SCHEDULING STATUS:

S0

GO PAIN ASPIRIN 300 mg tablet

Aspirin

Sugar free

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

GO PAIN ASPIRIN is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use GO PAIN ASPIRIN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share GO PAIN ASPIRIN with any other person.
- Ask you healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 – 5 days.

What is in this leaflet

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

1. What GO PAIN ASPIRIN is and what it is used for.

GO PAIN ASPIRIN is indicated for the short-term use in the relief of mild to moderate pain.

2. What you need to know before you take GO PAIN ASPIRIN

Do not take GO PAIN ASPIRIN:

- if you are hypersensitive (allergic) to aspirin (acetylsalicylic acid) or to the other ingredient of GO PAIN ASPIRIN (listed in section 6),
- if you have a history of asthma resulting from taking aspirin (salicylates), or from taking similar medicines such as non-steroidal anti-inflammatory drugs (NSAIDs),
- if you have a history of stomach ulcers, bleeding or ruptures related to previous use of NSAIDs, including GO PAIN ASPIRIN,
- if you currently suffer from, or have a history of recurrent ulcers / bleeding / ruptures,
- if you have a stomach ulcer,
- if you suffer from a blood clotting disorder, a low blood platelet count or other bleeding problems,
- If you are on blood-thinning medicines such as warfarin,
- if you have severe liver failure,
- if you have severe kidney damage,
- if you have heart failure,
- if are taking methotrexate at doses of 15 mg or more per week,
- in the last three months of pregnancy.

Warnings and precautions

Do not use GO PAIN ASPIRIN continuously for more than 3 – 5 days without consulting your doctor.

Take special care with GO PAIN ASPIRIN:

- if you are allergic to pain medicine / medicine that reduce swelling / medicine for rheumatism and in the presence of other allergies,
- if you have kidney problems, poor blood flow or heart problems, as GO PAIN ASPIRIN may increase the risk of kidney damage and kidney failure,
- if you have severe liver disease or reduced liver function,
- if you have a history of stomach ulcers or bleeding,
- if you suffer from indigestion,
- if you have an iron deficiency,
- if you are dehydrated.

GO PAIN ASPIRIN may cause difficulty breathing, asthma attacks or other allergic reactions. Risk factors are pre-existing asthma, hay fever, nasal polyps or other lung diseases. Your risk is also higher if you previously had allergic reactions, such as rash or itching, to other medicines.

You should stop taking GO PAIN ASPIRIN 1 week before surgery.
GO PAIN ASPIRIN may lead to increased bleeding during and after an operation.
This includes minor surgeries such as tooth extractions.

Low doses of GO PAIN ASPIRIN can trigger gout attacks.

GO PAIN ASPIRIN can cause swelling and fluid retention and can lead to heart failure in patients with heart problems. Caution is required if you have a high blood pressure or heart problems.

The elderly are more at risk of side effects, especially abdominal bleeding and rupture, which could lead to death. The risk of abdominal bleeding and rupture is higher with higher doses of GO PAIN ASPIRIN, and if you have a history of ulcers. Stop taking GO PAIN ASPIRIN immediately if this occurs.

GO PAIN ASPIRIN should be given with caution to patients with a history of gastrointestinal diseases as the conditions may be worsened.

Serious skin reactions, some of them fatal, including exfoliative dermatitis (redness and peeling of the skin), Stevens-Johnson syndrome and toxic epidermal necrolysis (rare, life-threatening skin conditions) have been reported. Stop taking GO PAIN ASPIRIN at the first appearance of skin rash or any other sign of an allergic reaction.

In patients suffering from severe glucose-6-phosphatedehydrogenase (GP6PD) deficiency, GO PAIN ASPIRIN may cause the destruction of red blood cells. The risk is higher with a high dosage, fever, or acute infections.

If you take GO PAIN ASPIRIN at higher than recommended doses or for a long period of time, the potassium levels in your blood can become very low and your kidneys may become damaged which affects their ability to remove acids properly from your blood into the urine (renal tubular acidosis). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

Children and adolescents

GO PAIN ASPIRIN should not be used in children and adolescents for viral infections (e.g., chickenpox, the flu) with or without fever, without consulting a doctor. Prolonged vomiting in conjunction with such illnesses could be a sign of Reye's syndrome, a very rare but life-threatening disease which requires immediate medical attention.

Other medicines and GO PAIN ASPIRIN

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

Do not take GO PAIN ASPIRIN if you are taking:

- Methotrexate at doses of 15 mg/week or more (see '**Do not take GO PAIN ASPIRIN**').

Tell your doctor if you are taking any of the following:

- Alcohol.
- Blood thinners such as warfarin, or medicines that prevent blood clotting.
- Certain antidepressants, called selective serotonin re-uptake inhibitors (SSRIs).
- Medicines used to treat high blood pressure, called angiotensin converting enzyme inhibitors (ACEI). Digoxin, used for certain heart conditions.
- Diuretics (water pills), used for swelling or for high blood pressure.
- Medicines used to treat gout, such as benzbromarone, probenecid, sulphinpyrazone.
- Medicines used to treat high blood sugar (diabetes), including insulin and oral antidiabetics.

- Medicines used to treat pain, fever and inflammation, called non-steroidal anti-inflammatory drugs (NSAIDs).
- Methotrexate at doses below 15 mg/week.
- Sedatives such as barbiturates, used for anxiety and sleeping.
- Sulphonamides, antibiotics used to treat infection.
- Valproic acid, used for certain mental conditions.

