SOUTH AFRICAN 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

ZA_ALVITBINJ_1611_01

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

A-LENNON VITAMIN B12 INJECTION 1 ml

A-LENNON VITAMIN B12 INJECTION 10 ml

Solution

Read all of this leaflet carefully before you are given A-LENNON VITAMIN B12 INJECTION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- A-LENNON VITAMIN B12 INJECTION has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT A-LENNON VITAMIN B12 INJECTION CONTAINS

Each 1 ml of A-LENNON VITAMIN B12 INJECTION 1 ml contains 1 000 µg (1 mg) cyanocobalamin (vitamin B_{12})

The other ingredients are:

Sodium chloride, water for injection.

Sugar free

Each 1 ml of A-LENNON VITAMIN B12 INJECTION 10 ml contains 1 000 µg (1 mg) cyanocobalamin (vitamin B_{12})

The other ingredients are:

Benzyl alcohol, sodium chloride, water for injection.

Preservative: Benzyl alcohol 1 % *v/v*

Sugar free

WHAT A-LENNON VITAMIN B12 INJECTION IS USED FOR

A-LENNON VITAMIN B12 INJECTION is used for treatment of conditions caused by lack of vitamin B_{12}, such as:

- Blood condition in which very large red blood cells are formed (macrocytic and megaloblastic anaemia).
- Decrease in the number of red blood cells in the blood (pernicious anaemia) which may cause breakdown of the spinal cord.
- Poor absorption of vitamin B_{12} from the intestine or after surgical removal of part of the stomach (gastrectomy) or conditions of the small intestine which affect absorption of vitamin B_{12}.

A-LENNON VITAMIN B12 INJECTION may also be used to prevent a lack of vitamin B_{12} if there is a lack of vitamin B_{12} in your diet or if you are a strict vegetarian.

BEFORE YOU RECEIVE A-LENNON VITAMIN B12 INJECTION

You should not be administered A-LENNON VITAMIN B12 INJECTION

- If you are hypersensitive (allergic) to vitamin B_{12} or any of the other ingredients of A-LENNON VITAMIN B12 INJECTION.
- If you have a condition called toxic amblyopia (poor vision which may be due to lack of vitamin B_{12}).
- If you are pregnant and have megaloblastic anaemia (a condition causing very large red blood cells).
- A-LENNON VITAMIN B12 INJECTION 10 ml contains benzyl alcohol which should not be given to premature or new-born babies, and may cause harmful or allergic reactions in infants and children up to 3 years old.

Take special care with A-LENNON VITAMIN B12 INJECTION

- A-LENNON VITAMIN B12 INJECTION should only be used if your doctor has confirmed that you need to be treated for a lack of vitamin B_{12}.
- If you are receiving A-LENNON VITAMIN B12 INJECTION, your doctor may want you to have regular blood tests to check your condition. This is to make sure that your medicine is working properly and that the dose you are receiving is right for you.
- Low blood potassium levels and irregular heart beat have been reported during early stages of treatment and should be monitored by your doctor.
- A-LENNON VITAMIN B12 INJECTION should not be injected into your veins.

Pregnancy and breastfeeding

The safety of A-LENNON VITAMIN B12 INJECTION during pregnancy and whilst breastfeeding has not been established.

If you are pregnant or breastfeeding please inform your healthcare provider before this medicine is administered to you.

A-LENNON VITAMIN B12 INJECTION should not be used in pregnancy for treating a kind of anaemia called megaloblastic anaemia.

A-LENNON VITAMIN B12 INJECTION is found in breast milk.

Driving and using machinery

A-LENNON VITAMIN B12 INJECTION may make you feel dizzy.

- Do not drive until you are certain that A-LENNON VITAMIN B12 INJECTION does not interfere with your ability to drive safely.
- Do not operate any tools or machines until you are certain that A-LENNON VITAMIN B12 INJECTION does not interfere with your ability to operate tools or machines safely.

Important information about some of the ingredients in A-LENNON VITAMIN B12 INJECTION

A-LENNON VITAMIN B12 INJECTION 10 ml contains benzyl alcohol which should not be given to premature or new-born babies, and may cause harmful or allergic reactions in infants and children up to 3 years old.

