

Asasantin[®] SR

sustained release capsules

Dipyridamole and Aspirin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Asasantin SR. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Asasantin SR against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

Keep this leaflet with the medicine.

You may need to read it again.

What Asasantin SR is used for

Asasantin SR contains dipyridamole and aspirin. It is used to help prevent the recurrence of stroke in people who have had a previous stroke or transient ischaemic attack (TIA).

This type of medication is called an antithrombotic agent. An antithrombotic agent is a drug that

reduces the formation of blood clots (thrombi).

Dipyridamole and aspirin work by preventing blood clots from forming. These drugs work on the blood cells which help blood to clot (platelets) and help prevent them from clumping and sticking together. This reduces the risk of forming blood clots that can lead to a stroke. The effects of these drugs are additive.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you take Asasantin SR

When you must not take it

Do not take Asasantin SR if you have an allergy to:

- any medicines containing dipyridamole or aspirin
- any of the ingredients listed at the end of this leaflet
- any other non-steroidal anti-inflammatory drugs (NSAIDs).

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Asasantin SR if you:

- have severe kidney disease

- are taking the medicine ketorolac
- have an ulcer of the stomach or intestine
- have any conditions that increases your risk of bleeding.

Do not take this medicine if you are intolerant to fructose or galactose.

Each capsule contains 53 mg lactose and 11.3 mg sucrose resulting in 106 mg lactose and 22.6 mg sucrose per maximum recommended daily dose.

Do not take this medicine if you are more than 6 months pregnant.

It may affect your developing baby if you take it during late pregnancy.

Do not give this medicine to a child.

Safety and effectiveness in children have not been established.

Do not give Asasantin SR to children or adolescents with a fever or a viral infection (with or without a fever) except on doctor's advice.

The aspirin component of Asasantin SR can cause a very rare disease called 'Reye's Syndrome' if given to children or adolescents who have a fever or a viral infection (with or without a fever).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any of the following conditions:

- any heart condition (e.g. angina, heart attack or failure, heart valve problems)
- severe muscle disease (myasthenia gravis)
- gallstones
- asthma or hay fever
- any unusual growth or tumour inside the nose (e.g. nasal polyps)
- long-term stomach or intestinal problems
- kidney or liver disease
- deficiency of the enzyme glucose-6-phosphate dehydrogenase, which may lead to a condition known as haemolytic anaemia (reduced red blood cells and iron stores).

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

This medicine should not be used during late pregnancy. Your doctor can discuss with you the risks and benefits involved.

The active ingredients in Asasantin SR pass into breast milk. There is a possibility that your baby may be affected.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Asasantin SR may interfere with each other. These include:

- medicines used to thin your blood (e.g. warfarin, dabigatran, apixaban, rivaroxaban) or prevent blood cells from clotting (e.g.

eptifibatide, ticlopidine, clopidogrel, tirofiban)

- other NSAIDs (e.g. diclofenac, ibuprofen)
- any medicines used to treat high blood pressure (e.g. diltiazem and verapamil)
- medicines used to treat rapid heart rhythm (e.g. quinidine and adenosine).
- medicines used to treat myasthenia gravis (e.g. neostigmine, distigmine and related medicines)
- medicines used to control blood sugar levels
- alcohol
- alendronate, a medicine used to treat and prevent osteoporosis
- antacids
- methotrexate, a medicine used to treat certain types of cancer, autoimmune diseases such as psoriasis and rheumatoid arthritis
- medicines used to treat epilepsy (e.g. phenytoin and sodium valproate)
- medicines used in the treatment of depression known as selective serotonin reuptake inhibitors (SSRIs) (e.g. fluoxetine)
- spironolactone, a diuretic (water pill)
- corticosteroids and substances that control the actions of corticosteroids (e.g. corticotropin)
- nicotinic acid
- zafirlukast, a medicine used to prevent asthma symptoms
- medicines that promote the excretion of uric acid in the urine (e.g. probenecid)
- anagrelide, a medicine used to treat the overproduction of blood platelets.

