1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

A-LENNON DICLOFENAC 25 mg (tablet)

A-LENNON DICLOFENAC 50 mg TABLET

A-LENNON DICLOFENAC 100 mg SUPPOSITORY

COMPOSITION

A-LENNON DICLOFENAC 25 mg:

Each film-coated tablet of A-LENNON DICLOFENAC 25 mg contains 25 mg of diclofenac sodium

Excipients:

Colloidal anhydrous silica, iron oxide yellow (C.I. 77492), lactose monohydrate, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, simethicone, sodium lauryl sulfate, sodium starch glycolate, starch maize, talc, titanium dioxide (C.I. 77891), triethyl citrate

Contains sugar: Lactose monohydrate 85 mg

A-LENNON DICLOFENAC 50 mg TABLET:

Each film-coated tablet of A-LENNON DICLOFENAC 50 mg TABLET contains 50 mg of diclofenac sodium

Excipients:

Colloidal anhydrous silica, iron oxide red (C.I. 77491), lactose monohydrate, magnesium stearate, methacrylic acid copolymer, povidone, simethicone, sodium bicarbonate, sodium lauryl sulphate, starch maize, talc, titanium dioxide (C.I. 77891), triethyl citrate, yellow iron oxide (C.I. 77492)

Contains sugar: Lactose monohydrate 86 mg

A-LENNON DICLOFENAC 100 mg SUPPOSITORY:

Each suppository of A-LENNON DICLOFENAC 100 mg SUPPOSITORY contains 100 mg of diclofenac sodium

Excipient:

Suppocire

CATEGORY AND CLASS

A 3.1 Antirheumatics (anti-inflammatory agents)

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Diclofenac is a non-steroidal compound with analgesic, anti-inflammatory, antirheumatic and antipyretic properties.

Pharmacokinetic properties

A single 50 mg dose of enteric-coated tablets results in maximum plasma concentrations of about 1 500 ng/ml at 1,5 to 2 hours after ingestion.

Diclofenac sodium is eliminated principally by metabolism and subsequently urinary and biliary excretion of glucuronide and sulphate conjugates of the metabolites. The principle metabolite in man is the 4-hydroxy derivative of diclofenac sodium. The amount excreted in the urine accounts for 20 to 30 % of the dose, and that in bile for 10 to 20 %. The mean terminal elimination half-life is 1,2 to 1,8 hours.

INDICATIONS

Tablets

Rheumatoid arthritis, osteo-arthritis and ankylosing spondylitis. Treatment of post-traumatic pain and inflammation. Symptomatic treatment of primary dysmenorrhoea.

Suppositories

Rheumatoid arthritis, osteo-arthritis and ankylosing spondylitis. Treatment of post-traumatic pain and inflammation. For use as initial therapy for inflammatory and degenerative rheumatic diseases.

CONTRAINDICATIONS

Patients with porphyria.

Children under the age of two years.

Patients with a history of active gastrointestinal bleeding or peptic ulceration.

Severe hepatic or renal impairment.

Contraindicated in aspirin sensitive patients, patients sensitive to any other non-steroidal anti-inflammatory agent and in patients sensitive to any of the ingredients in these products.

Safety during pregnancy and lactation has not yet been established.

The use of suppositories is contraindicated in proctitis.

WARNINGS AND SPECIAL PRECAUTIONS

Patients with congestive heart failure, cirrhosis, diuretic-induced volume depletion or renal insufficiency are at a greater risk of developing renal dysfunction due to non-steroidal anti-inflammatory medicine-induced inhibition of renal prostaglandin synthesis.

It is advisable to perform blood counts in patients undergoing prolonged treatment.

A-LENNON DICLOFENAC should be given with care to patients with cardiovascular disease, bleeding disorders, in those who are receiving coumarin anti-coagulants and in patients with impaired hepatic or renal function.

Should be used with caution in patients with asthma or bronchoconstriction.

Use with care in elderly patients.

In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Excipients

Lactose warning:

A-LENNON DICLOFENAC tablets contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take A-LENNON DICLOFENAC tablets.

INTERACTIONS

Serious interactions have been reported after the use of high dose methotrexate with diclofenac.

Plasma concentrations are significantly decreased by the concomitant administration of therapeutic doses of aspirin.

When given together with preparations containing lithium or digoxin, diclofenac sodium may raise their plasma concentrations.

Concomitant administration of glucocorticoids or other non-steroidal anti-inflammatory agents may aggravate gastro-intestinal side effects.

Concomitant administration with two or more non-steroidal anti-inflammatory agents may promote the occurrence of side effects.