Taking other medicines with A-LENNON VITAMIN B12 INJECTION

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- *Antibiotics* (for treating infections) and *antimetabolites* (medicines which stop cells from dividing): may interfere with tests used to measure vitamin B_{12} in your blood or urine.
- *Nitrous oxide* (used to make you sleep during surgery): prolonged nitrous oxide anaesthesia inactivates vitamin B_{12}.
- *Oral contraceptives* (for birth control): may decrease blood levels of vitamin B_{12}.
- *Folic acid* (vitamin): may decrease blood levels of vitamin B_{12} if large doses of folic acid are given for a long time.
- *Chloramphenicol* (antibiotic used to treat infections), as you may not respond well to A-LENNON VITAMIN B12 INJECTION if you are also taking chloramphenicol.
- *Vitamin C:* may destroy vitamin B_{12}.

HOW TO RECEIVE A-LENNON VITAMIN B12 INJECTION

A-LENNON VITAMIN B12 INJECTION will be injected into your muscle by a healthcare provider.

Your doctor will determine the frequency of your injections and how long your treatment with A-LENNON VITAMIN B12 INJECTION will last.

If you have the impression that the effect of A-LENNON VITAMIN B12 INJECTION is too strong or too weak, tell your doctor or pharmacist.

If you have received more A-LENNON VITAMIN B12 INJECTION than you should

Since a healthcare provider will administer this medicine, he/she will control the dosage. However, if you suffer any discomfort or side effects, you should tell your doctor.

POSSIBLE SIDE EFFECTS

A-LENNON VITAMIN B12 INJECTION can have side effects.

Not all side effects reported for A-LENNON VITAMIN B12 INJECTION are included in this leaflet. Should your general health worsen or if you experience any untoward effects after receiving A-LENNON VITAMIN B12 INJECTION, please consult your healthcare provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to A-LENNON VITAMIN B12 INJECTION. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice the following:

- changes in the way your heart beats, for example, if you notice an irregular heartbeat.

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

- feeling or being sick (nausea)

- frequent/loose watery stools
- dizziness
- hot flushing (reddening of the face/neck)
- chills
- fever
- muscle tremor (unintentional muscle movement)
- vague feeling of bodily discomfort; a general feeling of being unwell
- acne-like rash or blisters
- pain at the site of injection
- hard or dead skin at the site of injection.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORAGE AND DISPOSING OF A-LENNON VITAMIN B12 INJECTION

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF A-LENNON VITAMIN B12 INJECTION

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.

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

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IDENTIFICATION OF A-LENNON VITAMIN B12 INJECTION

A-LENNON VITAMIN B12 INJECTION 1 ml

A dark red solution.

A-LENNON VITAMIN B12 INJECTION 10 ml

A dark red solution.

REGISTRATION NUMBER

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NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

Tel: +27 11 239 6200 (Other)

DATE OF PUBLICATION

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1 ml:	BOT1001623
10 ml:	BOT0600849

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

ZA_ALVITBINJ_1611_01

SUID-AFRIKAANSE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

SKEDULERINGSTATUS

S3

EIENDOMSNAAM EN DOSEERVORM

A-LENNON VITAMIN B12 INJECTION 1 ml (oplossing)

A-LENNON VITAMIN B12 INJECTION 10 ml (oplossing)

SAMESTELLING

Elke 1 ml A-LENNON VITAMIN B12 INJECTION 1 ml oplossing bevat 1 000 µg (1 mg) sianokobalamien

Eksipiënte:

Natriumchloried, water vir inspuiting.

Suikervry

Elke 1 ml A-LENNON VITAMIN B12 INJECTION 10 ml oplossing bevat 1 000 µg (1 mg) sianokobalamien

Eksipiënte:

Bensielalkohol, natriumchloried, water vir inspuiting.

Preserveermiddel: Bensielalkohol 1 % *v/v*

Suikervry

KATEGORIE EN KLAS

A 22.2 Vitamiene: Ander

FARMAKOLOGIESE WERKING

Farmakodinamiese eienskappe

Sianokobalamien is deur middel van die deelname daarvan in die vorming en metabolisme van puriene en pirimidiene, betrokke in die sintese van nukleoproteïene, en dus in die handhawing van normale hemopoïese.

