1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

NAFASOL EC - 250 (tablet)

NAFASOL EC - 500 (tablet)

COMPOSITION

NAFASOL EC – 250: Each film-coated tablet contains 250 mg of naproxen.

Excipients:

Dye acryl-eze yellow, lactose monohydrate, magnesium stearate, polysorbate, povidone K25, purified talc, sodium starch glycollate, starch maize

Contains sugar: lactose monohydrate 54,000 mg

NAFASOL EC – 500: Each film-coated tablet contains 500 mg of naproxen.

Excipients:

Dye acryl-eze yellow, lactose monohydrate, magnesium stearate, polysorbate, povidone K25, purified talc, sodium starch slycollate, starch maize

Contains sugar: Lactose monohydrate 108,000 mg

CATEGORY AND CLASS

A3.1 Antirheumatics (anti-inflammatory agents)

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Naproxen is an 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 EC 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 tendonitis) and in gout.

CONTRAINDICATIONS

- History of gastrointestinal bleeding or perforation (PUBs) related to previous NSAIDs. Active or history of recurrent ulcer/haemorrhage/perforations.
- Pregnancy and lactation.
- Sensitivity to naproxen.
- Patients who are sensitive to aspirin or other non-steroidal anti-inflammatory agents, since the potential for cross-sensitivity exists.
- Not to be used in children under the age of 16 years except when used in juvenile rheumatoid arthritis.
- Heart failure.

WARNINGS AND SPECIAL PRECAUTIONS

Caution is required in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with NAFASOL EC therapy.

Elderly: The elderly has an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation (PUBs) which may be fatal.
The risk of gastrointestinal bleeding or perforation (PUBs) is higher with increasing doses of NAFASOL EC, in patients with a history of ulcers, and the elderly.
When gastrointestinal bleeding or ulceration occurs in patients receiving NAFASOL EC, treatment with NAFASOL EC should be stopped.

NAFASOL EC should be given with caution to patients with a history of gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as the condition may be exacerbated.
Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolyis have been reported. NAFASOL EC should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

NAFASOL EC 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).

Excipients

NAFASOL EC contains lactose monohydrate 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 NAFASOL EC.

INTERACTIONS

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

NSAIDs: use of two or more NSAIDs concomitantly could result in an increase in side effects.

Corticosteroids: increased risk of gastrointestinal ulceration or bleeding (PUBs).

Anti-coagulants: NAFASOL EC may enhance the effects of anti-coagulants such as warfarin.

Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding.

HUMAN REPRODUCTION

The use of NAFASOL EC in pregnancy and lactation is contraindicated.

DOSAGE AND DIRECTIONS FOR USE

Use the lowest effective dose for the shortest possible duration of treatment.

NAFASOL EC – 250 and NAFASOL EC – 500 tablets should be swallowed whole and not broken or crushed.

Antirheumatic (anti-inflammatory):

Adults: Usual dose is 500 mg to 1 g of NAFASOL EC daily in 2 divided doses.

Juvenile Rheumatoid Arthritis:

Children over 5 years: A dose of 10 mg/kg body-weight daily of NAFASOL EC in 2 divided doses.

Analgesic:

Adults: Usual initial dose is 500 mg of NAFASOL EC followed by 250 mg every 6 or 8 hours.

Anti-gout agent:

Adults: Initial dose of 750 mg of NAFASOL EC followed by 250 mg every 8 hours.

The tablets should be taken with food**.**

SIDE EFFECTS

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

Gastrointestinal:

The most commonly observed adverse events are gastrointestinal in nature. Diarrhoea, flatulence, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis may occur.

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

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

Hypersensitivity reactions which include bronchospasm and anaphylactic/anaphylactoid reactions with angio-oedema, respiratory distress and circulatory collapse have occurred.

Bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Refer to “SIDE EFFECTS”.

Treatment

Treatment is symptomatic and supportive.

IDENTIFICATION

NAFASOL EC – 250: A yellow, enteric film-coated biconvex tablet.

NAFASOL EC – 500: A yellow, enteric film-coated biconvex tablet.

PRESENTATION

NAFASOL EC – 250:

30 tablets are packed in a clear polyvinylchloride film sealed with an aluminium foil backing. One or more blister strips are packed into an outer cardboard carton together with a leaflet.

100 or 250 tablets are packed in a white, cylindrical polypropylene container with a white, low density polyethylene cap, together with a white, round, flat foam insert and leaflet.

100 or 250 tablets are packed in a white, round, opaque, high density polyethylene container with a white, opaque, high density polyethylene screwcap with an induction liner, together with a leaflet.
250 tablets are packed in a white, round, high density polyethylene bottle with a white, opaque, polypropylene cap with an induction liner, together with a leaflet.

NAFASOL EC – 500:

30 tablets are packed in a clear polyvinylchloride film sealed with an aluminium foil backing. One or more blister strips are packed into an outer cardboard carton together with a leaflet.

30 tablets are packed in a white, round, high density polyethylene bottle with a white, opaque, polypropylene cap with an induction liner, together with a leaflet.

100 tablets are packed in a white, round, high density polyethylene bottle with a white, opaque, polypropylene cap with an induction liner, together with a leaflet.

30 or 100 tablets are packed in a white, cylindrical, opaque polypropylene container with a white, low density polyethylene cap, together with a white, round, flat foam insert and leaflet.

30 or 100 tablets are packed in a white, round, opaque, high density polyethylene container with a white, opaque, high density polyethylene screwcap with an induction liner, together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

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 NUMBERS

NAFASOL EC – 250: 27/3.1/0437

NAFASOL EC – 500: 27/3.1/0438

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: 24 September 1993

Date of the most recent amendment to the professional information as approved by the Authority: 21 June 1995

BOTSWANA: S2	
NAFASOL EC - 250	B9322560
NAFASOL EC - 500	B9322565

Namibia: NS2	
NAFASOL EC - 250	04/3.1/0129
NAFASOL EC - 500	04/3.1/0128