1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

A-LENNON VITAMIN B COMPLEX INJECTION 2 ml

A-LENNON VITAMIN B COMPLEX INJECTION 10 ml

COMPOSITION

Each 1 ml of A-LENNON VITAMIN B COMPLEX INJECTION 2 ml contains:

Nicotinamide 100 mg

Thiamine hydrochloride 10 mg

d-panthenol 5 mg

Pyridoxine hydrochloride 5 mg

Riboflavin 2 mg

Excipients:

Water for injection

Sugar free.

Each 1 ml of A-LENNON VITAMIN B COMPLEX INJECTION 10 ml contains:

Nicotinamide 100 mg

Thiamine hydrochloride 10 mg

d-panthenol 5 mg

Pyridoxine hydrochloride 5 mg

Riboflavin 2 mg

Excipients:

Chlorbutol, water for injection

Preservative: Chlorbutol 0,5 % m/v

Sugar free.

CATEGORY AND CLASS

A 22.2 Vitamins: Other

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Nicotinamide

Nicotinamide is a water-soluble vitamin of the vitamin B complex. Nicotinamide functions as a component of two coenzymes, nicotinamide adenine dinucleotide and nicotinamide adenine dinucleotide phosphate (NADP). These coenzymes participate in many metabolic processes including glycolysis, tissue respiration, lipid, amino acids and purine metabolism.

Thiamine hydrochloride

Thiamine is a water-soluble vitamin of the vitamin B complex. It is also known as vitamin B_1. Thiamine functions as a coenzyme in the oxidative decarboxylation of alpha-ketoacids (involved in energy production) and in the transketolase reaction of the pentose phosphate pathway (involved in carbohydrate metabolism). Thiamine is also important in nerve transmission (independently of coenzyme function).

d-Panthenol

d-Panthenol is the alcohol of pantothenic acid (vitamin B_5). It is a congener of pantothenic acid, a precursor of coenzyme A. Pantothenic acid functions mainly as a component of coenzyme A and acyl carrier protein. Coenzyme A has a central role as a cofactor for enzymes involved in the metabolism of lipids, carbohydrates and proteins. It is also required for the synthesis of cholesterol, steroid hormones, acetylcholine and porphyrins. As a component of acyl carrier protein, pantothenic acid is involved in various transfer reactions and in the assembly of acetate units into longer-chain fatty acids.

Pyridoxine hydrochloride

Pyridoxine is a water-soluble member of the vitamin B complex. Vitamin B_6 is a generic term used to describe compounds that exhibit the biological activity of pyridoxine.
Pyridoxine is converted in erythrocytes to pyridoxal phosphate and, to a lesser extent, pyridoxamine phosphate. It acts as a cofactor for enzymes that are involved in reactions affecting protein, lipid and carbohydrate metabolism. Pyridoxal phosphate is also involved in the synthesis of several neurotransmitters; the metabolism of several vitamins (e.g. the conversion of tryptophan to niacin); and haemoglobin and sphingosine formation.

Riboflavin

Riboflavin is a water-soluble vitamin of the vitamin B complex. It is also known as vitamin B_2. Riboflavin functions as a component of two flavin coenzymes, flavin mononucleotide (FMN) and flavin adenine dinucleotide (FAD). It participates in oxidation – reduction reactions in numerous metabolic pathways and in energy production. Examples include the oxidation of glucose, certain amino acids and fatty acids; reactions with several intermediaries of the Krebs cycle; conversion of pyridoxine to its active coenzyme; and conversion of tryptophan to niacin.

Pharmacokinetic properties

Nicotinamide

Distribution

Nicotinamide is widely distributed in the body tissues.

Metabolism

The main route of metabolism is their conversion to *N*-methylnicotinamide and the 2-pyridone and 4-pyridone derivatives: nicotinuric acid is also formed.

Elimination

Small amounts of nicotinamide are excreted unchanged in urine after therapeutic doses, however the amount excreted unchanged is increased with larger doses.

