Bayer (Pty) Ltd	**Date of revision of text: 30 June 2022**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

BAYER ASPIRIN CARDIO 100
100 mg Enteric Coated Tablets
Acetylsalicylic acid
Sugar free

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

BAYER ASPIRIN CARDIO 100 is avilable without a doctor's prescription, for you to treat an illness. Nevertheless, you still need to use BAYER ASPIRIN CARDIO 100 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BAYER ASPIRIN CARDIO 100 with any other person.
- Ask our health care provider or pharmacist if you need more information or advice.
- If you have further questions, please ask your doctor or pharmacist.
- BAYER ASPIRIN CARDIO 100 may have been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BAYER ASPIRIN CARDIO 100 is and what it is used for.
2. What you need to know before you take BAYER ASPIRIN CARDIO 100.
3. How to take BAYER ASPIRIN CARDIO 100.
4. Possible side effects.
5. How to store BAYER ASPIRIN CARDIO 100.
6. Contents of the pack and other information.

1. WHAT BAYER ASPIRIN CARDIO 100 IS USED FOR

BAYER ASPIRIN CARDIO 100 inhibits the adhesion and clumping of blood platelets (Thrombocytes) and in this way prevent blood clots (thrombi) from developing (inhibition of platelet aggregation).

BAYER ASPIRIN CARDIO 100 is used in adults:

- For reducing the risk of myocardial infarction (heart attack) in patients with unstable angina(unexpected chest pains) or in patients who have had a previous myocardial infarction.
- For reducing the risk of recurrent transient ischaemic attacks (repeat mini strokes) or stroke in patients who have had transient ischaemia of the brain due to fibrin platelet emboli.
- For reducing the risk of graft occlusion (blockage of vascular bypass graft) following aortocoronary by-pass surgery.
- For reducing the risk of having myocardial ischaemic events (heart attacks) in people with increased cardiovascular risk.

2. What you need to know before you take BAYER ASPIRIN CARDIO 100:

If you are pregnant or breastfeeding your baby while taking BAYER ASPIRIN CARDIO 100 please consult your doctor, pharmacist or other health care professional for advice.

Do not take BAYER ASPIRIN CARDIO 100:

If

- You are allergic to acetylsalicylic acid, to other salicylates, or to any of the other ingredients of BAYER ASPIRIN CARDIO 100
- You have a history of reacting to certain medicines against pain, fever, or inflammation (salicylates or non-steroidal anti-inflammatory medicines) with asthma attacks or other allergic reactions.
- You have a history of stomach ulcers (gastric or duodenal ulcers) or bleeding related to previous use of NSAIDs (medicines against pain, fever or inflammation) including BAYER ASPIRIN CARDIO 100
- You have acute stomach (gastric or duodenal) ulcers
- You have a pathologically increased tendency to bleed (haemorrhagic diathesis)
- You have severe liver (Child-Pugh C) or kidney failure (eGFR < 30 mL/minute)
- You have severe heart failure (NYHA grade III or IV)
- You are concurrently taking methotrexate (a medicine used to treat cancer and certain rheumatic disorders) at doses of 15 mg/week or more
- You are in the last trimester of pregnancy

Warnings and precautions

Talk to your doctor or pharmacist before taking BAYER ASPIRIN CARDIO 100

- if you are allergic to other analgesics/ anti-inflammatory agents/ antirheumatic medicines or if you suffer from other allergies;
- if you have a history of stomach ulcers (gastric or duodenal ulcers) including chronic or recurrent ulcer disease;
- if you have a history of bleeding in the stomach or bowel (digestive system bleeding);
- if you take anticoagulants or blood thinning products (medicines to prevent blood clots)(see Other medicines and BAYER ASPIRIN CARDIO 100)
- if your kidney function or your cardiovascular circulation are impaired (e.g., renal vascular disease, congestive heart failure, volume depletion, major surgery, sepsis or major haemorrhagic events), since acetylsalicylic acid may further increase the risk of kidney impairment and acute kidney failure;
- if you suffer from severe glucose-6-phosphate dehydrogenase (G6PD) deficiency (a human enzyme defect), since acetylsalicylic acid may cause the destruction of red blood cells with release of hemoglobin (hemolysis or hemolytic anemia). Factors that may increase the risk of haemolysis are, for example, high dosage, fever or acute infections;
- if you have impaired liver function;
- if you take metamizole or nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen and naproxen (medication against pain, fever or inflammation) (see Other Medicines and BAYER ASPIRIN CARDIO 100);
- if you have bronchial asthma, hay fever, swelling of the nasal mucosa (nasal polyps) or chronic respiratory tract diseases or are showing signs of allergic reaction to another substance;

