SCHEDULING STATUS **S0**

1. NAME OF THE MEDICINE

SOLUSPIRIN

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Aspirin 300 mg Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Tablet.

A flat, round, white tablet, scored on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Aspirin is effective for the relief of pain of mild to moderate intensity. It is indicated in a wide variety of febrile conditions.

4.2 Posology and method of administration

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

Children 16 years and over: 1 to 2 tablets not more than four times a day,

to a maximum of 10 tablets in 24 hours.

DO NOT USE CONTINUOUSLY FOR MORE THAN 10 DAYS WITHOUT CONSULTING YOUR DOCTOR. NOT TO BE TAKEN DURING THE FIRST AND THIRD TRIMESTERS OF PREGNANCY EXCEPT UNDER THE ADVICE AND SUPERVISION OF A MEDICAL DOCTOR. EXCESSIVE AND PROLONGED USE OF THIS MEDICINE MAY BE DANGEROUS.

Method of administration

Soluspirin tablets should be dissolved in water before administration.

4.3 Contraindications

Patients with peptic ulcer, haemophilia or intolerance (hypersensitivity) to aspirin, severe renal impairment and patients receiving oral anti-coagulant therapy.

4.4 Special warnings and precautions for use

Aspirin has been implicated in Reye's syndrome, a rare but serious illness, in children and teenagers with chickenpox and influenza. A doctor should be consulted before aspirin is used in such patients. Prolonged use of high doses may lead to anaemia, blood dyscrasias, gastrointestinal haemorrhage, peptic ulceration and renal papillary necrosis.

The use of aspirin during the first and third trimesters of pregnancy is not advised.

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

4.5 Interaction with other medicines and other forms of interaction

Aspirin may enhance the activity of coumarin anticoagulants, oral diabetic preparations and sulphonamides. Aspirin diminishes the effects 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.

4.6 Fertility, pregnancy and lactation

NOT TO BE TAKEN DURING THE FIRST AND THIRD TRIMESTERS OF PREGNANCY EXCEPT UNDER THE ADVICE AND SUPERVISION OF A MEDICAL DOCTOR see section 4.2).

4.7 Effects on ability to drive and use machines

The effects on the ability to drive and use machines has not been established.

4.8 Undesirable effects

Dizziness, irritation of the gastric mucosa and resultant dyspepsia, haematemesis, and melaena may occur in some cases. Some persons, especially asthmatics, exhibit notable sensitivity to aspirin, which may include skin eruption, paroxysmal bronchospasm and dyspnoea. Aspirin should be administered with caution to dehydrated patients and to patients with impaired renal function, dyspepsia, and anaemia.

Aspirin is a nonsteroidal anti-inflammatory agent and there have been reports of a risk of renal tubular acidosis (RTA) and hypokalaemia associated with the use of nonsteroidal anti-inflammatory agents (NSAIDs).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

These include dizziness, tinnitus, sweating, nausea, vomiting, mental confusion, hyperventilation, respiratory alkalosis, metabolic acidosis, ketosis and depression of the central nervous system. In children serious signs of overdosage may develop rapidly. In cases of overdosage, consult your doctor immediately. Treatment is supportive and symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 2.7 Anti-pyretic or anti-pyretic and anti-inflammatory analgesics

Aspirin has analgesic, anti-inflammatory and antipyretic actions. It inhibits the biosynthesis of prostaglandins.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Other ingredients: calcium carbonate, maize starch, citric acid anhydrous, purified talc, sodium saccharin, sodium lauryl sulphate.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Keep container well closed out of reach of children. Exposure to air should be kept to the minimum.

6.5 Nature and contents of container

Bottles containing 25, 100 and 1000 tablets. In aluminium foil packs of 2, 12, 14, 24, 48 and 96.

6.6 Special precautions for disposal and other handling

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Resmed Healthcare,

71 Rochdale Road, Springfield Park, Durban, 4051.

8. REGISTRATION NUMBERS

B/2.7/1482

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23-01-2001

10. DATE OF REVISION OF THE TEXT