This product has different legal status in different countries.
For current legal status in Sweden, please refer to the approved Swedish package leaflet published on MPAs Webb site.

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sifuprin 75 mg gastro-resistant tablets
Sifuprin 100 mg gastro-resistant tablets
Sifuprin 150 mg gastro-resistant tablets
Sifuprin 160 mg gastro-resistant tablets

Acetylsalicylic acid

<Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.>

<Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to take Sifuprin carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.>

<[To be completed nationally]>

In this leaflet:

1. WHAT SIFUPRIN IS AND WHAT IT IS USED FOR

Sifuprin contains acetylsalicylic acid, which in low doses belong to a group of medicines called anti-platelet agents. Platelets are tiny cells in the blood that cause the blood to clot and are involved in thrombosis. When a blood clot occurs in an artery it stops the blood flowing and cuts off the oxygen supply. When this happens in the heart it can cause a heart attack or angina; in the brain it can cause a stroke.

Sifuprin is taken to reduce the risk of blood clots forming and thereby prevent further:
- heart attacks
- strokes
- cardiovascular problems in patients who suffer from stable or unstable angina (a type of chest pain).

Sifuprin is also used to prevent the formation of blood clots after certain types of heart surgery in order to widen or to unblock the blood vessels.

This medicinal product is not recommended for emergencies. It can only be used as a preventive treatment.

2. BEFORE YOU TAKE SIFUPRIN

Do not take Sifuprin if you
- are allergic to acetylsalicylic acid or any of the ingredients in Sifuprin (see section 6 “Further information”)
- are allergic to other salicylates or non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs are often used for arthritis or rheumatism and pain
- 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
- currently have or have ever had an ulcer in your stomach or small intestine or any other type of bleeding like a stroke
- have ever had the problem of your blood not clotting properly
- have severe liver or kidney problems
- are in your last 3 months of pregnancy; you must not use higher doses than 100 mg per day (see section “Pregnancy and breast-feeding”)
- are taking a medicine called methotrexate (e.g. for cancer or rheumatoid arthritis) in doses higher than 15 mg per week

Take special care with Sifuprin
Before you take Sifuprin tell your doctor if you:
- have trouble with your kidneys, liver or heart
- have or have ever had problems with your stomach or small intestine
- have high blood pressure
- are asthmatic, have hay fever, nasal polyps or other chronic respiratory diseases; acetylsalicylic acid may induce an asthma attack
- have ever had gout
- have heavy menstrual periods

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 “Possible side effects”).

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

Acetylsalicylic acid 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 live threatening. For this reason, Sifuprin should not be given to children aged under 16 years, unless on the advice of a doctor.

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

This medicinal product is not suitable as a pain killer or fever reducer.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The effect of treatment may be influenced if acetylsalicylic acid is taken at the same time as some other medicines for:
- thinning of the blood/prevention of clots (e.g. warfarin, heparin, clopidogrel)
- rejection of organ after transplantation (cyclosporine, tacrolimus)
- high blood pressure (e.g. diuretics and ACE-inhibitors)
- regulation of the heart beat (digoxin)
- manic-depressive illness (lithium)

- pain and inflammation (e.g. NSAIDs such as ibuprofen, or steroids)
- gout (e.g. probenecid)
- epilepsy (valproate, phenytoin)
- glaucoma (acetazolamide)
- cancer or rheumatoid arthritis (methotrexate; in doses lower than 15 mg per week)
- diabetes (e.g. glibenclamide)
- depression (selective serotonin re-uptake inhibitors (SSRIs) such as sertraline or paroxetine).
- use as hormone replacement therapy when the adrenal glands or pituitary gland have been destroyed or removed, or to treat inflammation, including rheumatic diseases and inflammation of the intestines (corticosteroids)

Taking Sifuprin with food and drink
Drinking alcohol may possibly increase the risk of gastrointestinal bleeding and prolong bleeding time.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

Pregnant women should not take acetylsalicylic acid during pregnancy unless advised by their doctor.
You should not take Sifuprin if you are in the last 3 months of pregnancy, unless you are advised to do so by your doctor and then the daily dose should not exceed 100 mg (see section "Do not take Sifuprin"). Regular or high doses of this medicinal product during late pregnancy can cause serious complications in the mother or baby.

Breast-feeding women should not take acetylsalicylic acid unless advised by their doctor.

Driving and using machines
Sifuprin should not affect your ability to drive and use machines.

3. HOW TO TAKE SIFUPRIN

Always take Sifuprin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults
Prevention of heart attacks:
- The recommended dose is 75-160 mg once daily.

Prevention of strokes:
- The recommended dose is 75-325 mg once daily.

