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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SUID AFRIKAANSE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

SKEDULERINGSTATUS

S3

EIENDOMSNAAM EN DOSEERVORM

A-LENNON DICLOFENAC 25 mg (tablet)

A-LENNON DICLOFENAC 50 mg TABLET (tablet)

A-LENNON DICLOFENAC 100 mg SUPPOSITORY (setpil)

SAMESTELLING

A-LENNON DICLOFENAC 25 mg:

Elke A-LENNON DICLOFENAC 25 mg filmbedekte tablet bevat 25 mg natriumdiklofenak

Eksipiënte:

Anhidriese kolloïdale silika, geel ysteroksied (C.I. 77492), laktosemonohidraat, magnesiumstearaat, metakrielsuur-kopolimeer, mikrokristallyne sellulose, simetikoon, natriumlourielsulfaat, natriumstyselglikolaat, mieliestysel, talk, titaandioksied (C.I. 77891), triëtielsitraat

Bevat suiker: Laktosemonohidraat 85 mg

A-LENNON DICLOFENAC 50 mg TABLET:

Elke A-LENNON DICLOFENAC 50 mg TABLET filmbedekte tablet bevat 50 mg natriumdiklofenak

Eksipiënte:

Anhidriese kolloïdale silika, rooi ysteroksied (C.I. 77491), laktosemonohidraat, magnesiumstearaat, metakrielsuur-kopolimeer, povidoon, simetikoon, natriumbikarbonaat, natriumlourielsulfaat, mieliestysel, titaandioksied (C.I. 77891), talk, triëtielsitraat, geel ysteroksied (C.I. 77492)

Bevat suiker: Laktosemonohidraat 86 mg

A-LENNON DICLOFENAC 100 mg SUPPOSITORY:

Elke A-LENNON DICLOFENAC 100 mg SUPPOSITORY setpil bevat 100 mg natriumdiklofenak

Eksipiënt:

Suppocire

KATEGORIE EN KLAS

A 3.1 Rumatiekmiddels (anti-inflammatoriese middels)

FARMAKOLOGIESE WERKING

Farmakodinamiese eienskappe

Diklofenak is ’n nie-steroïdale verbinding met pynstillende, anti-inflammatoriese, antirumatiese en antipiretiese eienskappe.

Farmakokinetiese eienskappe

’n Enkel 50 mg dosis enteries bedekte tablette lei tot maksimum plasmakonsentrasies van ongeveer 1 500 ng/ml binne 1,5 tot 2 ure na inname.

Natriumdiklofenak word hoofsaaklik geëlimineer deur metabolisme en gevolglike urinêre en bilière uitskeiding van glukuronied- en sulfaatkonjugate van die metaboliete. Die hoofmetaboliet by die mens is die 4-hidroksiderivaat van natriumdiklofenak. Die hoeveelheid wat in die urine uitgeskei word doen verantwoording vir 20 tot 30 % van die dosis en dié in gal vir 10 tot 20 %. Die gemiddelde terminale eliminasiehalfleeftyd is 1,2 tot 1,8 ure.

INDIKASIES

Tablette

Rumatoïede artritis, osteoartritis en ankiloserende spondilitis. Behandeling van post-traumatiese pyn en inflammasie. Simptomatiese behandeling van primêre dismenorree.

Setpille

Rumatoïede artritis, osteoartritis en ankiloserende spondilitis. Behandeling van post-traumatiese pyn en inflammasie. Vir gebruik as aanvangsterapie vir inflammatoriese en degeneratiewe rumatiese siektes.

KONTRA-INDIKASIES

Pasiënte met porfirie.

Kinders onder die ouderdom van twee jaar.

Pasiënte met ’n geskiedenis van aktiewe gastroïntestinale bloeding of peptiese ulserasie.
Ernstige hepatiese- of renale inkorting.

Teenaangedui by aspirien-sensitiewe pasiënte, pasiënte sensitief teenoor enige ander nie-steroïdale anti-inflammatoriese middel en by pasiënte sensitief teenoor enige van die bestanddele in hierdie produkte.