Thiamine hydrochloride

Distribution

Thiamine is transported in the plasma bound to albumin, and stored in the heart, liver, muscle, kidneys and brain. Only small amounts are stored and turnover is relatively high.

Metabolism

Thiamine is rapidly converted to its biologically active form, thiamine pyrophosphate (TPP).

Elimination

Thiamine is eliminated mainly in the urine (as metabolites). Excess beyond requirements is excreted as free thiamine. Thiamine crosses the placenta and is excreted in breast milk.

d-Panthenol

Distribution

Pantothenic acid is widely distributed in body tissues (particularly in the liver, adrenal glands, heart and kidneys), mainly as coenzyme A.

Elimination

About 70 % is excreted unchanged in the urine and 30 % in the faeces.

Pyridoxine hydrochloride

Distribution

Pyridoxine is stored in the liver, muscle and brain. Pyridoxal phosphate is transported in the plasma (bound to albumin) and in erythrocytes (in association with haemoglobin).

Elimination

Pyridoxine is eliminated primarily in the urine (mainly as metabolites), but excess amounts are excreted largely unchanged. It also appears in breast milk.

Riboflavin

Distribution

Some circulating riboflavin is loosely associated with plasma albumin, but significant amounts complex with other proteins. Conversion of riboflavin to its coenzymes occur in most tissues (particularly in the liver, heart and kidney).

Elimination

Riboflavin is excreted primarily in the urine (mostly as metabolites); excess amounts are excreted unchanged. Riboflavin crosses the placenta and is excreted in breast milk.

INDICATIONS

A-LENNON VITAMIN B COMPLEX INJECTION is indicated as a dietary supplement where a deficiency of vitamins exists.

CONTRAINDICATIONS

A-LENNON VITAMIN B COMPLEX INJECTION is contraindicated in patients with hypersensitivity to any of the active ingredients (see COMPOSITION).

WARNINGS AND SPECIAL PRECAUTIONS

Thiamine hydrochloride

Hypersensitivity reactions have occurred with thiamine, mainly after parenteral doses. These reactions have ranged in severity from very mild to, very rarely, fatal anaphylactic shock.

Pyridoxine

Effects of levodopa are reversed by pyridoxine (even doses as low as 5 mg daily). Pyridoxine supplements should be avoided (see INTERACTIONS).

Riboflavin

Large doses of riboflavin result in a bright yellow discolouration of the urine that may interfere with certain laboratory tests.

Effects on ability to drive and use machines

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

INTERACTIONS

Thiamine hydrochloride

- *Alcohol:* excessive alcohol intake induces thiamine deficiency.
- *Furosemide:* may increase urinary loss of thiamine; prolonged furosemide therapy may induce thiamine deficiency.

d-Panthenol

- *Alcohol:* excessive alcohol intake may increase requirement for pantothenic acid.
- *Oral contraceptives*: may increase requirement for pantothenic acid.

Pyridoxine hydrochloride

- *Alcohol:* increases turnover of pyridoxine.
- *Anti-epileptic medication*: enzyme-inducing anti-epileptic medicines (phenytoin, carbamazepine) may cause pyridoxine deficiency.
- *Cycloserine*: may cause anaemia or peripheral neuritis by acting as pyridoxine antagonist.
- *Hydralazine*: may cause anaemia or peripheral neuritis by acting as pyridoxine antagonist.
- *Isoniazid*: may cause anaemia or peripheral neuritis by acting as pyridoxine antagonist.
- *Levodopa*: effects of levodopa are reversed by pyridoxine (even doses as low as 5 mg daily). Pyridoxine supplements should be avoided (see WARNINGS AND SPECIAL PRECAUTIONS).
- *Oestrogens*: (including oral contraceptives) may increase requirement for pyridoxine.
- *Penicillamine*: may cause anaemia or peripheral neuritis by acting as pyridoxine antagonist.
- *Theophylline*: may increase requirement for pyridoxine.

Riboflavin

- *Alcohol*: excessive alcohol intake induces riboflavin deficiency.

