

PRODUCT SUMMARY

1. NAME OF THE MEDICINAL PRODUCT

Cytacon tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 micrograms Cyancobalamin BP.

3. PHARMACEUTICAL FORM

Tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Recommended Clinical Indications:

Treatment of nutritional Vitamin B₁₂ deficiency.

Treatment of vitamin B 12 deficiency following partial gastrectomy.

Treatment of tropical sprue, alone or with folic acid.

Treatment of pernicious anaemia when parenteral administration is not possible or not advised.

4.2 Posology and Method of administration

Dosage: Adults: - One to three tablets or more daily at the discretion of the physician. Alternatively, one or two 5ml spoonfuls of Cytacon liquid two or three daily, or more at the discretion of the physician. In pernicious anaemia, intramuscular therapy is preferable for initial correction of vitamin B 12 deficiency. The oral route may be follow this at dose of at least 300mcg daily.

Elderly: - As for adults. Alternatively, one or two 5ml spoonfuls of Cytacon liquid two or three daily, or more at the discretion of the physician.

Children: - One tablet daily at the discretion of the physician. Alternatively, one 5ml spoonful of Cytacon liquid two or three times daily, or more at the discretion of the physician.

When possible, Cytacon doses should be taken between meals.

Method of administration: Oral.

4.3 Contra-indications

Hypersensitivity to the product or any of the excipients.

4.4 Special Warnings and Special Precautions For Use

For pernicious anaemia, an adequate dose must be used and the blood picture must be examined regularly at least every three months for 18 months until stabilised, and then annually.

Indiscriminate administration of Cytacon may mask precise diagnosis.

4.5 Interactions with other Medicinal products and other Forms of Interaction

Absorption may be reduced by Para-aminosalicylic acid, colchicine, biguanides, neomycin, cholestyramine, potassium chloride, methyldopa, and cimetidine.

Patients treated with chloramphenicol may respond poorly to Cytacon.

Serum levels of Cyancobalamin may be lowered by oral contraceptives. These interactions are unlikely to have clinical significance.

Anti-metabolites and most antibiotics invalidate vitamins B12 assays by microbiological techniques.

4.6 Pregnancy and Lactation

Cytacon should not be used to treat megaloblastic anaemia of pregnancy because this is due to folate deficiency.

4.7 Effects on Ability to Drive and Use Machines

None.

4.8 Undesirable Effects

Sensitisation to cyanocobalamin is rare, but may present as an itching exanthema, and exceptionally as anaphylactic shock.

Acneform and bullous eruptions have been reported rarely.

Patients who have become sensitised to cyanocobalamin by injection are often able to tolerate cyanocobalamin by the oral route without trouble.

4.9 Overdose

Overdosage is unlikely to require treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Cytacon tablets contain cyanocobalamin vitamin B 12, which is used for the treatment of pernicious anaemia, and nutritional deficiencies of vitamin B 12 which results in macrocytic anaemia.

5.2 Pharmacokinetic Properties

The absorption of cobalamins from the gut is dependent upon the glycoprotein intrinsic factor. Cobalamins are transported rapidly into the blood bound to protein, known as transcobalamins. Cobalamins are stored in the liver and excreted in the bile. They are known to cross the placenta.

5.3 Preclinical Safety Data

No further relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Lactose BP
Maize Starch BP
Magnesium Stearate BP
Purified Water BP

Film coat

Hydroxypropyl Methylcellulose 2910 Ph.Eur
Ethylcellulose Ph.Eur
Acetylated Monoglyceride
Speedcolour White 27120 Ansteads HSE (Titanium dioxide, talc and polysorbate)
Isopropyl Alcohol BP
Dichloromethane BP

6.2 Incompatibilities

None stated.

6.3 Shelf Life

36 months in securitaners
24 months in blisters

6.4 Special Precautions for Storage

Securitainer

Protect from light.
Store in well closed containers.

Blisters
Store below 25°C, protected from light.

6.5 Nature and Contents of Container

Polypropylene container with a tamper evident low density polyethylene lid, containing 50 or 100 Cytaccon tablets.

Tampertainer staysafe made from high density polyethylene containing 50 or 100 tablets.

PVC/PVdC /Aluminium blister packs with 28, 56 or 112 tablets.

6.6 Instructions for Use, Handling and Disposal

None

ADMINISTRATIVE DATA

7. MARKETING AUTHORISATION HOLDER

Goldshield Group Limited
NLA Tower
Croydon
Surrey
CR0 OXT

Trading as Golshield Pharmaceuticals.

8. MARKETING AUTHORISATION NUMBER

PL 10972/0028

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16th November 1993

10. DATE OF (PARTIAL) REVISION OF TEXT

06/12/2011