Farmakokinetiese eienskappe

Verspreiding

Vitamien B_{12} bind aan transkobalamien II, ’n plasma β-globulien, vir vervoer na weefsels. Vitamien B_{12} gebonde aan transkobalamien II, word vinnig vanuit plasma opgeruim en word by voorkeur versprei na hepatiese parenchiemale selle. Die lewer is die bergingsdepot vir ander weefsels. By normale volwassenes is soveel as 90 % van die liggaam se store van vitamien B_{12}, vanaf 1 mg tot 10 mg, in die lewer. Vitamien B_{12} versprei oor en verskyn ook in borsmelk.

Metabolisme

Vitamien B_{12} word gestoor as die aktiewe koënsiem met ’n omset-tempo van 0,5 µg tot 8 µg per dag, afhangende van die grootte van die liggaamstore.

Eliminasie

Vitamien B_{12} ondergaan omvattende entero-hepatiese herwinning. Ongeveer 3 µg van sianokobalamien word daagliks in gal uitgeskei, waarvan 50 tot 60 % nie vir herabsorpsie bestem is nie.

’n Gedeelte van ’n toegediende dosis word in die urine uitgeskei, meeste daarvan binne die eerste 8 uur; urinêre uitskeiding geld egter slegs vir ’n klein gedeelte van die vermindering van totale liggaamstore verkry deur middel van die dieet. Nadat sianokobalamien ingespuit is, word ’n groot gedeelte binne 24 uur in die urine uitgeskei.

INDIKASIES

A-LENNON VITAMIN B12 INJECTION is aangedui by vitamien B_{12} tekorte, wat manifesteer deur:

- Megaloblastiese anemie en neurologiese toestande.
- Pernisieuse anemie en die neurologiese komplikasie daarvan, subakute gekombineerde degenerasie van die spinale koord.
- Makrositiese anemieë wat verband hou met voedingstekorte.
- Intestinale wanabsorpsie, megaloblastose, dieetverwante tekort, post-gastrektomie.

Indikasies vir profilakse sluit streng vegetarisme, post-gastrektomie en ileale reseksie in, asook toestande van die dunderm wat na voorspelling ’n tekort aan vitamien B_{12} sal veroorsaak.

KONTRA-INDIKASIES

A-LENNON VITAMIN B12 INJECTION is teenaangedui by:

- Pasiënte met hipersensitiwiteit teenoor vitamien B_{12} of teenoor enige van die eksipiënte in A-LENNON VITAMIN B12 INJECTION (sien SAMESTELLING).
- Behandeling van toksiese ambliopieë.
- A-LENNON VITAMIN B12 INJECTION moenie gebruik word om megaloblastiese anemie van swangerskap te behandel nie.
- A-LENNON VITAMIN B12 INJECTION 10 ml bevat bensielalkohol wat nie aan vroeggebore- of pasgebore babas gegee moet word nie, en kan toksiese- en

anafilaktoïede reaksies by babas en kinders tot en met 3 jaar oud veroorsaak.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

- Vitamien B_{12} moet slegs profilakties gegee word wanneer daar ’n redelike aanduiding is. Dieet-tekort by die streng vegetariër, die voorspelbare wanabsorpsie van vitamien B_{12} by pasiënte wat ’n gastrektomie gehad het en sekere siektes van die dunderm maak sulke aanduidings uit.
- A-LENNON VITAMIN B12 INJECTION moenie gegee word vir die behandeling van ’n tekort totdat die diagnose ten volle vasgestel is nie.
- Toediening van sianokobalamien dosisse groter as 10 µg daagliks kan hematologiese reaksie by pasiënte met folaat-tekort tot gevolg hê.
- Indien megaloblastiese anemie nie reageer teenoor A-LENNON VITAMIN B12 INJECTION nie, moet folaat metabolisme ondersoek word.
- Hartdisritmieë sekondêr tot hipokalemie gedurende aanvanklike terapie kan voorkom. Plasma-kalium moet dus gedurende hierdie tydperk gemoniteer word.
- Plaatjietelling moet gemoniteer word gedurende die eerste weke van gebruik by megaloblastiese anemie weens die moontlike voorkoms van reaktiewe trombositose.
- Langtermynterapie met A-LENNON VITAMIN B12 INJECTION moet met tussenposes van 6 tot 12 maande nagegaan word by pasiënte wat andersins gesond is. Indien daar ’n bykomende siekte of toestand is wat die vereiste vir die vitamien kan verhoog, moet herevaluasie meer gereeld uitgevoer word. Dit is belangrik om vitamien B_{12} konsentrasies in plasma te moniteer en om perifere bloedtellings met tussenposes van 3 tot 6 maande te verkry om die toereikendheid van terapie te bevestig. Aangesien hardnekkigheid teenoor terapie op enige tydstip kan ontwikkel, moet evaluasie regdeur die pasiënt se lewe voortduur.
- Moenie intraveneus toegedien word nie.