May increase the half-life of probenecid.

Use with care with other protein-bound medicines e.g. tolbutamide, coumarin and hydantoin.

HUMAN REPRODUCTION

Safety during pregnancy and lactation has not yet been established.

DOSAGE AND DIRECTIONS FOR USE

A-LENNON DICLOFENAC 25 mg and A-LENNON DICLOFENAC 50 mg TABLET

In adults, the dosage is 25 mg to 50 mg three times daily depending on the severity of the condition. The maintenance dose should be adjusted to the minimum that will provide continuous therapeutic control. The tablets should be swallowed whole, with or after a meal.

The dose in children is 2 mg per kilogram body mass per day in three divided doses.

A-LENNON DICLOFENAC 100 mg SUPPOSITORY

Suppositories should never be divided for administration as the active substance may be distributed unevenly.

The average adult dose is 100 mg each evening.

SIDE EFFECTS

Gastrointestinal disorders, including epigastric pain, eructation, nausea and vomiting may occur.

Peptic ulceration and gastrointestinal bleeding have been reported. Other side effects include vertigo, headache, skin rashes, pruritus, tinnitus, depression, drowsiness, nervousness, insomnia, irritability, agitation, minor hearing disorders, oedema, palpitations, blurred vision and other ocular reactions.

Hypersensitivity reactions may occur and include fever and rashes. Hepatotoxicity and aseptic meningitis which occur less frequently may also be hypersensitivity reactions.

Diclofenac may cause cystitis and haematuria, as well as acute renal failure, interstitial nephritis and nephrotic syndrome.

Other adverse effects include anaemia, thrombocytopenia, neutropenia, eosinophilia, agranulocytosis and abnormalities in liver function tests.

Allergic reactions which include angio-oedema, bronchospasm, urticaria and anaphylactic reactions have occurred. Because of the possibility of cross-sensitivity due to structural relationships which exist among non-steroidal anti-inflammatory medicines, acute allergic reactions may be more likely to occur in patients who have exhibited allergic reactions to these compounds.

Decreased platelet aggregation with increased bleeding time may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

See SIDE EFFECTS and WARNINGS AND SPECIAL PRECAUTIONS.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

A-LENNON DICLOFENAC 25 mg:

Yellowish-mustard, film-coated, shallow biconvex, enteric-coated tablet.

A-LENNON DICLOFENAC 50 mg TABLET:

Light brown, film-coated, shallow biconvex, enteric-coated tablet.

A-LENNON DICLOFENAC 100 mg SUPPOSITORY:

A large, white, torpedo-shaped suppository.

PRESENTATION

A-LENNON DICLOFENAC 25 mg:

30 or 100 tablets are packed in clear polyvinylchloride blister strips sealed with a silver aluminium foil backing. The blister strips are packed into an outer cardboard carton.

500 tablets are packed in a white polypropylene securitainer with a white low density polyethylene closure together with a rayon insert, or in a white, round, high density polyethylene container with a white high density polyethylene screw cap with induction seal liner.

A-LENNON DICLOFENAC 50 mg TABLET:

15 or 21 tablets are packed in clear polyvinylchloride blister strips sealed with a silver aluminium foil backing. The strips are packed into an outer cardboard carton.

21 and 500 tablets are packed in a white polypropylene securitainer with a white low density polyethylene closure together with a foam insert, or in a white high-density polyethylene container with a high-density polyethylene screw-cap with induction seal liner.

A-LENNON DICLOFENAC 100 mg SUPPOSITORY:

10 suppositories are packed in a white opaque polyvinylchloride/polyethylene laminated strip and packed into an outer cardboard carton.

Not all strengths, packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from moisture.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

A-LENNON DICLOFENAC 25 mg:	27/3.1/0314
A-LENNON DICLOFENAC 50 mg TABLET:	27/3.1/0315
A-LENNON DICLOFENAC 100 mg SUPPOSITORY:	29/3.1/0257

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:

A-LENNON DICLOFENAC 25 mg:	29 April 1993
A-LENNON DICLOFENAC 50 mg TABLET:	05 October 1993
A-LENNON DICLOFENAC 100 mg SUPPOSITORY:	23 March 1995

Date of the most recent amendment to the professional information as approved by the Authority: 23 March 1995

Namibia:	NS2
A-LENNON DICLOFENAC 25 mg	04/3.1/0055
A-LENNON DICLOFENAC 50 mg TABLET	04/3.1/0058
A-LENNON DICLOFENAC 100 mg SUPPOSITORY	04/3.1/0057

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