SCHEDULING STATUS:

S0

PROPRIETARY NAME (AND DOSAGE FORM):

DISPRIN REGULAR STRENGTH 300 mg Tablet

DISPRIN EXTRA STRENGTH 500 mg Tablet

COMPOSITION:

Each tablet contains:

DISPRIN REGULAR STRENGTH 300 mg Aspirin 300 mg

DISPRIN EXTRA STRENGTH 500 mg Aspirin 500 mg

Other ingredients: Calcium Carbonate, Citric Acid, Maize Starch, Sodium Lauryl Sulphate, Saccharin, Talc.

Sugar free

PHARMACOLOGICAL CLASSIFICATION:

A 2.7 Antipyretic or antipyretic and anti-inflammatory analgesics.

PHARMACOLOGICAL ACTION:

Disprin Regular Strength 300 mg and Disprin Extra Strength 500 mg have analgesic, antipyretic and anti- inflammatory actions. Aspirin inhibits the biosynthesis of prostaglandins.

INDICATIONS:

Disprin Regular Strength 300mg and Disprin Extra Strength 500mg are indicated for the relief of mild to moderate pain, and fever.

CONTRA-INDICATIONS:

Patients with peptic ulcers, haemophilia or intolerance (hypersensitivity) to aspirin, sever renal impairment and patients receiving oral anticoagulant therapy. Aspirin should not be taken during the first and trimesters of pregnancy and lactation. Not to be used in children under the age of 16 years.

WARNINGS

DO NOT USE CONTINUOUSLY FOR MORE THAN 10 DAYS WITHOUT CONSULTING YOUR DOCTOR.

There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease which affects the brain and liver and can be fatal. For this reason, aspirin should not be given to children under the age of 16 years unless specifically indicated by a doctor or pharmacist.

DOSAGE AND DIRECTIONS FOR USE:

Disprin Regular Strength 300 mg:

Adults: 1-3 tablets. Repeat 4 hourly if necessary but not more than 12 tablets during any 24-hour period.

Children 16 years and over: 1-2 tablets not more than four times a day, to a maximum of 10 tablets in 24 hours.

Disprin Regular Strength 300 mg can be dissolved in water, or if preferred, on the tongue.

Disprin Extra Strength 500 mg:

Adult: 1-2 tablets

Children over 16 years: 1 tablet

Repeat 4 hourly if necessary but not more than 8 tablets during 24 hour period, but if symptoms persist consult your doctor. In chronic Rheumatic disease, 1-2 tablets every 4 hours over long period.

In acute rheumatism, 2-4 tablets four times daily. Disprin Extra Strength 500 mg should be dissolved in water before being taken.

If symptoms persist consult your doctor. Do not use continuously for more than 10 days without consulting your doctor.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Dizziness, Irritation of the gastric mucosa and resultant dyspepsia, haematemesis and melaena may occur in some cases. Concomitant therapy with other gastric irritants, such as non-steroidal anti-inflammatory agents may increase the risk of gastric irritation. Disprin Regular Strength 300 mg and Disprin Extra Strength 500 mg should be withdrawn one week before surgery because of the possibility of increasing the bleeding times. Aspirin may cause allergic reactions, more commonly in asthmatics.

Some persons, especially asthmatics, exhibit notable sensitivity to aspirin which may provoke various hypersensitivity reactions which may include skin eruptions, paroxysmal bronchospasm and dyspnoea. Aspirin should be administered with caution to patients with impaired renal function, dyspepsia, anaemia and when the patient is dehydrated. Aspirin may enhance the activity of coumarin anticoagulants, methotrexate and oral anti-diabetic preparations and sulphonamides.

Aspirin diminishes the effect of anti-gout preparations such as probenecid and sulphinpyrazone. Barbiturates and other sedatives may mask the respiratory symptoms of aspirin overdosage and have been reported to enhance its toxicity. Prolonged use of high doses may lead to anaemia, blood dyscrasias, gastro-intestinal haemorrhage, peptic ulceration and renal papillary necrosis.

Interference with laboratory tests: Salicylates may produce falsely increased results for blood creatinine, urate (low dose aspirin) and urea. Falsely decreased results may be obtained for blood thyroxine and urate (>4g/day aspirin) and for urinary 5- HIAA (with nitrosoonaphthol method). Urinary VMA (HMMA) levels may be falsely increased or decreased depending on the method of analysis. Urinary glucose oxidase: Aspirin may cause a false negative test in the presence of glycosuria.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

These include dizziness, tinnitus, sweating, nausea, vomiting, altered glucose metabolism, mental confusion, hyperventilation, respiratory alkalosis, metabolic acidosis, ketosis, and fluid and electrolyte losses. Depression of the central nervous system may lead to coma Cardiovascular collapse and respiratory failure. In children, serious signs of overdosage may develop rapidly. In cases of overdosage, consult a doctor immediately. Treatment is symptomatic and supportive: the serum salicylate levels should be closely monitored and forced alkaline diuresis instituted if appropriate. Gastric lavage, restoration of fluid, electrolyte and acid balance, dialysis and supportive therapy may be required.

IDENTIFICATION:

DISPRIN REGULAR STRENGTH 300 MG: A flat, white tablet, 12.7 mm in diameter, with bevelled edges. The name “Disprin” and sword is imprinted on one side and the other side is plain. It effervesces in water.

DISPRIN EXTRA STRENGTH 500 MG: A flat, white tablet, 14 mm in diameter, with bevelled edges. A “D” and a sword motif and an “X” are imprinted on one side and the other side is plain. It effervesces in water.

PRESENTATION:

DISPRIN REGULAR STRENGTH 300 MG: In packs of 12, 24, 48 and 96 tablets packed in aluminium foil.

DISPRIN EXTRA STRENGTH 500 MG: In packs of 2, 16, 24, and 48 tablets packed in aluminium foil.

STORAGE INSTRUCTIONS:

Store below 25° C in a dry place, out of reach of children.

REGISTRATION NUMBER:

Disprin Regular Strength 300 mg: B/2.7/570

Disprin Extra Strength 500 mg: M/2.7/292

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road

Elandsfontein 1601

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

20 October 1980

Namibia: 90/2.7/001388 NS0
Zimbabwe: L77/2.1/900 HR 2.1 Analgesics and Antipyretics (single ingredient product)