

APO-Dipyridamole/Aspirin

Modified Release Capsules

Contains the active ingredients Dipyridamole and Aspirin

Consumer Medicine Information

For a copy of a large print leaflet,
Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Dipyridamole/Aspirin Modified Release Capsules.

It contains the active ingredients dipyridamole and aspirin.

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

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

This medicine is available only with a doctor's prescription.

How it works

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

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

There is limited information about the use of Dipyridamole/Aspirin SR in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
 - fructose intolerance. Each capsule contains 4.56 mg sucrose resulting in 9.12 mg sucrose per maximum recommended daily dose.
 - severe kidney disease
 - taking the medicine ketorolac
 - more than 6 months pregnant
 - an ulcer of the stomach or intestine, or
 - any condition that increases your risk of bleeding
- **You are pregnant.** Dipyridamole/Aspirin may affect your developing baby if you take it during pregnancy.
- **You are breastfeeding.** The active ingredient in Dipyridamole/Aspirin SR passes into breast milk.

- **You are hypersensitive to, or have had an allergic reaction to:**

- dipyridamole
- aspirin, or NSAIDs, non-steroidal anti-inflammatory medicines
- or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **Do not give Dipyridamole/Aspirin 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 this medicine 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).

- **The expiry date (EXP) printed on the pack has passed.**

The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- 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
- hay fever
- 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.

3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding.
5. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop

Taking other medicines

Some medicines may interact with Dipyridamole/Aspirin.

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

- medicines used to thin your blood such as warfarin.

- medicines 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
- alcohol
- alendronate
- antacids
- methotrexate
- phenytoin
- spironolactone
- corticosteroids (steroid hormones)
- corticotropin (substances which control the actions of corticosteroids)
- quinidine
- sodium valproate
- diltiazem
- verapamil
- nicotinic acid
- fluoxetine or any other medicines known as selective serotonin reuptake inhibitors or SSRIs (used in the treatment of depression)
- zafirlukast
- aspirin or other NSAIDs (e.g. diclofenac, ibuprofen)
- any medicine that promotes the excretion of uric acid in the urine (eg. probenecid, sulphapyrazone)
- any medicine which prevents blood cells from clotting (eg. eptifibatid, ticlopidine, clopidogrel, tirofiban)

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with dipyridamole and aspirin.

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

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

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 this medicine 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 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.

How to take it

Swallow the capsule whole without chewing.

When to take it

Take this medicine at 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 and will also help you remember when to take it.

How long to take it for

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

This medicine helps control your condition, but does not cure it. Therefore you must take this medicine every day.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

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 to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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 this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- **you are taking any other medicines or are about to be started on a new medicine**
This applies to all medicines obtained with or without a doctor's prescription.
- **If you experience a headache or migraine-like headache, especially when you start taking this medicine. Do not treat the headache or migraine-like headache with analgesic doses of aspirin.**
- **you plan to have 'pharmacological stress testing', surgery or other treatment (even at the dentist).**

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine 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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking this medicine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- headache or migraine-like headache, especially when you start taking this medicine
- 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 (eg. 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 effect during or after using this medicine, so that these may be properly treated

Allergic reactions

If you think you are having an allergic reaction to this medicine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

You may require urgent medical attention.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

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 this medicine.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, 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 this medicine 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Dipyridamole/Aspirin Modified Release Capsules looks like

The gelatin shell of the capsule consists of a red opaque cap and an ivory opaque body.

Available in blister 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.

It also contains the following inactive ingredients:

- tartaric acid
- povidone
- methacrylic acid copolymer (Eudragit S 100)
- talc
- acacia
- hypromellose
- hypromellose phthalate
- simethicone
- cetostearyl alcohol ethoxylate
- sodium benzoate
- triacetin
- stearic acid
- microcrystalline cellulose
- starch pregelatinised
- sucrose
- gelatin
- and the colouring agents:
- titanium dioxide
- iron oxide red (E172) and
- iron oxide yellow (E172).

This medicine is gluten-free, contains sucrose.

Australian Registration Numbers

APO-Dipyridamole/Aspirin SR
(HDPE bottle with CR cap):
AUST R 210813.

Sponsor

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