Scheduling status: S1
Proprietary name (and dosage form):

Athru-Derm Lotion

Composition:
Athru-Derm Lotion contains:
Diclofenac sodium 1,08 g equivalent to Diclofenac 1 g per 100 g.

Preservatives:	
Imidurea	0,25 % m/m
Sodium propyl paraben	0,25 % m/m
Methyl paraben	0,22 % m/m
Anti-oxidant:	
Butylated hydroxyanisole	0,0075 % m/m
Butylated hydroxytoluene	0,0225 % m/m

Pharmacological classification:
A 3.1 Anti-rheumatics (anti-inflammatory agents)

Pharmacological action:
Athru-Derm Lotion has anti-inflammatory and analgesic properties.

Indications:
Athru-Derm Lotion is indicated for the symptomatic relief of localised traumatic inflammation and pain.

Contra-indications:
Hypersensitivity to diclofenac, aspirin and other nonsteroidal anti-inflammatory medicines. Diffuse skin diseases, burns and ulcers. Athru-Derm Lotion should not be used by patients with porphyria.
Confine use to adults as safety and efficacy have not been established in children.
The safety of Athru-Derm Lotion in pregnancy has not been established.

Dosage and directions for use:
Apply Athru-Derm Lotion to intact skin three to four times daily.

Side-effects and special precautions:
Itching, reddening, or smarting of the skin or outbreak of a rash may occur. When Athru-Derm Lotion is applied to relatively large areas of skin and over a prolonged period, the possibility of systemic side-effects cannot be completely excluded. Side-effects as experienced with systemically absorbed diclofenac sodium include the following:
gastrointestinal disturbances such as nausea and vomiting, gastrointestinal bleeding or activation of peptic ulcer; headache, slight dizziness, nervousness, tinnitus, depression, drowsiness and insomnia. Hypersensitivity reactions such as fever and rashes; hepatotoxicity, aseptic meningitis, bronchospasm in patients with asthma, cystitis, haematuria, acute renal failure, interstitial nephritis and nephrotic syndrome.
Other side-effects experienced after oral administration are anaemias, thrombocytopenia, eosinophilia, agranulocytosis, abnormalities in liver function tests, blurred vision, changes in visual colour perception and toxic amblyopia.

Precautions:
Athru-Derm Lotion should be applied to intact skin surfaces, andnot to skin wounds or open injuries. It should not be
allowed to come into contact with the eyes or with mucous membranes.
Not to be taken by mouth.

Interactions as experienced with systemically absorbed Diclofenac sodium:
When given concomitantly with lithium, digoxin or methotrexate, diclofenac sodium raised the concentration thereof in the blood.
The bioavailability of Athru-Derm Lotion is reduced by aspirin and that of aspirin by Athru-Derm Lotion, when the two medicines are administered together.

Known symptoms of overdosage and particulars of its treatment:
In the event of significant systemic side-effects occurring as a result of improper use or accidental overdosage, general therapeutic measures of the kind normally adopted in order to treat poisoning with non-steroidal antiinflammatory medicines, should be applied.

Identification:
A smooth, white, milky lotion.

Presentation:
HDPE tubes containing 50 g or 100 g of Athru-Derm Lotion.

Storage instructions:
Store below 25 °C, protect from light. Keep well closed.

For external use only.
KEEP OUT OF THE REACH OF CHILDREN.

Registration number:
31/3.1/0383

Name and business address of the holder of the certificate of registration:
MeyerZall Laboratories (Pty) Ltd
Reg. No.: 1992/004344/07
Innovation and Research Building,
Nelson Mandela Metropolitan University,
Saasveld Road, Saasveld, George, 6529.

Marketed by Activo Health (Pty) Ltd t/a
Activo Pharmaceuticals.

Date of publication of this package insert:
September 2007

ATH/PI/A

Final Approval Legend

Job/Project & No.: ATHRU-DERM PI
Proof Number: ONE
Date of final/playout: 24.11.2010
Dosage Form: LOTION
Component Type: LOTION PI ENGLISH
CD/Art Format: Illustrator - Apple MAC
Dimensions: 145 x 200 mm

NO OF COLOURS USED FOR THE JOB AND PANTONE REFERENCES:

☐ Pantone: XXX	☐ Pantone: XXX	☐ Pantone: XXX
☐ Pantone: XXX	■ Black:	☐ Pantone:
☐ Pantone: DIE	☐ Black:	☐ CMYK

Applicant Approval: _____ _____
Name: _____ Date

Product Principal: _____ _____
Name: _____ Date

Activo Marketing: _____ _____
Name: _____ Date

Activo Regulatory: _____ _____
Name: _____ Date

Note:

Skeduleringstatus: S1
Eiendomsnaam (en doseervorm):

Athru-Derm Lotion

Samestelling:
Athru-Derm Lotion bevat: Natriumdiklofenak 1,08 g ekwivalent aan diklofenak 1 g per 100 g

Preserveermiddels:

Imidurea	0,25 % m/m
Natriumpropielparabeen	0,25 % m/m
Metielparabeen	0,22 % m/m
Anti-oksidante:	
Gebutileerde hidroksianisool	0,0075 % m/m
Gebutileerde hidroksietolueen	0,0225 % m/m

Farmakologiese klassifikasie:
A 3.1 Rumatiekmiddels (anti-inflammatoriese middels)

Farmakologiese werking:
Athru-Derm Lotion het anti-inflammatoriese en analgetiese eienskappe.

Aanwysings:
Wend Athru-Derm Lotion aan vir die simptomatiese verligting van gelokaliseerde troumatiese inflammasie en pyn.

Teenaanwysings:
Hipersensitiwiteit vir diklofenak, aspirien en ander niesteroïdale anti-inflammatoriese middels. Diffuse vel siektes, brandwonde en ulkusse. Athru-Derm Lotion behoort nie aangewend te word aan pasiënte wat porfirie het nie.
Beperk gebruik tot volwassenes aangesien die veiligheid en effektiwiteit nie in kinders bewys is nie.
Die veiligheid van die gebruik van Athru-Derm Lotion tydens swangerskap is nie bewys nie.

Dosis en gebruiksaanwysings:
Wend Athru-Derm Lotion aan heel vel drie tot vier maal daagliks.

Newe-effekte en spesiale voorsorgmaatreëls:
Jeuk sensasies, rooiheid, of branderigheid van die vel of 'n uitslag kan voorkom.
As Athru-Derm Lotion aangewend word aan groot areas en oor 'n lang tydperk kan die moontlikheid van sistemiese newe-effekte nie uitgesluit word nie. Newe-effekte as gevolg van sistemies geabsorbeerde natriumdiklofenak sluit in die volgende: gastroïntestinale versteuringe soos naarheid en braking, gastroïntestinale bloeding of die aktivering van 'n peptiese ulkus; hoofpyn, effense duiseligheid, senuweeagtigheid, tinnitus, depressie, lomerigheid en slaaploosheid. Hipersensitiwiteitsreaksies soos koors en uitslag; hepatotoksisiteit, aseptiese meningitis, brongospasma by pasiënte met asma, sistitis, hematurie, akute renale versaking, interstisiële nefritis en nefrotiese sindroom.
Ander newe-effekte na orale toediening is anemieë, trombositopenie, eosinofilie, agranulositose, abnormale lewerfunksie toetse, versteurde visie, veranderinge in visuele kleur persepsie en toksiese ambliopie.

Voorsorgmaatreëls:
Athru-Derm Lotion behoort net aan heel vel oppervlaktes aangewend te word en nie aan velwonde of oop beserings nie.
Vermy kontak met die oë en slymvliesmembrane.
Nie vir orale toediening nie.

Interaksies ondervind met sistemies geabsorbeerde Natriumdiklofenak:
Verhoogde bloedkonsentrasies van litium, digoksien en metotreksaat kan voorkom as dit saam met natriumdiklofenak toegedien word.
Die biobeskikbaarheid van Athru-Derm Lotion en aspirien word beide verlaag met gelyktydige toediening.

Bekende simptome van oordosering en besonderhede van behandeling daarvan:
In geval van erge sistemiese newe-effekte as gevolg van verkeerdelike aanwending of oordosering, behoort die pasiënt algemene terapeutiese behandeling te ontvang, wat normaalweg gegee word vir vergiftiging met niesteroïdale anti-inflammatoriese middels.

Identifikasie:
'n Gladde, wit, melkerige smeermiddel.

Aanbieding:
HDPE buise bevattende 50 g of 100 g Athru-Derm Lotion.

Bergingsinstruksies:
Bewaar benede 25 °C, bewaar teen lig. Hou dig toe.
Vir uitwendige gebruik alleenlik.
HOU BUITE DIE BEREIK VAN KINDERS.

Registrasienommer:
31/3.1/0383

Naam en besigheidsadres van die houer van die sertifikaat van registrasie:
MeyerZall Laboratories (Pty) Ltd
Reg. No.: 1992/004344/07
Innovation and Research Building,
Nelson Mandela Metropolitan University,
Saasveldweg, Saasveld, George, 6529.

Bemark deur Activo Health (Pty) Ltd h/a
Activo Pharmaceuticals.

Datum van publikasie van hierdie voubiljet:
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