Veiligheid tydens swangerskap en laktasie is nog nie vasgestel nie.

Die gebruik van die setpille word teenaangedui by proktitis.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

Pasiënte met kongestiewe hartversaking, sirrose, diuretika-geïnduseerde volume-uitputting of renale ontoereikendheid het ’n groter risiko om renale disfunksie te ontwikkel, as gevolg van nie-steroïdale anti-inflammatoriese medisyne-geïnduseerde inhibisie van renale prostaglandien sintese.

Dit is raadsaam om bloedtellings uit te voer by pasiënte wat langdurige behandeling ontvang.

A-LENNON DICLOFENAC moet sorgvuldig gegee word aan pasiënte met kardiovaskulêre siekte, bloedingsversteurings, by die wat kumarien stollingsteenmiddels ontvang en by pasiënte met ingekorte hepatiese- of renale funksie.

Moet met omsigtigheid gebruik word by pasiënte met asma of brongokonstriksie.

Gebruik sorgvuldig by bejaarde pasiënte.

In die lig van die produk se inherente potensiaal om vloeistofretensie te veroorsaak, kan hartversaking by sommige gekompromitteerde pasiënte ontketen word.

Eksipiënte

Laktose waarskuwing:

A-LENNON DICLOFENAC tablette bevat laktose wat ’n effek op die glisemiese beheer van pasiënte met diabetes mellitus kan hê.

Pasiënte met die seldsame oorerflike toestande van galaktose onverdraagsaamheid bv. galaktosemie, die Lapp-laktase tekort, glukose-galaktose wanabsorpsie of fruktose onverdraagsaamheid moenie A-LENNON DICLOFENAC tablette neem nie.

INTERAKSIES

Ernstige interaksies is aangemeld na die gebruik van hoë dosis metotreksaat met diklofenak.

Plasmakonsentrasies word beduidend deur die meegaande toediening van terapeutiese dosisse aspirien verminder.

Wanneer dit saam met preparate wat litium of digoksien bevat gegee word, kan natriumdiklofenak hul plasmakonsentrasies verhoog.

Meegaande toediening van glukokortikoïede of ander nie-steroïdale anti-inflammatoriese middels kan gastroïntestinale newe-effekte vererger.

Meegaande toediening van twee of meer nie-steroïdale anti-inflammatoriese middels kan die voorkoms van newe-effekte bevorder.

Kan die halfleeftyd van probenesied verhoog.

Gebruik sorgvuldig met ander proteïengebonde medisyne bv. tolbutamied, kumarien en hidantoïen.

MENSLIKE VOORTPLANTING

Veiligheid tydens swangerskap en laktasie is nog nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS

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

By volwassenes is die dosis 25 mg tot 50 mg drie keer daagliks afhangende van die erns van die toestand. Die instandhoudingsdosis moet tot die minimum, wat volgehoue terapeutiese beheer sal voorsien, aangepas word. Die tablet moet heel gesluk word, met of na ’n maaltyd. Die dosis by kinders is 2 mg per kilogram liggaamsmassa per dag in drie verdeelde dosisse.

A-LENNON DICLOFENAC 100 mg SUPPOSITORY

Setpille moet nooit vir toediening verdeel word nie, aangesien die aktiewe bestanddeel oneweredig versprei kan word.

Die gemiddelde volwasse dosis is 100 mg elke aand.

NEWE-EFFEKTE

Gastroïntestinale versteurings, insluitende epigastriese pyn, eruktasie, naarheid en braking kan voorkom.

Peptiese ulserasie en gastroïntestinale bloeding is aangemeld. Ander newe-effekte sluit vertigo, hoofpyn, veluitslae, pruritus, tinnitus, depressie, lomerigheid, senuweeagtigheid, slapeloosheid, prikkelbaarheid, agitasie, geringe gehoorversteurings, edeem, palpitasies, dowwe visie en ander okulêre reaksies in.

