

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

Myoprin 100 mg tablets
Aspirin**Myoprin contains sugar (40,0 mg lactose monohydrate per tablet)**
Myoprin contains sweetener (saccharin sodium 1,00 mg per tablet)

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

Myoprin 100 mg is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Myoprin carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Myoprin with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What Myoprin is and what it is used for

The active ingredient is 100 mg acetylsalicylic acid (aspirin) and is a platelet aggregation inhibitor.

Myoprin is used:

- To reduce the risk of myocardial infarction (heart attack) in patients with unstable angina or in patients who have had a previous myocardial infarction.
- To reduce the risk of recurrent transient ischaemic attacks or stroke in men who have had transient ischaemia of the brain due to fibrin platelet emboli.
- To reduce the risk of graft occlusion following aortocoronary by-pass surgery.

2. What you need to know before you take Myoprin

If you are taking medicines on a regular basis, using this medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

If you are pregnant or breastfeeding your baby while taking Myoprin 100 mg please consult your doctor, pharmacist or other healthcare provider for advice.

Do not take Myoprin if:

- you are hypersensitive to acetylsalicylic acid (aspirin) or any of the other ingredients of Myoprin (listed in section 6)
- you have an intolerance to aspirin (especially if you get asthma after you have taken aspirin)
- you have aspirin induced nasal polyps
- you have a heart condition or heart failure that is not well controlled
- you have active or history of recurrent ulcer/haemorrhage/perforations
- you have a history of asthma caused by salicylates or substances with a similar action, notably non-steroidal anti-inflammatory medicines
- you have gout
- you have a tendency to bleed
- you have severe kidney problems
- you have severe liver problems
- you are taking methotrexate at doses of 15 mg/week or more
- you are 20 weeks or more pregnant or if you are breastfeeding your baby

Warnings and precautions

Take special care with Myoprin:

- if you have a history of high blood pressure or heart failure
- if you have risk factors for heart conditions (high cholesterol, diabetes mellitus or smoking)
- if you are elderly – you have an increased frequency of adverse reactions to NSAIDs such as Myoprin, especially gastrointestinal perforation, stomach ulcer and/or bleeding
- stop using Myoprin if you suspect you have a stomach ulcer or stomach bleeding
- if you have a history of gastrointestinal diseases such as ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease or gut problems

- if you have serious skin reactions, you should stop using Myoprin at the first appearance of skin rash, mucosal lesions or any other sign of hypersensitivity
- pre-existing asthma, hay fever, nasal polyps, or chronic respiratory disease. This also applies to patients exhibiting allergic reactions (e.g. cutaneous reactions, itching, urticaria) to other substances
- hypersensitivity to analgesics/ anti-inflammatory medicines/ antirheumatic medicines and in the presence of other allergies
- if your liver is not working properly
- if you are also taking ibuprofen for pain
- you may need to stop taking Myoprin a week before you have any surgery done, including dental surgery. Check with your doctor if you should stop taking Myoprin and when you should start taking it again after you have had the surgery
- if you are due for routine surgery or certain anaesthetic procedures such as spinal or epidural anaesthesia. Myoprin reduces the ability of your blood to clot for one week after the last dose.

Tell your doctor that you are taking Myoprin

- viral infections such as influenza A, influenza B and varicella in children and adolescents under the age of 18. Should persistent vomiting occur with such diseases, this may be a sign of Reye's syndrome
- with other blood thinning products
- with other medicines for reducing uric acid
- if you have anaemia
- if you develop symptoms such as a high body temperature, widespread rash, swollen glands or facial swelling. This reaction can also include kidneys, liver, and heart dysfunction as well as blood test results (for example an abnormal increase in the number of disease-fighting white blood cells.)
- if you are 20 weeks or more than 20 weeks pregnant, taking Myoprin may cause serious kidney problems in your unborn baby. This may cause a delay in your babies' lung development as well as results in limb disabilities

Other medicines and Myoprin

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

If you are taking any of the following medicines, please consult your healthcare provider:

- Methotrexate
- Ibuprofen
- Anticoagulants, thrombolytics/other inhibitors of platelet aggregation/hemostasis
- Other non-steroidal anti-inflammatory medicines with salicylates at high doses

- Selective serotonin reuptake inhibitors (SSRIs)
- Digoxin
- Antidiabetics e.g. insulin, sulphonylureas
- Diuretics in combination with acetylsalicylic acid at higher doses.
- Systemic glucocorticoids, except hydrocortisone used as replacement therapy in Addison's disease
- Angiotensin converting enzyme inhibitors (ACE) in combination with acetylsalicylic acid at higher doses
- Valproic acid
- Alcohol
- Uricosurics such as benzbromarone and probenecid.