- *Barbiturate*s: prolonged use may induce riboflavin deficiency.
- *Oral contraceptives:* prolonged use may induce riboflavin deficiency.
- *Phenothiazines:* may increase the requirement for riboflavin.
- *Probenecid:* reduces gastrointestinal absorption and urinary excretion of riboflavin.
- *Tricyclic antidepressants:* may increase the requirement for riboflavin.

PREGNANCY AND LACTATION

The safety of LENNON VITAMIN B COMPLEX INJECTION in pregnancy and lactation has not been established.

No adverse effects have been noted at recommended doses. However animal studies are insufficient with respect to effects on pregnancy, embryonal/foetal development, parturition and/or postnatal development.

Thiamine crosses the placenta and is excreted in breast milk.

Pyridoxine appears in breast milk. Large doses may result in pyridoxine dependency in infants.

DOSAGE AND DIRECTIONS FOR USE

Deficiency can be reversed by thiamine in doses as small as 500 µg daily.

A therapeutic dose of 1 to 2 ml daily is recommended.

A-LENNON VITAMIN B COMPLEX INJECTION 2 ml:

IM or slowly and with caution IV.

A-LENNON VITAMIN B COMPLEX INJECTION 10 ml:

For IM use only.

A-LENNON VITAMIN B COMPLEX INJECTION must be injected slowly.

SIDE EFFECTS

A-LENNON VITAMIN B COMPLEX INJECTION is usually well tolerated.

Nervous system disorders

Less frequent: paraesthesia

Vascular disorders:

Less frequent: hypotension

General disorders and administrative site conditions

Less frequent: injection site reactions (including pain and swelling)

Nicotinamide:

Chronic administration of large doses may cause:

Nervous system disorders:

Less frequent: headache

Eye disorders

Less frequent: blurred vision

Respiratory, thoracic and mediastinal disorders

Less frequent: sore throat

Gastrointestinal disorders

Less frequent: nausea, heartburn

Skin and subcutaneous tissue disorders

Less frequent: dry skin, dry hair

General disorders and administrative site conditions

Less frequent: headaches, fatigue, sore throat, dry hair

Thiamine hydrochloride:

Immune system disorders

Less frequent: hypersensitivity reactions, anaphylactic reactions (coughing, difficulty in breathing and swallowing, flushing, skin rash, swelling of face, lips and eyelids) (see WARNINGS AND SPECIAL PRECAUTIONS)

d-Panthenol

Gastrointestinal disorders

Less frequent: diarrhoea

Pyridoxine:

Adverse effects usually occur with large doses only. Doses of 100–150 mg daily over 5-10 years has not generally been associated with toxicity.

Riboflavin

Riboflavin toxicity is unknown in humans.

Renal and urinary disorders

Less frequent: yellow discolouration of the urine (see WARNINGS AND SPECIAL PRECAUTIONS)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

A-LENNON VITAMIN B COMPLEX INJECTION contains water-soluble vitamins which are readily excreted.

In the event of an overdosage, treatment is symptomatic and supportive.

IDENTIFICATION

A clear yellow solution.

PRESENTATION

A-LENNON VITAMIN B COMPLEX INJECTION 2 ml: 1 x 2 ml amber Type 1 glass ampoule. 10 or 100 ampoules are packed in an outer container.

A-LENNON VITAMIN B COMPLEX INJECTION 10 ml: 1 x 10 ml amber Type 1 glass vial with a round flanged butyl rubber stopper and a green aluminium seal. 10, 50 or 100 vials are packed in an outer container.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store in a cool place at or below 25˚C.

Protect from light.

Do not freeze.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

H2412 (Act 101/1965)- A-LENNON VITAMIN B COMPLEX 2 ml

H2975 (Act 101/1965)- A-LENNON VITAMIN B COMPLEX INJECTION 10 ml

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

Dates of registration: Old medicines

Date of the most recent amendment to the professional information as approved by the Authority: 11 December 2019

Namibia:	NS1
2 ml	15/22.1.4/0126
10 ml	15/22.1.4/0127