**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** **S0**

# BAYER ASPIRIN 300 mg Tablets

## Acetylsalicylic Acid

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

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

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

**What is in this leaflet**


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

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## 1. What Bayer Aspirin is and what it is used for

Bayer Aspirin is an antipyretic (reduces fever) and anti-inflammatory analgesic indicated for short-term use in the relief of mild to moderate pain (headache, toothache, menstrual cramps, nerve pain, muscular and joint pain, back pain and pain associated with colds) and fever.

## 2. What you need to know before you take Bayer Aspirin

**Do not take Bayer Aspirin:**

- If you are hypersensitive (allergic) to acetylsalicylic acid or other salicylates or to any other ingredients of Bayer Aspirin
- If you are suffering from acute gastrointestinal ulcers
- If you are suffering from blood clotting disorder, a low blood platelet count or other bleeding tendencies
- If you have liver, kidney or heart failure
- If you are receiving oral anti-coagulant therapy (medicines that prevent the blood from clotting)
- If you have a history of asthma induced by the administration of aspirin
- If you are taking methotrexate at doses of 15 mg or more per week
- In the last three months of pregnancy
- If you have a history of a ruptured bowel, ulceration or bleeding related to previous NSAIDs use, including Bayer Aspirin
- If you have an active or history of recurrent ulcer/bleeding/perforation.

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**Warnings and precautions**

Consult your doctor if your symptoms persist. Do not use Bayer Aspirin continuously for more than 3 – 5 days without consulting your doctor.

Bayer Aspirin should be administered with cation in the following cases:

- If you are allergic to pain medication / medication that reduces swelling / medication for rheumatism and in the presence of other allergies
- If you have impaired kidney function or impaired cardiovascular circulation as Bayer Aspirin may further increase the risk of kidney impairment and acute kidney failure
- If you have severe liver disease
- If you have a history of gastrointestinal ulcers including chronic or recurrent ulcer disease or a history of gastrointestinal bleeding
- If you are taking anti-coagulants (medicines that prevent the blood from clotting)
- If your liver is not functioning properly

Bayer Aspirin may give rise to bronchospasm (sudden constriction of the small airways of the lungs) and induce asthma attacks or other allergic reactions.

You should stop taking Bayer Aspirin 1 week before surgery.

Bayer Aspirin may lead to an increased bleeding tendency during and after surgical operations.

Gout attacks can be triggered in predisposed patients at low doses of Bayer Aspirin.

In view of the medicine’s inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Fluid retention and oedema (swelling) have been reported in association with Bayer Aspirin therapy, thus caution is required in patients with a history of hypertension (high blood pressure) and/or heart failure.

In patients suffering from severe glucose-6-phosphatedehydrogenase (GP6PD) deficiency, Bayer Aspirin may induce hemolysis or hemolytic anemia (destruction of red blood cells). Factors that may increase the risk of hemolysis are high dosage, fever, or acute infections.

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Patients with a history of ulcer and the elderly have a higher risk of gastrointestinal bleeding or perforation (PUBs) with increased doses of Bayer Aspirin which may be fatal. Treatment with Bayer Aspirin should be stopped when gastrointestinal bleeding or ulceration occurs.

Bayer 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. Bayer Aspirin should be discontinued at the first appearance of skin rash, mucosal lesions or any other allergic reaction.

**Children and adolescents**

Bayer Aspirin should not be used in children and adolescents for viral infections 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 Bayer Aspirin**

Always tell your health care professional if you are taking any other medicine.

You should not take Bayer Aspirin if you are taking or using the following medicines:

- Methotrexate at doses of 15 mg/week or more
- Anticoagulants such as warfarin, heparin, enoxaparin
- Platelet aggregation inhibitors such as clopidogrel, dipyridazole,trotiban
- Digoxin
- Antidiabetics such as insulin, sulphonylureas (e.g. gliclazide, glibenclamide, glipizide)
- Valproic acid or sodium valproate
- Uricosurics such as probenecid, benzbromarone, sulfinpyrazone
- Angiotensin converting enzyme inhibitors such as captopril, enalapril

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- Systemic glucocorticoids (such as prednisone, prednisolone, dexamethasone), except hydrocortisone when used as replacement therapy in Addison's disease.
- Selective serotonin re-uptake inhibitors such as fluoxetine, fluvoxamine, paroxetine
- Alcohol

**Bayer Aspirin with food, drink and alcohol**

Bayer Aspirin tablets should be taken after meals with lots of water.