Effekte op die vermoë om te bestuur en masjinerie te gebruik

Aangesien ongunstige reaksies soos duiseligheid aangemeld is by pasiënte wat A-LENNON VITAMIN B12 INJECTION ontvang, moet pasiënte nie bestuur, masjinerie gebruik of enige take verrig wat konsentrasie verg nie, totdat hulle seker is dat A-LENNON VITAMIN B12 INJECTION nie hulle vermoë om dit veilig te doen ongunstig beïnvloed nie (sien NEWE-EFFEKTE).

INTERAKSIES

- *Antibiotika en antimetaboliete* maak vitamien B_{12} essais deur mikrobiologiese tegnieke ongeldig.
- *Stikstofoksied:* verlengde stikstofoksied-narkose maak vitamien B_{12} onaktief.
- *Mondelikse voorbehoedmiddels:* kan bloedvlakke van vitamien B_{12} verminder.
- *Foliensuur:* groot dosisse wat deurlopend gegee word kan vitamien B_{12} in bloed verminder.
- *Vitamien C:* kan vitamien B_{12} vernietig.
- *Chlooramfenikol-behandelde* pasiënte kan swak reageer teenoor A-LENNON VITAMIN B12 INJECTION.

MENSLIKE VOORTPLANTING

Die veiligheid van A-LENNON VITAMIN B12 INJECTION in swangerskap en laktasie is nie vasgestel nie.

Swangerskap

A-LENNON VITAMIN B12 INJECTION moenie gebruik word om megaloblastiese anemie van swangerskap te behandel nie.

Laktasie

A-LENNON VITAMIN B12 INJECTION word in borsmelk uitgeskei.

DOSIS EN GEBRUIKSAANWYSINGS

Word intramuskulêr toegedien.

In die afwesigheid van neurologiese betrokkenheid, kan A-LENNON VITAMIN B12 INJECTION intramuskulêr toegedien word in dosisse van 250 µg tot 1 000 µg elke tweede dag vir 1 tot 2 weke, dan 250 µg weekliks totdat die bloedtelling na normaal terugkeer. Instandhoudingsdosisse van 1 000 µg word maandeliks toegedien.
Indien daar neurologiese betrokkenheid is, kan A-LENNON VITAMIN B12 INJECTION gegee word in dosisse van 1 000 µg elke tweede dag en voortgesit word vir so lank as wat verbetering voorkom.

Vir die profilakse van anemie wat verband hou met vitamien B_{12}-tekort, wat die gevolg is van gastrektomie of wanabsorpsie sindrome, kan A-LENNON VITAMIN B12 INJECTION elke maand intramuskulêr gegee word in dosisse van 250 µg tot 1 000 µg.

NEWE-EFFEKTE

Bloed en die limfstelsel versteurings

Minder dikwels: Reaktiewe trombositose kan voorkom gedurende die eerste weke van gebruik by megaloblastiese anemie, tekens van polisitemie vera kan ontmasker word, hipokalemie

Immuunstelsel versteurings

Minder dikwels: Hipersensitiwiteitsreaksies, insluitende velreaksies (bv. uitslag, jeuk) en anafilakse

Senuweestelsel versteurings

Minder dikwels: Duiseligheid, bewing

Hartversteurings

Minder dikwels: Hartdisritmieë

Gastroïntestinale versteurings

Minder dikwels: Naarheid, diarree

Vel- en onderhuidse weefsel versteurings

Minder dikwels: Akneeagtige en bulleuse uitbarstings, jeukerige vel

Algemene versteurings en toedieningsplek toestande

Minder dikwels: Inspuitingsplek reaksies insluitende pyn by die inspuitingsplek, inspuitplek verharding en inspuitplek nekrose. Kouekoors, warm gloede, malaise, koors

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Simptome

Sien NEWE-EFFEKTE.

