PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

AZPAMIN Enteric coated tablets

Aspirin

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share AZPAMIN with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

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

1. What AZPAMIN is and what it is used for

AZPAMIN 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.

AZPAMIN is used to prevent the formation of blood clots following a heart attack or stroke or to help prevent heart attacks and strokes in patients who have previously suffered from these conditions. It may have been prescribed for you if you have recently had by-pass surgery.

2. What you need to know before you take AZPAMIN

Do not take AZPAMIN:

- If you are hypersensitive (allergic) to aspirin or any of the ingredients of this medicine (listed in section 6).
- If you are allergic to other salicylates or non-steroidal anti-inflammatory drugs (NSAIDs).
- If you have had an asthma attack or swelling of some parts of the body e.g. face, lips throat or tongue (angioedema) after taking salicylates or NSAIDs.
- If you currently have or have ever had an ulcer in your stomach or small intestine or have had any other type of bleeding like a stroke.
- If you have bleeding disorders and your blood does not clot properly.
- If you have gout.
- If you have severe kidney or liver problems.
- If you have severe heart problems which can cause shortness of breath and swelling of the ankles.
- If you are in your first or last three months of pregnancy (see section "**Pregnancy and breastfeeding**").
- If you are scheduled to have surgery, you should stop taking AZPAMIN a week before the surgery.
- If you are taking a medicine called methotrexate (e.g. for cancer or rheumatoid arthritis) in doses higher than 15 mg per week.

Warnings and Precautions

Tell your doctor before taking AZPAMIN:

- If you have trouble with your kidneys, liver or heart.
- If you have or have ever had problems with your stomach or small intestine.
- If you have uncontrolled high blood pressure.

- If you are asthmatic, have hay fever, nasal polyps or other chronic respiratory diseases; aspirin may induce an asthma attack.
- If you have ever had gout.
- If you have heavy menstrual periods.
- If you suffer from a deficiency of the glucose-6-phosphate dehydrogenase (G6PD) enzyme.
- If you have had a serious skin reaction to any medicine, accompanied by a fever, swollen or enlarged lymph nodes and/or facial swelling.

You must immediately seek medical advice if your symptoms get worse or if you experience severe or unexpected side effects e.g. unusual bleeding symptoms, serious skin reactions or any other sign of serious allergy (see section 4 "**Possible side effects**").

Inform your doctor if you are planning to have an operation (even a minor one, such as tooth extraction) since aspirin is blood-thinning and there may be an increased risk of bleeding.

Aspirin may cause Reye's syndrome when given to children. Reye's syndrome is a very rare disease which affects the brain and liver and can be life threatening. For this reason, AZPAMIN should not be given to children aged under 18 years, unless advised by a doctor.

You should take care not to become dehydrated (you may feel thirsty with a dry mouth) since the use of aspirin at the same time may result in deterioration of kidney function.

Children and adolescents

Aspirin may cause Reye's syndrome when used by 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 aspirin should not be administered to children and adolescents younger than 18 years,

unless prescribed by a doctor (see section 2 “**Warnings and precautions**”).

Other medicines and AZPAMIN

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

AZPAMIN may affect the way some medicines work.

Before taking AZPAMIN, tell your doctor if you are using any of the following medicines.

The effect of treatment may be influenced if AZPAMIN is taken at the same time as some other medicines for:

- Thinning of the blood/prevention of clots (e.g. warfarin, heparin, clopidogrel, alteplase).
- Rejection of organ after transplantation (e.g. ciclosporin, tacrolimus).
- High blood pressure (e.g. diuretics and ace-inhibitors).
- Regulation of the heartbeat (e.g. digoxin).
- Manic-depressive illness (e.g. lithium).
- Pain and inflammation (e.g. NSAIDs such as ibuprofen or steroids).
- Gout (e.g. probenecid).
- Epilepsy (e.g. valproate, phenytoin).
- Glaucoma (e.g. acetazolamide).
- Cancer or rheumatoid arthritis (e.g. methotrexate; in doses lower than 15 mg per week).
- Diabetes (e.g. glibenclamide, insulin).
- Depression (selective serotonin re-uptake inhibitors [SSRIs] such as sertraline or paroxetine).
- Use of hormone replacement therapy when the adrenal glands or pituitary gland have been destroyed or removed, or the use of corticosteroids to treat inflammation, including rheumatic diseases and inflammation of the intestines.

