PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS S3

PROPRIETARY NAME AND DOSAGE FORM

A-LENNON VITAMIN B12 INJECTION 1 ml (solution)

A-LENNON VITAMIN B12 INJECTION 10 ml (solution)

COMPOSITION

Each 1 ml solution of A-LENNON VITAMIN B12 INJECTION 1 ml contains 1 000 µg (1 mg) cyanocobalamin

Excipients:

Sodium chloride, water for injection.

Sugar free

Each 1 ml solution of A-LENNON VITAMIN B12 INJECTION 10 ml contains 1 000 µg (1 mg) cyanocobalamin

Excipients:

Benzyl alcohol, sodium chloride, water for injection.

Preservative: Benzyl alcohol 1 % *v/v*

Sugar free

CATEGORY AND CLASS

A 22.2 Vitamins: Other

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Cyanocobalamin is involved by way of its participation in the formation and metabolism of purines and pyrimidines, in the synthesis of nucleoproteins, and thus in the maintenance of normal haemopoiesis.

Pharmacokinetic properties

Distribution

Vitamin B_{12} binds to transcobalamin II, a plasma β-globulin, for transport to tissues. Vitamin B_{12} bound to transcobalamin II is rapidly cleared from plasma and preferentially distributed to hepatic parenchymal cells. The liver is the storage depot for other tissues. In normal adults, as much as 90 % of the body's stores of vitamin B_{12}, from 1 mg to 10 mg, is in the liver.
Vitamin B_{12} diffuses across and also appears in breast milk.

Metabolism

Vitamin B_{12} is stored as the active coenzyme with a turnover rate of 0,5 µg to 8 µg per day, depending on the size of the body stores.

Elimination

Vitamin B_{12} undergoes extensive enterohepatic recycling. Approximately 3 µg of cyanocobalamin is secreted into bile each day, 50 to 60 % of which is not destined for reabsorption.

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. After injection of cyanocobalamin a large proportion is excreted in the urine within 24 hours.

INDICATIONS

A-LENNON VITAMIN B12 INJECTION is indicated in vitamin B_{12} deficiencies manifested by:

- Megaloblastic anaemia and neurological conditions.
- Pernicious anaemia and its neurological complication, subacute combined degeneration of the spinal cord.
- Macrocytic anaemias associated with nutritional deficiencies.
- Intestinal malabsorption, megaloblastosis, diet-related deficiency, post-gastrectomy.

Indications for prophylaxis include strict vegetarianism, post-gastrectomy, and ileal resection and conditions of the small intestine that would predictably cause deficiency.

CONTRAINDICATIONS

A-LENNON VITAMIN B12 INJECTION is contraindicated in:

- Patients with hypersensitivity to vitamin B_{12} or to any of the excipients in A-LENNON VITAMIN B12 INJECTION (see COMPOSITION).
- Treatment of toxic amblyopias.
- A-LENNON VITAMIN B12 INJECTION should not be used to treat megaloblastic anaemia of pregnancy.
- A-LENNON VITAMIN B12 INJECTION 10 ml contains benzyl alcohol which must not be given to premature babies or neonates and may cause toxic reactions and anaphylactoid

reactions in infants and children up to 3 years old.

WARNINGS AND SPECIAL PRECAUTIONS

- Vitamin B_{12} should be given prophylactically only when there is a reasonable indication. Dietary deficiency in the strict vegetarian, the predictable malabsorption of vitamin B_{12} in patients who have had gastrectomy, and certain diseases of the small intestine constitute such indications.
- A-LENNON VITAMIN B12 INJECTION should not be given for treatment of deficiency until the diagnosis is fully established.
- Administration of cyanocobalamin doses greater than 10 µg daily may produce haematological response in patients with folate deficiency.
- If megaloblastic anaemia fails to respond to A-LENNON VITAMIN B12 INJECTION, folate metabolism should be investigated.
- Cardiac dysrhythmias secondary to hypokalaemia during initial therapy may occur. 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.
- Long-term therapy with A-LENNON VITAMIN B12 INJECTION must be evaluated at intervals of 6 to 12 months in patients who are otherwise well. If there is an additional illness or a condition that may increase the requirement for the vitamin, reassessment should be performed more frequently. It is important to monitor vitamin B_{12} concentrations in plasma and to obtain peripheral blood counts at intervals of 3 to 6 months to confirm the adequacy of therapy. Since refractoriness to therapy can develop at any time, evaluation must continue throughout the patient's life.
- Must not be administered intravenously.