These medicines may be affected by Asasantin SR or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Asasantin SR

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The recommended dose for adults is one capsule twice a day.

Tell your doctor if you experience headaches when you first start Asasantin SR at the recommended dose.

Your doctor may change your dose for one week. The changed dose will be one Asasantin SR capsule at bedtime and low dose aspirin (e.g. 75 mg, 100 mg or 150 mg) in the morning. After this time, your doctor will put you back onto your normal dose.

How to take it

Swallow the capsules whole with a full glass of water.

When to take it

Take your medicine at about the same time each day, usually one in the morning and one in the evening, preferably with meals.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is

important to keep taking your medicine even if you feel well.

If you forget to take it

If you miss a dose, take it as soon as you remember.

If you remember when it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Asasantin SR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include feeling warm, flushing, sweating, restlessness, dizziness, weakness, rapid breathing, ringing in the ears, nausea, vomiting, vision and hearing disturbances and confusion. There may be effects on the heart and circulation causing chest pain, an increase in heart rate and a drop in blood pressure. In severe overdose, symptoms may include severe mental confusion, shaking, difficulty in breathing, sweating, bleeding, dehydration, reduced body temperature and coma.

While you are taking Asasantin SR

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Asasantin SR.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Asasantin SR can slow down blood clotting.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor or pharmacist if you experience headache or migraine-like headache, so that it can be properly treated.

Do not treat the headache or migraine-like headache with aspirin.

Tell your doctor or dentist that you are taking Asasantin SR if you plan to have 'pharmacological stress testing' or other treatments (even at the dentist).

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Asasantin SR to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Asasantin SR affects you.

This medicine may cause dizziness and confusion in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Asasantin SR.

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache or migraine-like headache, especially when you start taking Asasantin SR
- dizziness
- indigestion, vomiting, nausea, stomach pain, diarrhoea.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- muscle aches and pains
- hot flushes
- symptoms of low blood pressure (e.g. lightheadedness)
- signs of anaemia (e.g. tiredness, being short of breath, dizziness, looking pale)
- symptoms of a reduced blood platelet count (e.g. bruising or

bleeding more easily than normal, reddish or purplish blotches under the skin).

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Emergency at your nearest hospital:

- vomiting blood or material that looks like coffee grounds or bleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea
- bleeding (including nose bleeds, bleeding within the head, bleeding in the eyes or increased bleeding during or after surgery)
- fainting
- worsening of symptoms of heart disease (e.g. chest pain, fast heart beat)
- skin rash, hives or itching, swelling of the face, lips or tongue, difficulty in breathing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Asasantin SR

Storage

Keep your capsules in the bottle until it is time to take them.

If you take the capsules out of the bottle they may not keep well.

Keep your capsules in a cool, dry place where the temperature stays below 30°C.

Do not store Asasantin SR or any other medicine in the bathroom or

near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

Asasantin SR is the brand name of your medicine. One half of the capsule is red and the other half is ivory.

Asasantin SR capsules are available in bottles of 20*, 30*, 50*, 60 or 100* capsules.

* Not distributed in Australia.

Ingredients

Active ingredients

Asasantin SR capsules contain:

- 200 mg of dipyridamole in a sustained-release form
- 25 mg of aspirin in a standard (immediate) release form.

Inactive ingredients:

- tartaric acid
- povidone
- methacrylic acid copolymer (Eudragit S 100)
- talc
- acacia
- hypromellose
- hypromellose phthalate
- glycerol triacetate
- dimethicone

- stearic acid
- lactose
- aluminium stearate
- colloidal silica
- maize starch
- microcrystalline cellulose
- sucrose
- gelatin
- titanium dioxide (as colouring agent)
- iron oxide red (CI77491) (as colouring agent)
- iron oxide yellow (CI77492) (as colouring agent).

Supplier

Asasantin SR is supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

78 Waterloo Road

NORTH RYDE NSW 2113

This leaflet was revised in August 2015.

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Australian Registration Number

AUST R 68051