Myoprin with food and alcohol

Myoprin should be taken with food.

Concomitant use of Myoprin with alcohol will increase damage to gastrointestinal mucosa and prolong bleeding time.

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 Myoprin.

You should not take Myoprin if you are 20 weeks or more pregnant, unless you are advised to do so by your healthcare provider.

Regular or high doses of Myoprin during late pregnancy can cause serious complications in the mother or baby.

Do not breastfeed your baby if you are taking Myoprin.

Driving and using machines

It is not always possible to predict to what extent Myoprin may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which Myoprin affects you.

Some of the symptoms that you may experience with chronic Myoprin overdose include dizziness, tinnitus, deafness, nausea, headache, vomiting and mental confusion.

Myoprin contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Myoprin.

3. How to take Myoprin

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

Always take Myoprin exactly 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 one tablet daily at the same time each day with a meal.

You should swallow the whole tablet with some liquid.

In some circumstances a higher dose may be appropriate, especially in the short term, and up to 300 mg daily may be used on the advice of a doctor.

If you take more Myoprin than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of overdose may include dizziness, ringing in the ears, deafness, sweating, nausea, headache, vomiting and mental confusion. Symptoms of acute or severe intoxication following overdose includes hyperventilation, fever, ketosis, respiratory alkalosis and metabolic acidosis.

If you forget to take Myoprin

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

If you stop taking Myoprin

Do not stop taking Myoprin without speaking to your doctor.

4. Possible side effects

Myoprin can have side effects.

Not all side effects reported for Myoprin are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Myoprin, please consult your healthcare provider for advice.

If any of the following happens, stop taking Myoprin 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 or itching,
- fainting.

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

Tell your doctor if you notice any of the following:

Frequent side effects

- nausea, stomach pain or discomfort, indigestion or heartburn

- liver damage

Less frequent side effects

- bleeding in the brain
- gastrointestinal tract (from the mouth to the rectum) bleeding
- inflammation in the stomach, stomach ulcer or bleeding stomach ulcer
- localised bleeding outside of blood vessel, increased risk of bleeding
- unusual bleeding, such as coughing up blood, nose bleeding, blood in your vomit or urine, or black stools
- impaired liver function
- hives, swelling in lower legs, skin eruptions
- swelling in the arms or legs, high blood pressure, heart failure
- cramps in the lower respiratory tract, asthma attack
- runny nose
- breathing difficulty
- severe diarrhoea, vomiting, winds (flatulence), constipation
- ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis
- severe skin reactions such as blistering and peeling and life-threatening forms Stevens-Johnson syndrome

Frequency unknown side effects

- If you develop flu-like symptoms with a high body temperature, widespread rash, swollen glands, facial swelling and abnormal blood results (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

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, pharmacist or nurse. You can also report side effects to the South African Health Products Regulatory Authority (SAHPRA) via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications. By reporting side effects, you can help provide more information on the safety of Myoprin.

5. How to store Myoprin

Store all medicine out of reach of children.

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

Foil strips should be kept in the outer carton until required for use.

Do not use the tablets after the expiry date shown on the container.

Return the expired medicine to your pharmacist for safe disposal.

6. Contents of the pack and other information

What Myoprin contains

The active ingredient is acetylsalicylic acid (aspirin) 100 mg per tablet.

The other ingredients are calcium carbonate heavy, citric acid monohydrate lactose monohydrate, maize starch, purified talc and saccharin sodium.

What Myoprin looks like and contents of the pack

Myoprin is a white, flat bevelled edge round tablet with break line on one side and plain on the other.

Foil strips consisting of plain aluminum foil and printed aluminum foil.

Myoprin 100 mg tablets are available in packs of 30 tablets (10 tablets per strip, with three strips inserted together with the package insert in an outer cardboard carton).

Holder of Certificate of Registration

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This leaflet was last revised in:

09 June 2022

Registration Number:

B/2.7/1117

The Full Professional Information Leaflet is available from iPharma (Pty) Ltd, please email info@ipharma.co.za to request a digital copy.