Hipersensitiwiteitsreaksies kan voorkom en sluit koors en uitslae in. Hepatotoksisiteit en aseptiese meningitis wat minder dikwels voorkom, kan ook hipersensitiwiteitsreaksies wees.

Diklofenak kan sistitis en hematurie, sowel as akute renale versaking, interstisiële nefritis en nefrotiese sindroom veroorsaak.

Ander ongunstige effekte sluit anemie, trombositopenie, neutropenie, eosinofilie, agranulositose en abnormaliteite in lewerfunksie toetse in.

Allergiese reaksies wat angio-edeem, brongospasma, urtikarie en anafilaktiese reaksies insluit, het voorgekom. As gevolg van die moontlikheid van kruis-sensitiwiteit weens strukturele verwantskappe wat tussen nie-steroïdale anti-inflammatoriese medisyne bestaan, kan akute allergiese reaksies meer waarskynlik voorkom by pasiënte wat allergiese reaksies teenoor hierdie verbindings getoon het.

Verminderde plaatjie aggregasie met verhoogde bloedingstyd kan voorkom.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELINGS DAARVAN

Simptome

Sien NEWE-EFFEKTE en WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS.

Behandeling

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

A-LENNON DICLOFENAC 25 mg:

Gelerige-mosterd kleurige, filmbedekte, vlak bikonvekse, enteriesbedekte tablet.

A-LENNON DICLOFENAC 50 mg TABLET:

Lig bruin, filmbedekte, vlak bikonvekse, enteriesbedekte tablet.

A-LENNON DICLOFENAC 100 mg SUPPOSITORY:

'n Groot, wit, torpedo-vormige setpil.

AANBIEDING

A-LENNON DICLOFENAC 25 mg:

30 of 100 tablette word verpak in deursigtige polivinielchloried stolpstroke verseël met 'n silwer aluminiumfoelie rugmateriaal. Die stolpstroke word verpak in 'n buitenste kartonhouer.

500 tablette word verpak in 'n wit polipropileen "securitainer" met 'n wit laedigtheidspoliëtileen sluiting saam met 'n rayon insetsel, of in 'n wit, ronde, hoëdigtheidspoliëtileen houer met 'n wit hoëdigtheidspoliëtileen skroefdop met 'n induksie-seël voering.

A-LENNON DICLOFENAC 50 mg TABLET:

15 of 21 tablette word verpak in deursigtige polivinielchloried stolpstroke verseël met 'n silwer aluminiumfoelie rugmateriaal. Die stroke word verpak in 'n buitenste kartonhouer.

21 en 500 tablette word verpak in 'n wit polipropileen "securitainer" met 'n wit laedigtheidspoliëtileen sluiting saam met 'n skuim insetsel, of in 'n wit hoëdigtheidspoliëtileen houer met 'n hoëdigtheidspoliëtileen skroefdop met 'n induksie-seël voering.

A-LENNON DICLOFENAC 100 mg SUPPOSITORY:

10 setpille word verpak in ’n wit ondeursigtige polivinielchloried/poliëtileen gelamineerde strook en verpak in ’n buitenste kartonhouer.

Nie alle sterktes, verpakkings en pakgroottes word noodwendig bemark nie.

BERGINGSAANWYSINGS

Bêre teen of benede 25 °C.

Beskerm teen vog.

Hou in die oorspronklike verpakking totdat dit benodig word vir gebruik.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

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

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

PHARMACARE LIMITED

Healthcare Park

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Woodmead 2191

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

Datum van registrasie:

A-LENNON DICLOFENAC 25 mg: 29 April 1993

A-LENNON DICLOFENAC 50 mg TABLET: 05 Oktober 1993

A-LENNON DICLOFENAC 100 mg SUPPOSITORY: 23 Maart 1995

Datum van die mees onlangse wysiging tot die professionele inligting soos goedgekeur deur die Gesag: 23 Maart 1995

Namibië:	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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