GO PAIN ASPIRIN with food, drink and alcohol

You should not take GO PAIN ASPIRIN tablets together with alcohol.

See "**How to take GO PAIN ASPIRIN**" for dosing instructions related to food.

Pregnancy, breastfeeding, and fertility

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 healthcare provider for advice before taking GO PAIN ASPIRIN.

Pregnancy

Safety in pregnancy has not been established.

GO PAIN ASPIRIN could increase the risk of miscarriage and damage to the foetus if taken in pregnancy. The risk increases with an increase in dose and duration of treatment.

Do not take GO PAIN ASPIRIN during the last three months of pregnancy (see **'Do not take GO PAIN ASPIRIN**').

Breastfeeding

Safety in breastfeeding has not been established.

GO PAIN ASPIRIN passes into breast milk in small quantities.

Fertility

Based on the limited published data available, human, and animal studies did not show any negative effect of GO PAIN ASPIRIN on fertility.

Driving and using machines

Do not drive or use machines if you experience dizziness.

It is not always possible to predict to what extent GO PAIN ASPIRIN may interfere with your daily activities. Do not engage in the above activities until you are aware of the measure to which GO PAIN ASPIRIN affects you.

3. How to take GO PAIN ASPIRIN

Always take GO PAIN ASPIRIN exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

GO PAIN ASPIRIN is for oral use. The tablets should preferably be taken after meals with plenty of water.

Adults and children 12 years and over:

300 – 1 000 mg as a single dose, to be repeated as needed after a minimum period of 4 hours.

Do not exceed 4 000 mg in 24 hours.

Use the lowest effective dose for the shortest possible duration of treatment. Do not use continuously for longer than ~~10~~ 3 – 5 days without consulting a doctor.

Excessive and prolonged use of this medicine may be dangerous.

Special populations

GO PAIN ASPIRIN should be used with caution in patients with abnormal liver or kidney function (see '**Warnings and precautions**').

Paediatric population

GO PAIN ASPIRIN is recommended for children below 12 years only under doctor's supervision.

If you take more GO PAIN ASPIRIN than you should

IN THE EVENT OF OVERDOSAGE, EVEN IF THE PERSON DOES NOT SHOW ANY SYMPTOMS OF OVERDOSAGE, CONTACT THE NEAREST DOCTOR, HOSPITAL OR POISON CONTROL CENTRE IMMEDIATELY. DO NOT EXCEED THE RECOMMENDED DAILY DOSE.

In children serious signs of overdosage may develop rapidly.

If you take more GO PAIN ASPIRIN than you should, you may experience any of the following:

- Rapid or deep breathing, fluid in the lungs, low oxygen levels, inability to breathe.
- Disturbance of the acid-base balance in the body.
- Fever, sweating.
- Nausea, vomiting, bleeding in the stomach or intestines.
- Irregular heartbeat, low blood pressure, heart attack.
- Dehydration, low urine output, kidney problems, kidney failure.
- High blood sugar or low blood sugar (especially in children).
- Ringing in the ears, a feeling that the world is spinning (vertigo), deafness.

- Blood thinning, increased bleeding.
- Restlessness, headache, brain damage, unresponsiveness, confusion, coma, fits (seizures).

If you take GO PAIN ASPIRIN at higher than recommended doses or for a long time, the potassium levels in your blood can become very low and your kidneys may become damaged (renal tubular acidosis). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

If you forget to take, GO PAIN ASPIRIN

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

GO PAIN ASPIRIN can have side effects.

Not all side effects reported for GO PAIN ASPIRIN are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking GO PAIN ASPIRIN, please consult your healthcare provider for advice.

If any of the following happens, stop taking GO PAIN ASPIRIN 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.
- Rash, hives or itching.
- Fainting.
- Blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS).

- Heart attack.
- Rupture of the stomach lining or intestines and bleeding inside the abdomen which can cause death.
- Persistent vomiting in patients who also suffer from viral infections such as chicken pox or the flu. This could be a sign of Reye's syndrome, a very rare but possibly life-threatening illness requiring immediate medical action, especially in children.

These are all very serious side effects. If you have them, you may have had a serious reaction to GO PAIN ASPIRIN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Stomach problems such as heartburn, sores in the mouth, stomach pain or swelling, stomach ulcers, feeling sick (nausea), throwing up, throwing up blood, loose stools, passing gas, difficulty passing stools, black stools or blood in the stool.
- Increased bleeding resulting in iron-deficiency with weakness, an unhealthy pale appearance and decreased blood flow through the body.
- Hypokalaemia (low levels of potassium in your blood)
- Dizziness, ringing in the ears.
- Swelling, high blood pressure.
- Liver or kidney problems.
- Renal tubular acidosis (the kidneys are damaged and can't remove a waste, called acid, rom the blood.)
- Falsely increased or decreased results of certain laboratory tests.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA online:

https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of GO PAIN ASPIRIN.

5. How to store GO PAIN ASPIRIN

Store all medicines out of reach of children.

Store at or below 25 °C, in a cool, dry place.

Protect from light.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What GO PAIN ASPIRIN contains

The active substance is aspirin.

Each tablet contains 300 mg aspirin.

The other ingredient is starch.

Sugar free.

What GO PAIN ASPIRIN looks like and contents of the pack

A plain, white, round, convex tablet.

PVC/aluminium foil blister, packed in a cardboard carton containing 10 or 20 tablets.

Holder of Certificate of Registration

Pharmacorp (Pty) Ltd

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South Africa

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Access to the corresponding Professional Information

Available on the SAHPRA website