Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cytamen 1000 micrograms/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains cyanocobalamin 1000 micrograms (1.0 mg)

Excipients: Each ml contains 3.5mg (0.154 mmol) of sodium.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

A clear red solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Addisonian pernicious anaemia.
Prophylaxis and treatment of other macrocytic anaemias associated with vitamin B12 deficiency and the Schilling test.

Investigational use in the Schilling test.

4.2 Posology and method of administration

The following dosage schemes are suitable for adults and children.

Addisonian pernicious anaemia and other macrocytic anaemias without neurological involvement:
Initially: 250 to 1,000 micrograms intramuscularly on alternate days for one or two weeks, then 250 micrograms weekly until the blood count is normal.
Maintenance: 1,000 micrograms monthly.

Addisonian pernicious anaemia and other macrocytic anaemias, anaemia with neurological complications:
Initially: 1,000 micrograms intramuscularly on alternate days as long as improvement is occurring.
Maintenance: 1,000 micrograms monthly.

Prophylaxis of macrocytic anaemia associated with vitamin B12 deficiency resulting from gastrectomy, some malabsorption syndromes and strict vegetarianism:
250 to 1,000 micrograms monthly.

Schilling test:
An intramuscular injection of 1,000 micrograms cyanocobalamin is an essential part of this test.

4.3 Contraindications

Hypersensitivity to cyanocobalamin or any other constituents.

Cytamen should not be used for the treatment of megaloblastic anaemia of pregnancy unless vitamin B12 deficiency has been demonstrated.

Not indicated for treatment of toxic amblyopias - use Neo-Cytamen.

4.4 Special warnings and precautions for use

The dosage schemes given above are usually satisfactory, but regular examination of the blood is advisable. If megaloblastic anaemia fails to respond to cyanocobalamin, folate metabolism should be investigated.

Doses in excess of 10 micrograms daily may produce an incomplete haematological response in patients with folate deficiency. Indiscriminate administration may mask the true diagnosis. The haematological and neurological state should be monitored regularly to ensure adequacy of therapy. Cardiac arrhythmias secondary to hypokalaemia during initial therapy have been reported. Plasma potassium should therefore be monitored during this period. Platelet count should be monitored during the first weeks of use in megaloblastic anaemia due to the possible occurrence of reactive thrombocytosis.

This medicinal product contains less than 1mmol sodium (23 mg) per dose, i.e. essentially 'sodium free'.

4.5 Interaction with other medicinal products and other forms of interaction

Chloramphenicol treated patients may respond poorly to Cytamen. Serum concentrations of cyanocobalamin may be lowered by oral contraceptives. Antimetabolites and most antibiotics invalidate vitamin B12 assays by microbial techniques.

4.6 Fertility, pregnancy and lactation

Cytamen should not be used for the treatment of megaloblastic anaemia of pregnancy unless vitamin B12 deficiency has been demonstrated. Cytamen is secreted into breast milk but this is unlikely to harm the infant, and may be beneficial if the mother and infant are vitamin B12 deficient.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

The following effects have been reported and are listed below by body system:

Blood and lymphatic system disorders:
Reactive thrombocytosis can occur during the first weeks of use in megaloblastic anaemia.

Disorders of the immune system:
Hypersensitivity reactions including skin reactions (e.g. rash, itching) and exceptionally anaphylaxis.

Gastro intestinal disorders:
Nausea

General disorders:
Fever, chills, hot flushing, dizziness, malaise and injection site reactions including injection site pain, injection site induration and injection site necrosis.

Neurological disorders:
Tremor.

Skin and subcutaneous tissue disorders:
Acneiform and bullous eruptions.

4.9 Overdose

Treatment is unlikely to be needed in cases of overdosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cyanocobalamin is a form of vitamin B12.

5.2 Pharmacokinetic properties

After injection of cyanocobalamin a large proportion is excreted in the urine within 24 hours; the body retains only 55% of a 100-microgram dose and 15% of a 1000-microgram dose. Vitamin B12 is extensively bound to specific plasma proteins called transcobalamins; transcobalamin II appears to be involved in the rapid transport of the cobalamins to tissues. Vitamin B12 is stored in the liver, excreted in the bile, and undergoes extensive enterohepatic recycling; part of an administered dose is excreted in the urine, most of it in the first 8 hours; urinary excretion, however, accounts for only a small fraction in the reduction of total body stores acquired by dietary means. Vitamin B12 diffuses across the placenta and also appears in breast milk.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Glacial Acetic acid (E260)
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf Life

Unopened: 18 months
Once opened, use immediately and discard any unused contents.

6.4 Special precautions for storage

Do not store above 25°C. Keep the ampoules in the outer carton in order to protect from light.

6.5 Nature and contents of container

Type 1 Glass ampoules of 1ml in boxes of 5.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use only. Discard any unused contents.

7 MARKETING AUTHORISATION HOLDER

RPH Pharmaceutical AB
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136 50 Haninge
Sweden

8 MARKETING AUTHORISATION NUMBER

PA 1638/3/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 06 May 1985

Date of last renewal: 06 May 2010

10 DATE OF REVISION OF THE TEXT

March 2011