PRESCRIBING INFORMATION

Cytacon 50mcg Tablets Cytacon 35mcg/5ml Syrup

(cyancobalamin)

Presentations: Each tablet contains 50 micrograms cyancobalamin BP; Each 5ml spoonful of the syrup contains 35 micrograms cyanocobalamin.

Indications: Treatment of nutritional vitamin B12 deficiency, vitamin B 12 deficiency following partial gastrectomy, tropical sprue, alone or with folic acid, pernicious anaemia when parenteral administration is not possible or not advised.

Dosage and administration: For oral administration. *Adults:* One to three tablets or more daily at the discretion of the physician. Alternatively, one or two 5ml spoonfuls of Cytacon syrup 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, may be followed by 300mcg daily orally.

Elderly: The dosage for tablets is the same as that for adults.

Children: One tablet daily at the discretion of the physician. For the syrup, one 5ml spoonful two or three times or more daily at the discretion of the physician.

Contra-indications: Hypersensitivity to the product or any of the excipients.

Precautions and warnings: 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. **Interactions:** Para-aminosalicylic acid, colchinine, biguanides, neomycin, cholestyramine, potassium

chloride, methyldopa, and cimetidine may reduce absorption of Cytacon. Treatment with chloramphenicol may lead to poor response to Cytacon. Oral contraceptives may lower serum levels of Cytacon. **Pregnancy and lactation:** Avoid as treatment of megaloblastic anaemia of pregnancy because this is due to folate deficiency.

Undesirable effects: Sensitisation to cyancobalamin 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 cyancobalamin by the oral route without trouble.

Please refer to the Summary of Product Characteristics for detailed information.

Overdose: Unlikely to require treatment. Legal category: P Basic NHS list price: £6.24 for 50 tablets and £6.24 for per bottle of 200mls Marketing Authorization Number: Tablets: PL 10972/0028 Syrup: PL 10972/0029 Marketing Authorisation Holder: Amdipharm Mercury Company Limited (AMCo), 1st Floor, Capital House, 85 King William Street, London, EC4N 7BL. Date of Preparation: July 2012 Date of Revision: December 2013

Adverse events should be reported to the local regulatory authority. Reporting forms and information can be found at http://www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Amdipharm Mercury Medical Information on 08700 70 30 33 or by email to medicalinformation@amcolimited.com