

PATIENT INFORMATION LEAFLET FOR AZPAMIN 100

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SCHEDULING STATUS: S2

AZPAMIN 100

Acetylsalicylic Acid (Aspirin)

Sugar free

AZPAMIN 100 contains salt (sodium, 0,29 mg per tablet)

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

AZPAMIN 100 is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use AZPAMIN 100 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share AZPAMIN 100 with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What AZPAMIN 100 is and what it is used for

AZPAMIN 100 contains aspirin which belongs to a group of medicines called antiplatelet medicines that help prevent your blood cells sticking together and forming a blood clot.



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AZPAMIN 100 is used for:

- For reducing the risk of myocardial infarction (heart attack) in patients with unstable angina angina (unexpected chest pains) or in patients who have had a previous heart attack.
- For reducing the risk of recurrent transient ischaemic attacks (repeat mini stroke) 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 AZPAMIN 100

Do not take AZPAMIN 100:

- If you are hypersensitive (allergic) to acetylsalicylic acid or other salicylates or to any of the ingredients of this medicine (listed in section 6)
- If you are suffering from blood clotting disorder, a low blood platelet count or other bleeding tendencies
- If you have a history of asthma induced by the administration of aspirin
- If you have severe kidney or liver problems
- If you are suffering from acute gastrointestinal ulcers
- If you are receiving oral anti-coagulant therapy (medicines that prevent the blood from clotting)
- If you have heart failure
- If you are taking methotrexate at doses of 15 mg or more per week
- If you have a history of a ruptured bowel, ulceration or bleeding related to previous NSAIDs use, including AZPAMIN 100

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- If you have an active or history of recurrent ulcer/bleeding/perforation.
- You are in the last trimester of pregnancy
- If you have growths in the nose or the sinuses.

Warnings and Precautions

AZPAMIN 100 should be administered with caution in the following cases:

- If you are allergic to pain medicine/medicine that reduces swelling/medicine for rheumatism and in the presence of other allergies
- If you have impaired cardiovascular circulation as AZPAMIN 100 may further increase the risk of kidney impairment and acute kidney failure

Take special care with AZPAMIN 100:

- AZPAMIN 100 may cause bronchospasm (sudden constriction of the small airways of the lungs) and induce asthma attacks or other allergic reactions.
- You should stop taking AZPAMIN 100 one week before surgery.
AZPAMIN 100 may lead to an increased bleeding tendency during and after surgical operations.
- Gout attacks can be triggered in predisposed patients at low doses of AZPAMIN 100.
- Because this medicine may cause fluid retention, heart failure may be triggered in some compromised patients. AZPAMIN 100 should be used with caution if you have reduced kidney function and if you are dehydrated.
- Fluid retention and oedema (swelling) have been reported in association with AZPAMIN 100 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, AZPAMIN 100 may cause 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 AZPAMIN 100 which may be fatal. Treatment with AZPAMIN 100 should be stopped when gastrointestinal bleeding or ulceration occurs.
- AZPAMIN 100 should be given with caution to patients with a history of gastrointestinal diseases such as ulcerative colitis and irritable bowel syndrome 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. AZPAMIN 100 should be discontinued at the first appearance of skin rash, mucosal lesions or any other allergic reaction.

Children and adolescents

AZPAMIN 100 may cause Reye's syndrome when given to children. Reye's syndrome is a rare disease in children and teenagers which affects the brain and liver and can be life threatening. For this reason, a doctor should be consulted before AZPAMIN 100 is given to such patients.

Other medicines and AZPAMIN 100

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

You should not take AZPAMIN 100 if you are taking or using the following medicines:

- Methotrexate (used as an immunosuppressant for cancer, skin problems, rheumatic problems, Crohn's disease) at doses of 15 mg/week or more
- Coumarin anticoagulants (such as warfarin, heparin, enoxaparin) used to thin your blood or prevent blood clots
- Selective Serotonin Re-uptake Inhibitors (SSRIs) such as citalopram, fluoxetine and sertraline used to treat depression and anxiety

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- Digoxin (used to treat various heart conditions)
- Antidiabetics medicines such as insulin, sulphonylureas (e.g. gliclazide, glibenclamide, glipizide)
- Systemic glucocorticoids (such as prednisone, prednisolone, dexamethasone), except hydrocortisone when used as replacement therapy in Addison's disease.
- Angiotensin converting enzyme inhibitors such as captopril, enalapril (used to treat high blood pressure or heart failure)
- Phenytoin and valproic acid (used to treat epilepsy)
- Probenecid and sulfinpyrazone (used for gout)
- Other NSAIDs (anti-inflammatory medicine).
- Metoclopramide (used to treat nausea and vomiting).
- Diuretics such as hydrochlorothiazide
- Antacids and citrates

AZPAMIN 100 with food and drink

AZPAMIN 100 can be taken with water or fruit juice.