Effects on ability to drive and use machines

Since adverse reactions such as dizziness have been reported in patients receiving A-LENNON VITAMIN B12 INJECTION, patients should not drive, use machinery or perform any tasks that require concentration, until they are certain that A-LENNON VITAMIN B12 INJECTION does not adversely affect their ability to do so (see SIDE EFFECTS).

INTERACTIONS

- *Antibiotics and antimetabolites* invalidate vitamin B_{12} assays by microbiological techniques.
- *Nitrous oxide:* prolonged nitrous oxide anaesthesia inactivates vitamin B_{12}.
- *Oral contraceptives:* may reduce blood levels of vitamin B_{12}.
- *Folic acid:* large doses given continuously may reduce vitamin B_{12} in blood.
- *Vitamin C:* may destroy vitamin B_{12}.
- *Chloramphenicol-treated* patients may respond poorly to A-LENNON VITAMIN B12 INJECTION.

HUMAN REPRODUCTION

The safety of A-LENNON VITAMIN B12 INJECTION in pregnancy and lactation has not been established.

Pregnancy

A-LENNON VITAMIN B12 INJECTION should not be used to treat megaloblastic anaemia of pregnancy.

Lactation

A-LENNON VITAMIN B12 INJECTION is secreted into breast milk.

DOSAGE AND DIRECTIONS FOR USE

Administered intramuscularly.

In the absence of neurological involvement, A-LENNON VITAMIN B12 INJECTION may be administered in doses of 250 µg to 1 000 µg intramuscularly on alternate days for 1 to 2 weeks, then 250 µg weekly until the blood count returns to normal. Maintenance doses of 1 000 µg are administered monthly.

If there is neurological involvement, A-LENNON VITAMIN B12 INJECTION may be given in doses of 1 000 µg on alternate days and continued for as long as improvement occurs.

For the prophylaxis of anaemia associated with vitamin B_{12} deficiency resulting from gastrectomy or malabsorption syndromes A-LENNON VITAMIN B12 INJECTION may be given in doses of 250 µg to 1 000 µg intramuscularly each month.

SIDE EFFECTS

Blood and the lymphatic system disorders

Less frequent: Reactive thrombocytosis can occur during the first weeks of use in megaloblastic anaemia, signs of polycythaemia vera may be unmasked, hypokalaemia

Immune system disorders

Less frequent: Hypersensitivity reactions, including skin reactions (e.g. rash, itching) and anaphylaxis

Nervous system disorders

Less frequent: Dizziness, tremor

Cardiac disorders

Less frequent: Cardiac dysrhythmias

Gastrointestinal disorders

Less frequent: Nausea, diarrhoea

Skin and subcutaneous tissue disorders

Less frequent: Acneiform and bullous eruptions, itching skin

General disorders and administrative site conditions

Less frequent: Injection site reactions including injection site pain, injection site induration and injection site necrosis. Chills, hot flushing, malaise, fever

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms

See SIDE EFFECTS.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

A-LENNON VITAMIN B12 INJECTION 1 ml: A dark red solution.

A-LENNON VITAMIN B12 INJECTION 10 ml: A dark red solution.

PRESENTATION

A-LENNON VITAMIN B12 INJECTION 1 ml:

1 x 1 ml amber Type 1 glass ampoule. 10 ampoules are packed in an outer cardboard carton together with a leaflet.

A-LENNON VITAMIN B12 INJECTION 10 ml:

1 x 10 ml amber Type 1 glass vial with an aluminium seal and red bromobutyl rubber stopper.

10, 50 or 100 vials are packed in an outer cardboard carton together with a leaflet.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

A-LENNON VITAMIN B12 INJECTION 1 ml: H2413 (Act 101/1965)

A-LENNON VITAMIN B12 INJECTION 10 ml: H2635 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Date of registration: Old medicine

Date of the most recent amendment to the professional information as approved by the Authority: 25 November 2016

Botswana:	S2
1 ml:	BOT1001623
10 ml:	BOT0600849

Namibia:	NS1
1 ml:	14/22.1/0218
10 ml:	14/22.1/0219

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