Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Neo-Cytamen 1000 micrograms/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml ampoule contains 1000 micrograms of hydroxocobalamin (as chloride)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection
A clear red-brown solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Addisonian pernicious anaemia. Prophylaxis and treatment of other macrocytic anaemias associated with vitamin B12 deficiency. Tobacco amblyopia and Leber's optic atrophy.

4.2 Posology and method of administration

Posology
Adults and children.

Addisonian pernicious anaemia and other macrocytic anaemias without neurological involvement:

Initially: 250 to 1,000 micrograms on alternate days for one or two weeks, then 250 micrograms weekly until the blood count is normal.
Maintenance: 1,000 micrograms every two or three months.

Addisonian pernicious anaemia and other macrocytic anaemias, anaemia with neurological complications:

Initially: 1,000 micrograms on alternate days as long as improvement is occurring.
Maintenance: 1,000 micrograms every two months.

Prophylaxis of macrocytic anaemia associated with vitamin B12 deficiency resulting from gastrectomy, some malabsorption syndromes and strict vegetarianism:

1,000 micrograms every two to three months.

Tobacco amblyopia and Leber's optic atrophy:

Initially: 1,000 micrograms or more daily for two weeks then twice weekly as long as improvement is occurring.
Maintenance: 1,000 micrograms monthly.

Method of administration
Intramuscular injection

4.3 Contraindications

Hypersensitivity to hydroxocobalamin or any other constituents.

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

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 hydroxocobalamin, 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.

Sodium
This medicinal product contains less than 1 mmol sodium (23mg) per ml, that is to say essentially 'sodium free'.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

Fertility
No studies on fertility have been performed

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

Breast feeding
Neo-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.

Cardiovascular disorders:
Arrhythmias secondary to hypokalaemia.

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

Gastro intestinal disorders:
Nausea, vomiting, diarrhoea.

General disorders:
Fever, chills, hot flushing, dizziness, malaise, pain. Injection site reactions including injection site pain, injection site erythema, injection site pruritus, injection site induration, and injection site swelling

Neurological disorders:

Headache, sensory abnormalities such as paraesthesiae**.**
Tremor

Renal and unrinary disorders:
Chromaturia

Skin and subcutaneous tissue disorders:
Acneiform and bullous eruptions.

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 HPRA Pharmacovigilance Website: www.hpra.ie

4.9 Overdose

Treatment is unlikely to be needed in cases of overdosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: B03BA 03, Vitamin B12 (cyanocbalamin and analogues).
Hydroxocobalamin is a form of vitamin B12.

5.2 Pharmacokinetic properties

After injection of hydroxocobalamin, 90% of a 100-microgram dose and 30% of a 1000-microgram dose are retained. 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: 3 years.
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 Pharmaceuticals AB
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101 32 Stockholm
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8 MARKETING AUTHORISATION NUMBER

PA1638/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 May 1995

Date of last renewal: 06 May 2010

10 DATE OF REVISION OF THE TEXT

April 2024