SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

NAFASOL SUPPOSITORIES

COMPOSITION

Each suppository of NAFSOL SUPPOSITORIES contains 500 mg naproxen.

Excipient:

Suppocire

CATEGORY AND CLASS

A 3.1 Antirheumatics (anti-inflammatory agents)

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Analgesic, antipyretic and non-steroidal anti-inflammatory.

Naproxen inhibits prostaglandin synthetase, however, the exact mechanism of its anti-inflammatory action is not known.

INDICATIONS

NAFASOL SUPPOSITORIES is used in the treatment of rheumatoid arthritis, osteo-arthritis, ankylosing spondylitis, mild to moderate pain associated with dysmenorrhoea, musculoskeletal

disorders (such as sprains and strains, cervical spondylitis and tendinitis) and in gout.

CONTRAINDICATIONS

- A history of or active gastrointestinal bleeding or peptiic ulceration.
- Pregnancy and lactation.
- Patients who are sensitive to aspirin or other non-steroidal anti-inflammatory agents, since the potential for cross-sensitivity exists.

WARNINGS AND SPECIAL PRECAUTIONS

NAFASOL SUPPOSITORIES should be given with care to patients with asthma, bronchospasm, bleeding disorders, cardiovascular disease, renal failure and in those who are receiving coumarin anticoagulants (due to naproxen being extensively bound to plasma proteins, an overdosage of coumarin can occur).

INTERACTIONS

- NAFASOL SUPPOSITORIES may inhibit clearance of lithium, leading to increasing lithium concentrations.
- NAFASOL SUPPOSITORIES may inhibit the diuretic and hypotensive effect of furosemide.
- NAFASOL SUPPOSITORIES may reduce the excretion of methotrexate, leading to toxicity with methotrexate.
- NAFASOL SUPPOSITORIES may interfere with some tests for 17-ketogenic steroids.

HUMAN REPRODUCTION

NAFASOL SUPPOSITORIES is contraindicated in pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE

Adult dosage:

Insert one suppository per rectum at bedtime.

Administered in conjunction with oral administration during the day.

Total daily dose administered orally and rectally must not exceed 1 gram per day.

SIDE EFFECTS

Side effects which may occur include nausea, vomiting, dyspepsia, constipation, peptic ulceration, gastrointestinal hemorrhage, insomnia or drowsiness, depression, headache, nervousness, dizziness, tinnitus, pruritus, skin eruptions and angio-oedema, visual disturbances and an increase in bleeding time.

Hypersensitivity reactions, abnormalities of liver function tests, impairment of renal function, agranulocytosis and thrombocytopenia have been observed.

In view of NAFASOL SUPPOSITORIES inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Refer to SIDE EFFECTS.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

A large, off-white torpedo-shaped suppository.

PRESENTATION

10 suppositories are packed in a white, opaque, polyvinylene chloride/polyethylene blister sealed with an aluminium foil backing. The blister strips are packed in a pre-printed cardboard unit carton together with a leaflet.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light and moisture.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

Y/3.1/131

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: 19 September 1991

Date of the most recent amendment to the professional information as approved by the Authority: 19 September 1991

Namibia: NS2 04/3.1/0127

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SUID AFRIKAANSE PROFESSIONELE INLIGTING VIR MEDISYNE VIR MENSLIKE GEBRUIK

SKEDULERINGSTATUS

S3

EIENDOMSNAAM EN DOSEERVORM

NAFASOL SUPPOSITORIES (setpil)

SAMESTELLING

Elke NAFASOL SUPPOSITORIES setpil bevat 500 mg naprokseen.

Eksipiënt:

Suppocire

KATEGORIE EN KLAS

A 3.1 Rumatiekmiddels (anti-inflammatoriese middels)

FARMAKOLOGIESE WERKING

Farmakodinamiese eienskappe

Pynstillende, koorswerende en nie-steroïedale anti-inflammatoriese middel.

Naprokseen inhibeer prostaglandiensintetase maar die presiese meganisme van sy anti-inflammatoriese werking is egter nie bekend nie.

INDIKASIES

NAFASOL SUPPOSITORIES word gebruik by die behandeling van rumatoïede artritis, osteoartritis, ankiloserende spondilitis, ligte tot matige pyn wat verwant is aan dismenorree, muskuloskeletale versteurings (soos verstuiting en verrekking, servikale spondilitis en

tendinitis) en jig.

KONTRA-INDIKASIES

- ’n Geskiedenis van of aktiewe gastroïntestinale bloeding of peptiese ulserasie.
- Swangerskap en laktasie.
- Pasiënte wat sensitief is teenoor aspirien of ander nie-steroïedale anti-inflammatoriese middels, aangesien die potensiaal vir kruissensitiwiteit bestaan.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

NAFASOL SUPPOSITORIES moet versigtig aan pasiënte gegee word met asma, brongospasma, bloedingsversteurings, kardiovaskulêre siekte, renale versaking en aan diegene wat kumarien stollingsteenmiddels ontvang (aangesien naprokseen breedvoerig aan plasmaproteïene gebonde is, kan oordosering van kumarien voorkom).

INTERAKSIES

- NAFASOL SUPPOSITORIES kan die opruiming van litium inhibeer, wat tot verhoogde litiumkonsentrasies lei.
- NAFASOL SUPPOSITORIES kan die diuretiese en hipotensiewe effek van furosemied inhibeer.
- NAFASOL SUPPOSITORIES kan die uitskeiding van metotreksaat verminder en tot metotreksaat toksisiteit lei.
- NAFASOL SUPPOSITORIES kan met sommige toetse vir 17-ketogeensteroïede inmeng.

MENSLIKE VOORTPLANTING

NAFASOL SUPPOSITORIES is teenaangedui tydens swangerskap en laktasie.

DOSIS EN GEBRUIKSAANWYSINGS

Volwasse dosering:

Plaas een setpil in die rektum teen slapenstyd.

Toegedien in kombinasie met mondelikse toediening gedurende die dag.

Totale daaglikse dosis toegedien per mond en rektum moenie 1 gram per dag oorskry nie.

NEWE-EFFEKTE

Newe-effekte wat kan voorkom sluit naarheid, braking, dispepsie, hardlywigheid, peptiese ulserasie, gastroïntestinale bloeding, slapeloosheid of lomerigheid, depressie, hoofpyn, senuweeagtigheid, duiseligheid, tinnitus, pruritus, veluitslag en angio-edeem, visuele versteurings en ’n toename in bloeitydperk in.

Hipersensitiwiteitsreaksie, abnormaliteite van lewerfunksietoetse, ingekorte renale funksie, agranulositose en trombositopenie is waargeneem.

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

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELINGS DAARVAN

Simptome

Verwys na NEWE-EFFEKTE.

Behandeling

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

’n Groot, naaswit torpedo-vormige setpil.

AANBIEDING

10 setpille word verpak in ’n wit, ondeursigtige, polivinilideenchloried/poliëtileen stolp verseël met ’n aluminiumfoelie rugmateriaal. Die stolpstroke word verpak in ’n voorafgedrukte eenheidskartonhouer saam met ’n voubiljet.

BERGINGSAANWYSINGS

Bêre teen of benede 25 °C.

Beskerm teen lig en vog.

Hou in oorspronklike verpakking totdat dit benodig word vir gebruik.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

Y/3.1/131

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

PHARMACARE LIMITED

Healthcare Park

Woodlandsrylaan

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

Datum van registrasie: 19 September 1991

Datum van die mees onlangse wysiging tot die professionele inligting soos goedgekeur deur die Gesag: 19 September 1991

Namibië: NS2 04/3.1/0127

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