If you need to have an operation (including minor surgery, such as dental extractions), tell your doctor or dentist if you have taken BAYER ASPIRIN CARDIO 100 since this may increase the bleeding tendency. If you cut or injure yourself, it may take longer than usual for the bleeding to stop. This is related to the action of BAYER ASPIRIN CARDIO 100. Minor cuts and injuries (e.g., when shaving) are generally not significant. If you experience unusual bleeding (at an unusual place or for an unusual length of time), consult your doctor.

At low doses, acetylsalicylic acid reduces the excretion of uric acid. This may cause a gout attack in patients who are more likely to get gout.

Children and adolescents

BAYER ASPIRIN CARDIO 100 should not be taken by children or adolescents with viral illnesses (e.g., flu) with or without fever. Prolonged vomiting 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 BAYER ASPIRIN CARDIO 100

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

Enhanced effects may lead to an increased risk of side effects:
- Methotrexate (a medicine used to treat cancer and certain rheumatic disorders): increased liver toxicity of methotrexate.
- NSAIDs (medicines against pain, fever or inflammation) and other antirheumatic medicines in general: increased risk of ulcers and bleeding in the digestive system.
- Anticoagulants ("blood-thinners" or medicines to prevent blood clots), thrombolytics (medicines that dissolve blood clots) or other medicines that affect the function of platelets (particles in the blood involved in blood clotting): increased risk of bleeding; pay attention to signs of external or internal bleeding (e.g., bruising) if you are undergoing such treatment.
- Selective Serotonin Re-uptake inhibitors (certain medicines for treatment of depression): increased risk of digestive system bleeding).
- Digoxin (a medicine used to strengthen the heart muscle contraction): increased digoxin in the blood.
- Antidiabetics (e.g., insulin, sulphonylureas): reduced blood sugar level.
- Systemic glucocorticoids (cortisones/corticosteroids/steroids taken by mouth or injection) except hydrocortisone replacement therapy for Addison's disease: risk of aspirin overdose when the glucocorticoid treatment is stopped, increased risk of ulcers and bleeding in the digestive system by using BAYER ASPIRIN CARDIO 100 and systemic glucocorticoids at the same time.
- Valproic acid (a medicine used to treat convulsions of the brain [epilepsy]): increased toxicity of valproic acid.
- Alcohol: increased digestive system bleeding and prolonged bleeding time.

Weakening of effects:
- Metamizole and some NSAIDs, such as ibuprofen and naproxen: decrease of BAYER ASPIRIN CARDIO 100's reduction of the sticking together and clumping of blood platelets (thrombocytes) and prevention of blood clots (thrombi); may limit BAYER ASPIRIN CARDIO 100's protection against heart attack and stroke.

- Diuretics (medicines that increase the excretion of water in urine): decreased filtration of the blood by the kidneys.
- Systemic glucocorticoids (cortisones/corticosteroids/steroids taken by mouth or injection) except hydrocortisone replacement therapy for Addison's disease: reduced level of aspirin in the blood.
- ACE (angiotensin converting enzyme) inhibitors (antihypertensives or medicines to treat high blood pressure): decreased filtration of the blood by the kidneys and decreased effect on high blood pressure.
- Uricosurics (gout remedies that promote the excretion of uric acid, e.g., benzbromarone, probenecid): decreased excretion of uric acid, which may cause a gout attack.

You should not take BAYER ASPIRIN CARDIO 100 in conjunction with any of the above-mentioned substances unless expressly instructed to do so by a doctor.

BAYER ASPIRIN CARDIO 100 and alcohol
You should not take BAYER ASPIRIN CARDIO 100 with alcohol.

Pregnancy, breastfeeding and fertility

If you discover that you are pregnant during treatment with BAYER ASPIRIN CARDIO 100, please notify your doctor without delay.

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.

If you take BAYER ASPIRIN CARDIO 100 on regular use, you should stop breastfeeding.

Driving and using machines

BAYER ASPIRIN CARDIO 100 has no or negligible influence on the ability to drive and use machines. However, due to possible side effect such as dizziness, you should check how you react to BAYER ASPIRIN CARDIO 100 before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

3. HOW TO TAKE BAYER ASPIRIN CARDIO 100

Do not share medicines prescribed for you with any other person.
Always take BAYER ASPIRIN CARDIO 100 exactkly as described in this leaflet or as your doctor,pharmacist or nurse have told you. Check with your doctor, pharmcits or nurse if you are not sure.