Prevention of cardiovascular problems in patients who suffer from stable or unstable angina (a type of chest pain):
- The recommended dose is 75-160 mg once daily.

Prevention formation of blood clots after certain types of heart surgery:
- The recommended dose is 75-160 mg once daily.

Elderly
As for adults. In general, acetylsalicylic acids should be used with caution in elderly patients who are more prone to adverse events. Treatment should be reviewed at regular intervals.

Children
Acetylsalicylic acid should not be administered to children and adolescents younger than 16 years, unless prescribed by a doctor (see section "Take special care with Sifuprin").

Method of administration
For oral use.

The tablets should be swallowed whole with sufficient fluid (1/2 glass of water). The tablets have a gastro-resistant coating which prevents irritant effects on the gut, and should therefore not be crushed, broken or chewed.

If you take more Sifuprin than you should
If you (or someone else) accidentally take too many tablets, you should tell your doctor at once or contact immediately the nearest casualty department. Show any left over medicines or the empty packet to the doctor.
Symptoms of overdose may include ringing in ears, hearing problems, headache, dizziness, confusion, nausea, vomiting and abdominal pain. A large overdose can lead to more rapid breathing than normal (hyperventilation), fever, excess sweating, restlessness, seizures, hallucinations, low blood sugar, coma and shock.

If you forget to take Sifuprin
If you miss a dose, wait until it is time for your next dose, then go on as normal.
Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sifuprin can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects, stop taking Sifuprin and contact a doctor immediately:
- Sudden wheezing, swelling of your lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction)**.**
- Reddening of the skin with blisters or peeling and may be associated with a high fever and joint pains. This could by 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.

<u>Common side effects (may occur in 1 to 10 out of 100 patients):</u>
- Indigestion.
- Increased tendency for bleeding.

<u>Uncommon side effects (may occur in 1 to 10 out of 1,000 patients):</u>
- Hives.
- Runny noses.
- Breathing difficulty.

<u>Rare side effects (may occur in 1 to 10 out of 10,000 patients):</u>
- Severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells.
- Nausea and vomiting.
- Cramps in the lower respiratory tract, asthma attack.
- Inflammation in the blood vessels.
- Bruising with purple spots (cutaneous bleeding).
- Severe skin reactions such as rash known as erythema multiforme and it's life threatening forms Stevens-Johnson syndrome and Lyell's syndrome.
- Hypersensitivity reactions, such as swelling of e.g. lips, face or body, or shock.
- Abnormal heavy or prolonged menstrual periods

<u>Side effects with unknown frequency</u>
- 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.
- Impaired liver function.
- High level of uric acid in the blood.

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE SIFUPRIN

Keep out of the reach and sight of children.

Store below 25°C.
Tablet container: Keep the container tightly closed in order to protect from moisture.
Blister: Store in the original package in order to protect from moisture.

Do not use Sifuprin after the expiry date which is stated on the carton or tablet container/blister after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Sifuprin contains

The active substance is acetylsalicylic acid. Each gastro-resistant tablet contains 75, 100, 150 or 160 mg of acetylsalicylic acid.

The other ingredients are: *tablet core:* microcrystalline cellulose, maize starch, colloidal anhydrous silica, stearic acid; *film-coating:* methacrylic acid – ethyl acrylate copolymer (1:1), polysorbate 80, sodium laurilsulfate, triethyl citrate, talc.

What Sifuprin looks like and contents of the pack

Sifuprin gastro-resistant tablets 75 mg are oval, white, biconvex film-coated tablets, 9.2 x 5.2 mm.
Sifuprin gastro-resistant tablets 100 mg are round, white, biconvex film-coated tablets with a diameter of 7.2 mm.
Sifuprin gastro-resistant tablets 150 mg are oval, white, biconvex film-coated tablets, 11.7 x 6.7 mm.
Sifuprin gastro-resistant tablets 160 mg are round, white, biconvex film-coated tablets with a diameter of 8.7 mm.

Pack sizes:
Blisters: 10, 20, 28, 30, 50, 56, 60, 90, 100 gastro-resistant tablets.
Tablet containers: 10, 30, 50, 100, 500 gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Actavis Group PTC ehf.
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland

Manufacturer
Actavis Limited
BLB 016, Bulebel Industrial Estate
Zejtun ZTN 3000
Malta

Balkanpharma Dupnitsa AD
3, Samokovsko Shosse Str.
2600 Dupnitsa
Bulgaria

This medicinal product is authorised in the Member States of the EEA under the following names:

France	Acide Acétylsalicylique 75 mg, 100 mg, 150 mg, 160 mg comprimé enrobé gastro-résistant
Sweden	Sifuprin

This leaflet was last approved in 2011-08-03