Patient Information Leaflet

SCHEDULING STATUS **S0**

SOLUSPIRIN

Aspirin soluble 300 mg per tablet.

Read all of this leaflet carefully because it contains important information for you

- SOLUSPIRIN is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SOLUSPIRIN carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share SOLUSPIRIN with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What SOLUSPIRIN is and what it is used for
2. What you need to know before you take SOLUSPIRIN
3. How to take SOLUSPIRIN
4. Possible side effects
5. How to store SOLUSPIRIN
6. Contents of the pack and other information

1. WHAT SOLUSPIRIN is and what it is used for

SOLUSPIRIN works by relieving moderate pain and fever.

2. What you need to know before you take SOLUSPIRIN:

Do not take SOLUSPIRIN if you:

- have a stomach ulcer
- suffer from haemophilia (a blood clotting disorder).
- are allergic (hypersensitive) to aspirin or any of the other ingredients (listed in section 6).

- have severe kidney problems.
- are receiving oral anti-coagulant therapy (medicines that prevent the blood from clotting).
- are in the first or last 3 months of pregnancy or are breastfeeding except under the advice and supervision of a medical doctor.

Do not use continuously for more than 10 days without consulting your doctor. Excessive and prolonged use of this medicine may be dangerous.

Warnings and precautions

Take special care with SOLUSPIRIN if:

- you are under 16 years of age, due to the risk of 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.

Other medicines and SOLUSPIRIN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

The effect of treatment may be influenced if SOLUSPIRIN is taken together with medicines such as:

- anticoagulants (which thin the blood)
- oral antidiabetic medicines
- sulphonamides
- anti-gout preparations such as probenecid and sulfinpyrazone
- barbiturates and other sedatives.

Pregnancy and Breastfeeding

Do not take SOLUSPIRIN if you are in the first or last 3 months of your pregnancy or if you are breastfeeding. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

3. How to take SOLUSPIRIN

Do not share medicines prescribed for you with any other person.

Always take SOLUSPIRIN as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is:

Adults: 1 to 2 tablets:

Children 16 years and over: 1 tablet

Repeat 4 hourly if necessary but not more than 8 tablets during any 24-hour period. If symptoms persist consult your doctor.

SOLUSPIRIN tablets should be dissolved in a glass of water. Then drink the contents of the whole glass.

If you take more SOLUSPIRIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available seek help at the nearest hospital or poison control centre. Symptoms of overdose include dizziness, ringing in the ears, sweating, nausea, vomiting, mental confusion and hyperventilation.

4. Possible Side Effects

SOLUSPIRIN can have side effects.

Side effects may include dizziness, irritation of the stomach lining with resultant indigestion, vomiting blood and bloody or black, tarry stools.

Some people, especially asthmatics, show notable sensitivity to aspirin. If any of the following happens, stop taking SOLUSPIRIN and tell your doctor immediately or go to the casualty department at your nearest hospital: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, chest tightness, rash or itching, fainting. These are all very serious side effects. If you have them, you may have had a serious reaction to SOLUSPIRIN. You may need urgent medical attention or hospitalisation.

SOLUSPIRIN should be taken with caution if you have kidney problems, anaemia or are dehydrated.

SOLUSPIRIN, especially when used at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood. Signs and symptoms include muscle weakness and light-headedness.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SOLUSPIRIN.

5. How to store SOLUSPIRIN

Keep all medicines out of the reach and sight of children.

Store at or below 25 ºC in a dry place.

6. Contents of the pack and other information

What SOLUSPIRIN contains

The active ingredient is aspirin and each tablet contains aspirin 300 mg. The other ingredients are anhydrous citric acid, maize starch, calcium carbonate, sodium saccharin, sodium lauryl sulphate and purified talc.

What SOLUSPIRIN looks like and contents of the pack

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

Packed in aluminium foil packs of 2,12,14, 24, 48 and 96 tablets.

Holder of Certificate of Registration

Resmed Healthcare

71 Rochdale Road, Springfield Park, Durban, 4051.

This leaflet was last revised in ……

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