1.3.2 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.

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.

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

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

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

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)

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DATE OF PUBLICATION

Date of registration: Old medicine

Date of the most recent amendment to the patient information leaflet 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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