You should not take Bayer Aspirin tablets together with alcohol.

**Pregnancy and breastfeeding and fertility**

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Bayer Aspirin tablets should not be taken in the first and second trimester of pregnancy unless clearly necessary. Do not take Bayer Aspirin during the last three months of pregnancy.

Bayer Aspirin passes into breast milk in small quantities. Breast feeding should be discontinued when Bayer Aspirin is taken on a regular basis or if high doses are being taken.

Based on the limited published data available, the studies in humans showed no consistent effect of Bayer Aspirin on impairment of fertility and there is no conclusive evidence from animal studies.

**Driving and using machines**

No effects on ability to drive and use machines have been observed.

## 3. How to take Bayer Aspirin

Do not share Bayer Aspirin prescribed for you with any other person.

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Always take Bayer Aspirin as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Bayer Aspirin should not be taken for more than 3 – 5 days without consulting your doctor.

Adults and children 12 years and over:

300 – 1000 mg as a single dose, to be repeated as needed after a minimum period of 4 hours.

A maximum daily dose of 4000 mg must not be exceeded.

Use the lowest effective dose for the shortest possible duration of treatment.

Special population:

- Bayer Aspirin should be used with caution in patients with abnormal hepatic (liver) function.
- Bayer Aspirin should be taken with caution in patient with abnormal renal (kidney) function.

Paediatric population:

- Bayer Aspirin is recommended for children below 12 years only under physician's supervision. In general, the daily dose of Bayer Aspirin in children is about 60 mg/kg, given as 4 to 6 divided doses, i.e. about 15 mg/kg every 6 hours or 10 mg/kg every 4 hours. In case of accidental administration or use in children, see section "Warnings and precautions".

For oral use.

The tablets should preferably be taken after meals with plenty of water.

**If you take more Bayer Aspirin tablets 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 center.

In the event that you take more Bayer Aspirin than you should, you may experience some of these symptoms: dizziness, sensation of motion, sweating, nausea, vomiting, ringing in the ears, headache and confusion.

## 4. Possible side effects

Bayer Aspirin can have side effects.

**Not all side effects reported for Bayer Aspirin are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine please consult your doctor, pharmacist or other health care professional for advice.**

The side effects include:

Bleeding, hypersensitivity, swelling of the skin, allergic reaction, anaphylactic reaction/shock, rash, hives, dizziness and ringing in the ears, gastrointestinal and abdominal pain, heartburn, nausea, belching, liver impairment, kidney impairment, life-threatening skin conditions, tightening of muscles in the lungs, shortness of breath.

If any of these side effects continue or bother you, tell 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 SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**" found online under SAHPRA publications: https://www.sahpra.org.za/Publications/Index/8. or you can report the side effects directly to Bayer Pharmacovigilance Department by sending an

email to zapv@bayer.com or via the Bayer website (www.bayer.co.za). By reporting side effects, you can help provide more information on the safety of Bayer Aspirin.

## 5. How to store Bayer Aspirin

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

Store at or below 25 °C.

Do not use after the expiry date stated on the blister pack and the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicines in drains or sewerage (e.g. toilets).

## 6. Contents of the pack and other information

### What Bayer Aspirin contains

The active substance is: Acetylsalicylic acid 300 mg

The other ingredients are: Cellulose powder and maize starch.

### What Bayer Aspirin looks like and contents of the pack

A round, white tablet that bulges outward on both sides, with the Bayer Cross on one side and Aspirin 0.3 on the other.

300 mg tablets in blister packs of 10, 20, 30, 50, 100, and 1000, packed in cartons.

### Holder of Certificate of Registration

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**Access to the corresponding Professional Information**

www.bayer.co.za

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