1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

A-LENNON CALCIFEROL

tablet

Read all of this leaflet carefully before you start using A-LENNON CALCIFEROL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- A-LENNON CALCIFEROL 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 CALCIFEROL CONTAINS

The active substance in each tablet of A-LENNON CALCIFEROL is 1,25 mg ergocalciferol (equivalent to 50 000 IU of vitamin D_2).

The other ingredients are acacia powder, benzoic acid, calcium carbonate light, cetyl palmitate, cocoa, gelatin, kaolin heavy, lactose monohydrate, Lennon red (C.I. 45430), Lennon violet, magnesium stearate, maize starch, propyl hydroxybenzoate sodium, purified talc, sodium benzoate, sodium ethyl parabenzoate, sodium methyl

parahydroxybenzoate, sucrose, titanium dioxide (dye Lennon white).

Contains sugar: Sucrose 140,13 mg and lactose monohydrate 136,1 mg

WHAT A-LENNON CALCIFEROL IS USED FOR

A-LENNON CALCIFEROL is a form of Vitamin D.

A-LENNON CALCIFEROL is used to treat:

- Weak bones and teeth (called rickets)
- Other problems with how bones are formed (called osteomalacia)
- Low levels of parathyroid hormone (hypoparathyroidism)

These disorders are due to poor absorption of Vitamin D.

BEFORE YOU TAKE A-LENNON CALCIFEROL

Do not TAKE A-LENNON CALCIFEROL

- If you are hypersensitive (allergic) to calciferol or any of the other ingredients of A-LENNON CALCIFEROL (see WHAT A-LENNON CALCIFEROL CONTAINS)
- If you have high levels of calcium in your blood.
- If you have kidney stone disease (whereby calculi called stones are formed within the renal pelvis and tubular lumens).
- If you have any severe kidney problems.
- If you have abnormal state resulting from excessive intake of one or more vitamins.
- If you are pregnant or breastfeeding your baby.

Take special care with A-LENNON CALCIFEROL

- If you are taking barbiturates or anticonvulsants (medicines used to treat epilepsy) as this may reduce the effects of A-LENNON CALCIFEROL.
- If you had intestinal bypass surgery or inflammation of the intestine, you may fail to absorb Vitamin D.
- If you have liver problems, you may have a problem to absorb Vitamin D.
- If you are already receiving adequate amount of calcium through your diet and exposure to sunlight.
- If you have heart disease, problems with your kidneys or with your circulation.
- If you suffer from sarcoidosis (inflammatory disease that affects the lungs mostly).
- If you require calcium supplementation, your doctor should monitor you.
- If you have nausea and vomiting after using A-LENNON CALCIFEROL.

Adverse events are generally associated with excessive intake of A-LENNON CALCIFEROL leading to the development of hypercalcaemia.

Taking A-LENNON CALCIFEROL with food and drink

A-LENNON CALCIFEROL tablet should be taken whole with water, preferably with your main meal of the day.

Pregnancy and breastfeeding

You should not take A-LENNON CALCIFEROL if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking A-LENNON CALCIFEROL.

Effects on ability to drive and use machines

Since adverse reactions such as dizziness and drowsiness have been reported in patients receiving A- LENNON CALCIFEROL, you should not drive, use machinery or perform any tasks that require concentration until you are certain that A- LENNON CALCIFEROL does not adversely affect your ability to do so.

Important information about some of the ingredients in A-LENNON CALCIFEROL

A-LENNON CALCIFEROL contains lactose monohydrate and sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption, fructose intolerance or sucrase-isomaltase insufficiency should not take A-LENNON CALCIFEROL.

Taking other medicines with A-LENNON CALCIFEROL

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:

- *Magnesium-containing antacids:* Used to treat stomach upset, acid indigestion and heartburn
- *Digoxin:* Used to treat congestive heart failure
- *Verapamil:* Used to treat hypertension (high blood pressure), angina (chest pain), and certain heart rhythm disorders.