Behandeling

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

A-LENNON VITAMIN B12 INJECTION 1 ml: ’n Donkerrooi oplossing.

A-LENNON VITAMIN B12 INJECTION 10 ml: ’n Donkerrooi oplossing.

AANBIEDING

A-LENNON VITAMIN B12 INJECTION 1 ml:

1 x 1 ml amberkleurige Tipe 1 glasampule. 10 ampules word verpak in ’n buitenste kartonhouer saam met ’n voubiljet.

A-LENNON VITAMIN B12 INJECTION 10 ml:

1 x 10 ml amberkleurige Tipe 1 glasflessie met ’n aluminiumseël en ’n rooi bromobutiel rubberprop. 10, 50 of 100 flessies word verpak in ’n buitenste kartonhouer saam met ’n voubiljet.

BERGINGSAANWYSINGS

Bêre teen of benede 25 °C.

Beskerm teen lig.

Hou in die oorspronklike verpakking totdat benodig word vir gebruik.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

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

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

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

PHARMACARE LIMITED

Healthcare Park

Woodlandsrylaan

Woodmead 2191

DATUM VAN PUBLIKASIE VAN DIE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

Datum van registrasie: Ou medisyne

Datum van die mees onlangse wysiging tot die professionele inligting soos goedgekeur deur die Gesag: 25 November 2016

Botswana:	S2
1 ml:	BOT1001623
10 ml:	BOT0600849

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

ZA_ALVITBINJ_1611_01

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS

S3

EIENDOMSNAAM EN DOSEERVORM

A-LENNON VITAMIN B12 INJECTION 1 ml

A-LENNON VITAMIN B12 INJECTION 10 ml

Oplossing

Lees hierdie hele pamflet versigtig deur voordat A-LENNON VITAMIN B12 INJECTION aan u gegee word

- Hou hierdie pamflet. Dit mag nodig wees dat u dit weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter of apteker.
- A-LENNON VITAMIN B12 INJECTION is vir u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit kan hulle skade aandoen, selfs indien hulle simptome dieselfde as u simptome is.

WAT A-LENNON VITAMIN B12 INJECTION BEVAT

Elke 1 ml A-LENNON VITAMIN B12 INJECTION 1 ml bevat 1 000 µg (1 mg) sianokobalamien (vitamien B_{12})

Die ander bestanddele is:

Natriumchloried, water vir inspuiting.

Suikervry

Elke 1 ml A-LENNON VITAMIN B12 INJECTION 10 ml bevat 1 000 µg (1 mg) sianokobalamien (vitamien B_{12})

Die ander bestanddele is:

Bensielalkohol, natriumchloried, water vir inspuiting.

Preserveermiddel: Bensielalkohol 1 % *v/v*

Suikervry

WAARVOOR A-LENNON VITAMIN B12 INJECTION GEBRUIK WORD

A-LENNON VITAMIN B12 INJECTION word gebruik vir die behandeling van toestande wat veroorsaak word deur ’n tekort aan vitamien B_{12} soos byvoorbeeld:

- Bloedtoestand waarin baie groot rooibloedselle gevorm word (makrositiese en megaloblastiese anemie).
- Verlaging in die aantal rooibloedselle in die bloed (pernisieuse anemie) wat afbraak van die ruggraat kan veroorsaak.
- Swak absorpsie van vitamien B_{12} vanuit die derm, óf na chirurgiese verwydering van ’n gedeelte van die maag (gastrektomie), óf toestande van die dunderm wat absorpsie van vitamien B_{12} beïnvloed.

A-LENNON VITAMIN B12 INJECTION kan ook gebruik word om ’n tekort aan vitamien B_{12} te verhoed indien daar ’n tekort aan vitamien B_{12} in u dieet is, of indien u ’n streng vegetariër is.