The usual dose is 100 mg daily.

Dosage in special cases
For reducing the risk of myocardial ischaemic events (heart attacks) in people with cardiovascular risk:
Take 100 mg every day, preferably at the same time each day or as the doctor has told you.

How to take
Swallow the tablets whole with plenty of water, preferably at least 30 minutes before meals. Do not crush, break or chew the tablets before swallowing because this will damage the enteric coating.

BAYER ASPIRIN CARDIO 100 is intended for long-term use. Your doctor will decide on the length of the treatment.

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

Dizziness and ringing in the ears, particularly in children and elderly patients, may indicate serious poisoning due to overdose.
Please contact your doctor if you suspect an overdose of BAYER ASPIRIN CARDIO 100. Your doctor will decide on the necessary measures to be taken depending on the severity of overdose/intoxication.

If you forget to take BAYER ASPIRIN CARDIO 100

If you have taken too little BAYER ASPIRIN CARDIO 100 or have forgotten to take a dose, do not, for example, take a double dose the next time. Instead, simply continue taking the medicine as described in the dosage instructions or as prescribed by your doctor.

If you stop taking BAYER ASPIRIN CARDIO 100
Please do not interrupt or stop treatment with BAYER ASPIRIN CARDIO 100 without first consulting your doctor.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

BAYER ASPIRIN CARDIO 100 can have side effects.
Not all side effects reported for BAYER ASPIRIN CARDIO 100 are included in this leaflet. Should your general health worsen while taking BAYER ASPIRIN CARDIO 100, please consult your health care provider for advice.

If any of the following happens, stop taking/using BAYER ASPIRIN CARDIO 100 and tell your doctor immediately or go to the casualty department at your nearest hospital:

Allergic reaction
Symptoms could be drop in blood pressure, attacks of difficult breathing, runny nose, stuffy nose, swelling of the face, tongue and larynx. Use of BAYER ASPIRIN CARDIO 100 should be stopped at the first signs of hypersensitivity or allergic reaction.

Bleeding
Long-term use of BAYER ASPIRIN CARDIO 100 may cause iron deficiency anaemia due to occult blood loss from the digestive system. If you pass black stools or vomit blood (signs of serious bleeding in the stomach), you must inform your doctor immediately.

Tell your doctor if you notice any of the following:

Frequent side effects
Dizziness, tinnitus-ringing in the ears, epistaxis-nose bleed, rhinitis-nasal congestion, dyspepsia-(heartburn, bloating, nausea, vomiting,discomfort and stomach pain), abdominal and gastrointestinal pains,gastrointestinal

inflammation, gastrointestinal haemorrhage-bleeding, rash, pruritis-itchy skin, urogenital haemorrhage-bleeding.

Less frequent side effects
Iron deficiency anaemia, hypersensitivity, allergic oedema-fluid retention, angioedema, cerebral and intracranial haemorrhage-bleeding in the brain, haematoma, nasal congestion, gingival bleeding-bleeding gums, gastrointestinal erosion and ulcer, hepatic impairment, urticaria-hives, haemorrhagic anaemia, anaphylactic reaction, haemorrhage, muscle haemorrhage, gastrointestinal ulcer perforation, increased transaminases-liver enzymes, renal impairment, acute renal failure.

Unknown frequency
Haemolysis-breakdown of red blood cells, haemolytic anaemia, anaphylactic shock, cardio-respiratory distress, procedural haemorrhage, aspirin-exacerbated respiratory disease, intestinal diaphraghm disease.

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 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 BAYER ASPIRIN CARDIO 100.

5. How to store BAYER ASPIRIN CARDIO 100

Store all medicines out of the reach of children.
Store at or below 30 °C.
Do not use after the expiry date on the carton.
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 BAYER ASPIRIN CARDIO 100 contains

The active ingredient is 100mg Acetylsalicylic acid per tablet.
The other ingredients are cellulose, maize starch, methacrylic acid- ethyl acrylate copolymer, talc, triethyl citrate, sodium lauryl sulphate, polysorbate 80

What BAYER ASPIRIN CARDIO 100 looks like and contents of the pack

BAYER ASPIRIN CARDIO 100 tablets are white, round and coated.
Each pack contains 100 mg tablets packed into blister packs of 30.

Holder of Certificate of Registration

Bayer (Pty) Ltd

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