

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

CYTACON 35 micrograms in 5ml LIQUID

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 5ml spoonful contains 35 micrograms of cyanocobalamin

3. PHARMACEUTICAL FORM

Syrup

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of nutritional Vitamin B₁₂ deficiency.

Treatment of vitamin B₁₂ 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 or two 5ml spoonfuls of Cytacon liquid two or three times daily, or more at the discretion of the physician.

Elderly: - The normal adult dose is appropriate for the elderly.

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

In pernicious anaemia intramuscular therapy is preferable for initial correction of vitamin B₁₂ deficiency. However, if necessary, the oral route may be used to follow this, in which case at least 300 micrograms should be given daily.

When possible, Cytacon doses should be taken between meals.

Method of administration: Oral.

4.3 Contra-indications

Hypersensitivity to the product.

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 3 months for 18 months until stabilised, and then annually.

Indiscriminate administration of Cytacon may mask the precise diagnosis.

Long term treatment with Cytacon Liquid may increase the risk of dental caries. It is important that adequate dental hygiene is maintained.

Medicines containing sugar should be administered with care to patients with Diabetes Mellitus.

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 chroamphenicol 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 of 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 B₁₂, which is used for the treatment of pernicious anaemia, and nutritional deficiencies of vitamin B₁₂ 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

Sodium carboxymethylcellulose
Syrup BP or Sucrose EP
Saccharin sodium BP
Methyl hydroxybenzoate BP
Ariavit amaranth (E123)
Citric acid monohydrate powder BP
Blackcurrant essence bush 36
Purified water

6.2 Incompatibilities

None stated.

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

Protect from light.
Store in well closed containers.

6.5 Nature and Contents of Container

200ml - Amber glass bottles with plastic child resistant closure or a polypropylene screwcap or a ropp aluminium closure with either a PVDC faced EPE wad or a LDPE faced PVDC/EPE wad.

2000ml - Amber glass bottles with screw-on polypropylene closure with natural expanded polyethylene wad, polyethylene faced.

6.6 Instructions for Use, Handling and Disposal

None

7 MARKETING AUTHORISATION HOLDER

Marketed by Goldshield Group Limited
NLA Tower,
Croydon
CR0 OXT
Trading as: Goldshield Pharmaceuticals

8. MARKETING AUTHORISATION NUMBER

PL 10972/0029

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

14th February 1994

10 DATE OF REVISION OF THE TEXT

08/10/2010