SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<Trade Name> <Strength> tablets

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 micrograms cyanocobalamin BP.

Excipient(s) with known effect:

<Regarding the approval>

For a full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Tablets

<Regarding the approval>

1. CLINICAL PARTICULARS
   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.

* 1. Posology and method of administration

Posology

*Elderly:*

The normal dose for adults is appropriate for the elderly.

*Adults:*

One to three tablets (50 to 150 micrograms) or more daily 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

*Paediatric population:*

One tablet (50 micrograms) daily at the discretion of the physician.

When possible, this medicine doses should be taken between meals.

Method of administration

Oral

* 1. Contraindications

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

Hypersensitivity to the product or any of the excipients.

* 1. Special warnings and 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 this medicine may mask precise diagnosis.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

* 1. Interaction with other medicinal products and other forms of interaction

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

Patients treated with chloramphenicol may respond poorly to this medicine.

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

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

* 1. Fertility, pregnancy and lactation

Pregnancy

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

* 1. Effects on ability to drive and use machines

None.

* 1. Undesirable effects

Sensitisation to this medicine 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 this medicine by injection are often able to tolerate the oral route without trouble.

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 Health Product Vigilance Center; HPVC, Thai FDA.

* 1. Overdose

Overdosage is unlikely to require treatment.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

This medicine 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.

ATC code: B03BA01

* 1. Pharmacokinetic properties

Absorption

The absorption of cobalamins from the gut is dependent upon the glycoprotein intrinsic factor.

Distribution

Cobalamins are transported rapidly into the blood bound to protein, known as transcobalamins.

Elimination

Cobalamins are stored in the liver and excreted in the bile. They are known to cross the placenta.

* 1. Preclinical safety data

No further relevant data.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<Regarding the approval>

* 1. Incompatibilities

<Regarding the approval>

* 1. Shelf life

<Regarding the approval>

* 1. Special precautions for storage

<Regarding the approval>

* 1. Nature and contents of container

<Regarding the approval>

* 1. Special precautions for disposal

<Regarding the approval>

1. MARKETING AUTHORISATION HOLDER

<Regarding the approval>

1. MARKETING AUTHORISATION NUMBER(S)

<Regarding the approval>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Regarding the approval>

1. DATE OF REVISION OF THE TEXT1

<Regarding the approval>