VOORDAT U A-LENNON VITAMIN B12 INJECTION ONTVANG

A-LENNON VITAMIN B12 INJECTION moenie aan u toegedien word nie

- Indien u hipersensitief (allergies) is vir vitamien B_{12} of enige van die ander bestanddele van A-LENNON VITAMIN B12 INJECTION.

- Indien u ’n toestand het wat toksiese ambliopie (swak visie wat die gevolg kan wees van te min vitamien B_{12}) genoem word.
- Indien u swanger is en megaloblastiese anemie (’n toestand wat baie groot rooibloedselle veroorsaak) het.
- A-LENNON VITAMIN B12 INJECTION 10 ml bevat bensielalkohol wat nie aan vroeggebore of pasgebore babas gegee moet word nie, en kan skadelike of allergiese reaksies by babas en kinders tot en met 3 jaar oud veroorsaak.

Neem spesiale sorg met A-LENNON VITAMIN B12 INJECTION

- A-LENNON VITAMIN B12 INJECTION moet slegs gebruik word indien u dokter bevestig het dat u vir ’n tekort aan vitamien B_{12} behandel moet word.
- Indien u A-LENNON VITAMIN B12 INJECTION ontvang, kan u dokter moontlik wil hê dat u vir gereelde bloedtoetse moet gaan om u toestand te moniteer. Dit is om seker te maak dat u medisyne behoorlik werk en dat die dosis wat u ontvang reg is vir u.
- Lae kalium bloedvlakke en onreëlmatige hartklop is aangemeld gedurende vroeë stadiums van behandeling en moet gemoniteer word deur u dokter.
- A-LENNON VITAMIN B12 INJECTION moenie in u are ingespuit word nie.

Swangerskap en borsvoeding

Die veiligheid van A-LENNON VITAMIN B12 INJECTION gedurende swangerskap en terwyl u borsvoed is nie vasgestel nie.

Indien u swanger is of borsvoed, laat weet asseblief u gesondheidsorgdeskundige voordat hierdie medisyne aan u toegedien word.

A-LENNON VITAMIN B12 INJECTION moenie gebruik word in swangerskap, vir die behandeling van ’n tipe anemie wat megaloblastiese anemie genoem word, nie.
A-LENNON VITAMIN B12 INJECTION word in borsmelk gevind.

Bestuur en gebruik van masjinerie

A-LENNON VITAMIN B12 INJECTION kan u laat duiselig voel.

- Moenie bestuur totdat u seker is dat A-LENNON VITAMIN B12 INJECTION nie inmeng met u vermoë om veilig te bestuur nie.
- Moenie enige gereedskap of masjinerie bedryf totdat u seker is dat A-LENNON VITAMIN B12 INJECTION nie met u vermoë om gereedskap of masjinerie veilig te bedryf, inmeng nie.

Belangrike inligting aangaande sommige van die bestanddele in A-LENNON VITAMIN B12 INJECTION

A-LENNON VITAMIN B12 INJECTION 10 ml bevat bensielalkohol wat nie aan vroeggebore of pasgebore babas gegee moet word nie, en kan skadelike of allergiese reaksies by babas en kinders tot en met 3 jaar oud veroorsaak.

Die neem van ander medisyne saam met A-LENNON VITAMIN B12 INJECTION

Vertel altyd u gesondheidsorgverskaffer indien u enige ander medisyne neem (dit sluit komplementêre of tradisionele medisyne in).

Vertel u dokter indien u enige van die die volgende medisyne neem:

- *Antibiotika* (vir die behandeling van infeksies) en *antimetaboliete* (medisyne wat selle laat ophou verdeel): kan inmeng met toetse wat gebruik word om vitamien B_{12} in u bloed of urine te meet.
- *Stikstofoksied* (gebruik om u te laat slaap gedurende chirurgie): verlengde stikstofoksied-narkose maak vitamien B_{12} onaktief.
- *Mondelikse voorbehoedmiddels* (vir geboortebeperking): kan vitamien B_{12} bloedvlakke verminder.
- *Foliensuur* (vitamien): kan bloedvlakke van vitamien B_{12} verlaag indien groot dosisse foliensuur vir ’n lang tydperk gegee word.

