

Method of administration
Novavita 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 B_{12} from the gastrointestinal tract can be reduced by aminoglycosides, aminosalicylic 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 Pregnancy and lactation

Pregnancy
No known risks during pregnancy.

Breastfeeding
Cyanocobalamin is excreted in breastmilk but at therapeutic doses of Novavita no effects on the breastfed newborns/infants are anticipated.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

	Rare ≥1/10,000, <1/1,000
Immune system disorders	Anaphylaxis. Fever
Skin and subcutaneous tissue disorders	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 [to be fulfilled nationally].

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 B_{12} treatment, ATC code: B03BA01

Vitamine B_{12} is essential for humans and is active particularly in two important enzyme systems. The adenosylated form is a co-factor for the mitocondrial enzyme methylmalonyl CoA-mutase. This reaction is of importance for normal fatty acid metabolism. The methylated form of vitamin B_{12} 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 B_{12} 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 intestine even without the presence of intrinsic factor. The extent of absorption is dose dependent and approximately 1% of one dose of 1 mg or 10-12 µg after one tablet Novavita. This dose is sufficient for maintenance therapy of patients with pernicious anaemia and other forms of malabsorption of vitamin B_{12}. Peroral treatment with higher doses can be administrated initially but at manifest B_{12} deficiency parenteral treatment should be preferred for a faster remission and liver deposit 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 this summary of product characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol (E421)
Starch, pregelatinised
Cellulose, microcrystalline (E460)
Magnesium stearate (E470b)
Stearic acid
Hypromellose (E464)
Macrogol
Titanium dioxide (E 171)
Erythrosine (E 127)
Iron oxide yellow (E 172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

HDPE bottle: 30, 50, 60, 100, 105, 110, 120, 125 and 250 tablets.
Alu-PVC/PVDC blister: 30, 50, 60 and 100 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Alternova A/S
Energivej 15
5260 Odense S
Danmark

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

2023-11-10