

DIASP SR sustained release capsules

dipyridamole and aspirin

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about DIASP SR. It does not contain all available information.

It does not take the place of talking to your doctor or pharmacist.

Ask your doctor or pharmacist if you have any concerns or questions about taking this medicine.

Keep this information with your capsules.

You may need to read it again.

What DIASP SR is used for

DIASP SR helps to prevent recurrence of stroke in people who have had a previous stroke or transient ischaemic attack (TIA).

DIASP SR works by preventing blood clots from forming. The ability of DIASP SR to prevent blood clots is due to its effect on blood cells known as platelets.

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 DIASP SR

When you must not take it

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

- aspirin or non-steroidal anti-inflammatory medicines (NSAIDs)
- dipyridamole

- any of the other ingredients listed at the end of this leaflet.

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 DIASP SR if you:

- have fructose intolerance. Each capsule contains 4.56 mg sucrose, resulting in 9.12 mg sucrose per maximum daily dose.
- have severe kidney disease
- are taking the medicine ketorolac
- are more than 6 months pregnant
- have an ulcer of the stomach or intestine, or
- any condition that increases your risk of bleeding.

Do not take this medicine if you are pregnant.

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

Do not breastfeed if you are taking this medicine.

The active ingredient in DIASP SR passes into breast milk.

Do not give this medicine to a child. There is limited information about the use of DIASP SR in children.

Do not give DIASP 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 DIASP SR can cause a very rare disease called 'Reye's Syndrome' if DIASP SR is 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.

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:

- an ulcer of the stomach or intestine
- any condition that increases your risk of bleeding
- any heart condition (e.g. angina, heart attack or failure, heart valve problems)
- severe muscle disease (myasthenia gravis)
- gallstones
- asthma
- hayfever
- any unusual growth or tumour inside the nose (e.g. nasal polyps)
- long-term stomach and 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).

If you are uncertain as to whether you have, or have had, any of these conditions you should tell your doctor.

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 Diasp 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 DIASP SR may interfere with each other.

In particular you must tell your doctor if you are taking:

- medicines used to thin your blood such as warfarin, dabigatran, apixaban, rivaroxaban used to treat high blood pressure
- neostigmine, distigmine and related medicines (used, for example, to treat myasthenia gravis)
- medicines used to control blood sugar levels
- medicines used to treat rapid heart rhythm (e.g. quinidine and adenosine).
- 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)
- spironolactone, a diuretic (water pill)
- corticosteroids (steroid hormones)
- corticotropin (corticosteroids and substances which control the actions of corticosteroids)
- quinidine
- diltiazem
- verapamil
- nicotinic acid
- fluoxetine or any other medicines known as selective serotonin reuptake inhibitors or SSRIs (used in the treatment of depression)
- zafirlukast, a medicine used to prevent asthma symptoms

- aspirin other NSAIDs (e.g. diclofenac, ibuprofen)
- any medicine that promotes the excretion of uric acid in the urine (e.g. probenecid, sulphapyrazone)
- anagrelide, a medicine used to treat the overproduction of blood platelets.
- any medicine which prevents blood cells from clotting (e.g. eptifibatide, ticlopidine, clopidogrel, tirofiban).

These medicines may be affected by DIASP 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 DIASP 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.

In some cases you may experience headache when you first start DIASP SR at the recommended dose.

See your doctor if this occurs.

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

When to take it

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

Swallow the capsule whole without chewing with a full glass of water.

How long to take it

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

DIASP SR helps control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well. Therefore you must take DIASP SR every day.

If you forget to take it

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

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Signs of 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 DIASP SR

Things you must do

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

Tell your doctor or pharmacist if you begin taking any other medicine while you are taking DIASP SR.

This applies to all medicines obtained with or without a doctor's prescription.

If you experience headache or migraine-like headache, especially when you start taking DIASP SR, do not treat the headache or migraine-like headache with analgesic doses of aspirin.

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

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

Diasp SR can slow down blood clotting.

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

If you plan to have 'pharmacological stress testing', surgery or other treatment (even at the dentist), tell your doctor or dentist that you are taking DIASP SR.

Be careful driving or operating machinery until you know how DIASP 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.

Things you must not do

Do not take DIASP 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.

Side effects

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

All prescription medicines carry some risks. Your doctor has weighed the risks of you taking DIASP SR against the benefits they expect it will have for you.

If side effects occur, they are usually mild and transient when DIASP SR is used at the recommended dose. In most cases these effects diminish or disappear as treatment is continued.

The following side effects have been

reported with DIASP SR:

- headache or migraine-like headache, especially when you start taking DIASP SR
- dizziness
- indigestion
- diarrhoea
- nausea
- stomach pain
- vomiting
- inflammation of and wearing of stomach lining
- ulcer of the stomach or intestine
- vomiting blood or material that looks like coffee grounds or bleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea
- muscle aches and pains
- hot flushes
- symptoms of low blood pressure (e.g. lightheadedness)
- fast heart beat
- skin bruising and blood clots
- bleeding (including nose bleeds, bleeding within the head, bleeding in the eyes or increased bleeding during or after surgery)
- prolonged bleeding time
- anaemia, a condition in which there is a decrease in the number of red blood cells or haemoglobin levels (signs of anaemia include tiredness, being short of breath, dizziness and looking pale)
- iron deficiency anaemia may result from prolonged bleeding
- reduction in blood platelet count (thrombocytopenia), which may result in bruising or bleeding more easily than normal, reddish or purplish blotches under the skin
- worsening of symptoms of heart disease
- fainting.

Tell your doctor as soon as possible if you experience any side effects during or after using DIASP SR, so that these may be properly treated.

Allergic reactions have been reported. Symptoms of an allergic reaction may include:

- skin rash, hives or itching
- swelling of the face, lips or tongue
- difficulty in breathing.

Tell your doctor immediately if you have an allergic reaction.

You may require urgent medical attention.

In addition, other side effects not listed above may also occur in some patients.

Tell your doctor or pharmacist if you notice anything unusual, during or after taking DIASP SR.

After taking DIASP SR

Storage

Leave all capsules in the container until it is time to take a dose.

The container will protect the capsules.

DIASP SR should be kept in a cool, dry place where the temperature stays below 25°C.

For example, do not leave your capsules in a car or store them in the bathroom. Heat and dampness will damage the capsules.

Keep DIASP SR where children cannot reach them.

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

DIASP SR is the brand name of the capsules prescribed for you by your doctor. One half of the capsule is red and the other half is ivory.

DIASP SR is available in packs of 60 capsules.

Ingredients

Each capsule contains:

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

There are also a number of other ingredients which are used in the formation of the capsule. These ingredients are:

- tartaric acid
- povidone
- methacrylic acid copolymer (Eudragit S 100)
- purified talc
- acacia
- hypromellose
- hypromellose phthalate
- simethicone
- cetostearyl alcohol ethoxylate
- sodium benzoate
- triacetin
- stearic acid
- microcrystalline cellulose
- pregelatinised maize starch
- sucrose
- gelatin
- and the colouring agents:
 - titanium dioxide
 - iron oxide red and
 - iron oxide yellow.

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia

Australian registration number:
DIASP SR – AUST R 210808

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