- Antacids (indigestion medicine).
- Metamizole (substance to decrease pain and fever) may reduce the effect of aspirin on platelet aggregation (blood cells sticking together and forming a blood clot), when taken concomitantly. Therefore, this combination should be used with caution in patients taking low dose aspirin for cardio protection.

AZPAMIN with food and drink

AZPAMIN can be taken with water or fruit juice.

Drinking alcohol may possibly increase the risk of gastrointestinal bleeding and prolong bleeding time.

Pregnancy and 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 this medicine.

Pregnancy

Do not take AZPAMIN tablets if you are pregnant unless advised by a doctor (see section "**Do not take AZPAMIN**"**).**

You should not take AZPAMIN if you are in the first or last 3 months of pregnancy, unless you are advised to do so by your doctor (see section "**Do not take AZPAMIN** "). Regular or high doses of AZPAMIN during late pregnancy can cause serious complications in the mother or baby.

Breastfeeding

You should not take AZPAMIN during breastfeeding unless advised by your doctor.

Driving and using machines

AZPAMIN may cause dizziness. You should not drive or operate machinery until you know how AZPAMIN affects you.

AZPAMIN contains salt

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

3. How to take AZPAMIN

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

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

To prevent blood clots:

Adults:

Your doctor will tell you how many tablets to take.

The usual dose is one to three tablets daily, preferably at the same time each day.

If you take more AZPAMIN than you should

Symptoms of overdose may include dizziness, ringing in the 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 and difficulty in 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

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

If you stop taking AZPAMIN

Do not stop taking AZPAMIN unless your doctor tells you to.

4. Possible side effects

AZPAMIN can have side effects.

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

If any of the following happens, stop taking AZPAMIN 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. 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 which 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:

- Feeling sick (nausea) or being sick (vomiting), diarrhoea.
- Indigestion.
- Increased tendency for bleeding.

Less frequent side effects:

- Hives.
- Runny nose.
- Breathing difficulty.
- Severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells.
- Cramps in the lower respiratory tract, asthma attack.
- Inflammation in the blood vessels.
- Bruising with purple spots (cutaneous bleeding).
- Reye's syndrome (a very rare disease in children which affects the brain and liver (see section 2 "**Children and adolescents**").
- Abnormal heavy or prolonged menstrual periods.

Side effects with unknown frequency:

- Ringing in your ears (tinnitus) or reduced hearing ability.
- Headache.

- Vertigo.
- Ulcers in stomach or small intestine and perforation.
- Prolonged bleeding time.
- Impaired kidney function, acute renal failure.
- Salt or water retention which may cause swelling of hands, feet, legs, stomach, breasts or face.
- Impaired liver function, increased liver enzymes.
- High level of uric acid in the blood or low levels of sugar in the blood.
- Severe skin rash with a fever, swollen or enlarged lymph nodes and/or facial swelling.

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. This includes any possible side effects not listed in this leaflet.

You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found on SAHPRA's website: www.sahpra.org.za under "online services". By reporting side effects, you can help provide more information on the safety of AZPAMIN.

5. How to store AZPAMIN

- Store at or below 25 °C.
- Protect from heat, cold, moisture and light.
- Preserve in tightly closed container.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- 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 contains

The active substance is 81 mg aspirin.

The other ingredients are cross carmellose codium, isopropyl alcohol, microcrystalline cellulose, pregelatinised maize starch, purified talc, sodium lauryl sulphate.

The tablet coating contains Wincoat WT-TR-5002 and Wincoat WT-NAQ-6015 Orange.

What AZPAMIN looks like and contents of the pack

Orange coloured, round shaped, enteric coated tablet having “81” engraved on one side and plain on other side.

Contents of the pack

Blisters:

Aluminium- PVC/PE/PVDC triplex foil blister pack of 10 tablets and such 3, 5 or 10 blisters are packed
in an outer carton.

Pack size: 30, 50 or 100 enteric coated tablets.

Bottle:

Enteric coated tablets are packed in a polypropylene bag inside a white HDPE bottle with a white cap. The bottle is packed in an outer carton.

Pack size: 200 or 1000 enteric coated tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

Forrester Pharma (Pty) Ltd

2 Waterford Mews

Waterford Place

Century City

7441

Cape Town

South Africa

This leaflet was last revised in

13 August 2024

Registration number

56/8/0993