AZPAMIN 100 should not be used with alcohol because it may increase the damage to the lining of your intestines 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 health care provider for advice before taking AZPAMIN 100.

Pregnancy

Do not take AZPAMIN 100 if you are in your first or last three months of pregnancy (see "**Do not**

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take AZPAMIN 100”).

Breastfeeding

AZPAMIN 100 passes into breast milk in small quantities. Breast feeding should be discontinued when AZPAMIN 100 is taken on a regular basis or if high doses are being taken.

Do not take AZPAMIN 100 while you are breastfeeding your baby (see “**Do not take AZPAMIN 100**”).

Fertility

No consistent data is available on the effect of AZPAMIN 100 on fertility.

Driving and using machines

AZPAMIN 100 may cause dizziness. It is not always possible to predict to what extent AZPAMIN 100 may interfere with your daily activities. You should not drive or operate machinery until you know how AZPAMIN 100 affects you.

AZPAMIN 100 contains salt (sodium)

AZPAMIN 100 contains less than 23 mg sodium (salt) per tablet, that is to say essentially ‘sodium-free’.

3. How to take AZPAMIN 100

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

Always take AZPAMIN 100 exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 100 mg daily.



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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.

Special population:

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

AZPAMIN is for oral use.

Swallow the tablets whole with plenty of water, preferably at least 30 minutes before meals.

If you have the impression that the effect of AZPAMIN 100 is too strong or too weak, tell your doctor or pharmacist.

If you take more AZPAMIN 100 than you should

Symptoms of overdose may include dizziness, ringing in ears, hearing problems, sweating, nausea (feeling sick), headache, vomiting (being sick) and confusion. A large overdose can lead to more rapid breathing than normal (hyperventilation), fever, restlessness, coma, low blood sugar difficulty breathing.

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

If you forget to take AZPAMIN 100

If you have missed your dose by only a few hours, take the missed dose as soon as you remember.

If it is almost time for your next dose, skip the missed dose and take AZPAMIN 100 at the next



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

4. Possible side effects

AZPAMIN 100 can have side effects.

Not all side effects reported for AZPAMIN 100 are included in this leaflet. Should your general health worsens, or if you experience any untoward effects while taking AZPAMIN 100, please consult your healthcare provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips, 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 AZPAMIN 100. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Reddening of the skin with blisters or peeling and may be associated with a high fever and joint pains (this could be erythema multiforme, Stevens-Johnson syndrome or Lyell's syndrome),
- Unusual bleeding, such as coughing up blood, blood in your vomit or urine, or black stools

These are serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

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- Feeling or being sick, diarrhoea,
- Indigestion,
- Constipation,
- Increased winds,
- Stomach ulcers,
- Mouth ulcers.

Less frequent side effects:

- Increased liver enzymes.

Side effects with unknown frequency:

- Runny nose,
- Breathing difficulty,
- Cramps in the lower respiratory tract, asthma attack,
- Low blood platelet count,
- Blood disorders,
- Prolonged bleeding time,
- Salt or water retention which may cause swelling of hands, feet, legs, stomach, breasts or face.
- Impaired liver function,
- High level of uric acid in the blood,
- Increased blood pressure.

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

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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 Med Safety APP Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of AZPAMIN 100.

5. How to store AZPAMIN 100

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from heat, cold, moisture and light.
- Preserve in tightly closed container.
- Do not use after the expiry date printed on the label or the carton.
- Return all unused tablets to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems.

6. Contents of the pack and other information

What AZPAMIN 100 contains

The active substance is 100 mg or 300 mg aspirin (acetylsalicylic acid).

The other ingredients are cross carmellose sodium, microcrystalline cellulose PH -102, pre-gelatinised starch, purified talc, sodium lauryl sulphate and stearic acid.

What AZPAMIN 100 looks like and contents of the pack

White to off-white coloured, round shaped, uncoated tablet, plain on one side and break line on other side.

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Aluminium-PVDC blister strips packed in an outer carton.

Pack size: 28 or 30 tablets.

White HDPE ribbed container with white cap: Pack size: 1 000 tablets

Not all pack sizes may be marketed.

Holder of certificate of registration

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