- *Chlooramfenikol* (antibiotika wat gebruik word om infeksies te behandel), aangesien u moontlik nie goed mag reageer teenoor A-LENNON VITAMIN B12 INJECTION, indien u chlooramfenikol ook neem nie.
- *Vitamien C:* kan vitamien B_{12} vernietig.

HOE OM A-LENNON VITAMIN B12 INJECTION TE ONTVANG

A-LENNON VITAMIN B12 INJECTION sal in u spier ingespuit word deur ’n gesondheidsorgverskaffer.

U dokter sal die frekwensie van u inspuitings bepaal asook hoe lank u behandeling met A-LENNON VITAMIN B12 INJECTION sal voortduur.

Indien u die indruk kry dat die effek van A-LENNON VITAMIN B12 INJECTION te sterk of te swak is, vertel u dokter of apteker.

Indien u meer A-LENNON VITAMIN B12 INJECTION ontvang as wat u moet

Aangesien ’n gesondheidsorgdeskundige hierdie medisyne sal toedien, sal hy/sy die dosis beheer. Indien u egter aan enige ongemak of newe-effekte ly, moet u u dokter vertel.

MOONTLIKE NEWE-EFFEKTE

A-LENNON VITAMIN B12 INJECTION kan newe-effekte hê.

Nie alle newe-effekte wat vir A-LENNON VITAMIN B12 INJECTION aangemeld is, word in hierdie pamflet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste effekte ervaar nadat u A-LENNON VITAMIN B12 INJECTION ontvang het, raadpleeg asseblief u gesondheidsorgdeskundige vir advies.

Indien enige van die volgende gebeur, vertel onmiddellik vir u dokter of gaan na die ongevalle afdeling by u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat sluk- of asemhalingsprobleme kan veroorsaak
- uitslag of jeuk
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit het, kon u ’n ernstige allergiese reaksie teenoor A-LENNON VITAMIN B12 INJECTION gehad het. U mag dringende mediese aandag of hospitalisasie benodig.

Vertel onmiddellik u dokter of gaan na die ongevalle afdeling by u naaste hospitaal indien u enige van die volgende opmerk:

- verandering in die manier wat u hart klop, byvoorbeeld, indien u opmerk dat u hart onreëlmatig klop.

Hierdie is ’n ernstige newe-effek. U mag dringende mediese aandag benodig.

Vertel u dokter indien u enige van die volgende opmerk:

Die volgende newe-effekte is minder dikwels aangemeld:

- siek voel of siek wees (naarheid)
- gereelde/los waterige stoelgange
- duiseligheid
- warm gloede (verrooiing van die gesig/nek)
- koue koors
- koors
- spierbewing (onbedoelde spierbeweging)
- vae gevoel van liggaamsongemak; ’n algemene gevoel van ongesteldheid
- akneeagtige uitslag of blase
- pyn by die plek van inspuiting

- harde of dooie vel by die plek van inspuiting.

Indien u enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief u dokter of apteker in kennis.

BERGING EN WEGDOENING VAN A-LENNON VITAMIN B12 INJECTION

Bêre teen of benede 25 °C.

Beskerm teen lig.

Hou in die oorspronklike vepakking totdat benodig word vir gebruik.

Moenie in ’n badkamer bêre nie.

Moenie gebruik na die vervaldatum wat op die etiket vertoon word nie.

Neem alle ongebruikte medisyne terug na u apteker.

Moenie van ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) wegdoen nie.

BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

AANBIEDING VAN A-LENNON VITAMIN B12 INJECTION

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’n Donkerrooi oplossing.

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

NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

PHARMACARE LIMITED

Healthcare Park

Woodlandsrylaan

Woodmead 2191

Blitslyn: 0800 122 912 (Suid-Afrika)

Tel: +27 11 239 6200 (Ander)

DATUM VAN PUBLIKASIE

Datum van registrasie: Ou medisyne

Datum van die mees onlangse wysiging tot die pasiëntinligtingspamflet soos goedgekeur deur die Gesag: 25 November 2016

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