- *Anti-convulsants:* Medicines that prevent or reduce the severity and the number of seizures (a sudden attack, spasm, or convulsion) in various types of epilepsy e.g. carbamazepine, phenobarbitone, phenytoin and primidone).
- *Thiazide diuretics:* Decrease the blood volume by diuresis (discharge of urine, in unusually large amounts) and are used in the treatment of high blood pressure.
- *Rifampicin:* Antibiotic used to treat various types of bacterial infection.
- *Isoniazid:* Antibiotic used in the treatment of tuberculosis (TB).
- *Glucocorticoids:* Medicines that are used for inflammatory disorders.
- *Orlistat:* Treatment for obesity.
- *Liquid paraffin:* Medicine used to treat constipation.
- *Cholestyramine:* Medicine used to remove bile from your body.
- *Actinomycin:* Medicine used to treat cancer.
- *Antifungal medicines:* Medicines used to treat fungal infections.

HOW TO TAKE A-LENNON CALCIFEROL

Do not share medicines prescribed for you with any other person.

Always take A-LENNON CALCIFEROL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual doses are:

In the treatment of rickets and osteomalacia:

One tablet daily (50 000 units)

In the treatment of hypoparathyroidism:

One to four tablets daily (50 000 to 200 000 units)

Your doctor will tell you how long your treatment with A-LENNON CALCIFEROL will last.

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

If you take more A-LENNON CALCIFEROL than you should:

You may experience the following due to increased calcium levels in your blood: feeling sick, feeling weak, weight loss, stiffness, constipation, diarrhoea, abdominal pain, muscle weakness and bone pain.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of A-LENNON CALCIFEROL

Take your missed dose as soon as you remember, if within a few hours after missing a dose. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

A-LENNON CALCIFEROL can have side effects.

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

If any of the following happens, stop taking A-LENNON CALCIFEROL and 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to A-LENNON CALCIFEROL. 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 any of the following:

- Hypercalcaemia (increased calcium levels in your blood),
- changes in the way your heart beats, for example, if you notice it beating faster,
- kidney failure (symptoms of kidney failure are due to the build-up of waste products and excess fluid in the body that may cause weakness, shortness of breath, lethargy, swelling, and confusion. Inability to remove potassium from the bloodstream may lead to abnormal heart rhythms and sudden death).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- Elevated serum creatinine levels.

The following side effects have been reported less frequently:

- Pruritus (severe itching of the skin),

- urticaria (hives),
- hypercalciuria (increased calcium in the urine).

The following side effects have been reported with a frequency unknown:

- Anorexia (not eating),
- weight loss,
- mild acidosis (increase in acidity of the blood),
- polydipsia (abnormally great thirst),
- mental disturbances, irritability, decrease libido (sex drive), overt psychosis (mental disorder),
- headache,
- somnolence (sleepiness),
- conjunctivitis (eye infection), photophobia (condition in which bright light affects your eyes),
- vertigo (sensation of feeling off-balance),
- generalised vascular calcification (complication of chronic kidney disease), hypertension (high blood pressure),
- rhinorrhoea (runny nose),
- nausea,
- vomiting,
- dry mouth,
- constipation,
- diarrhoea,
- abdominal pain,
- pancreatitis (inflammation of the pancreas),

- muscle weakness or pain,
- bone pain,
- ectopic calcification (deposit of calcium salts in bone),
- nephrocalcinosis (deposit of calcium in the kidney),
- polyuria (production of abnormally large volumes of dilute urine),
- nocturia (excessive urination at night),
- albuminuria (presence of albumin on the urine),
- reversible uraemia (a raised level in the blood of urea and other nitrogenous waste compounds that are normally eliminated by the kidneys),
- fatigue (tiredness),
- weakness,
- hyperthermia (the condition of having a body temperature greatly above normal),
- elevated BUN,
- elevated AST and ALT.

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

STORAGE AND DISPOSING OF A-LENNON CALCIFEROL

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 CALCIFEROL

100 tablets packed in a white, polypropylene securitainer with a white low density polyethylene closure together with a carbon pillow pack and leaflet.

IDENTIFICATION OF A-LENNON CALCIFEROL

Mauve sugar coated normal biconvex tablet.

REGISTRATION NUMBER

H2053 (Act 101/1965)

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE APPLICANT

PHARMACARE LIMITED

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