

Applicant: Aurogen South Africa (Pty) LTD

Product Name: APRATE 5 mg and 10 mg.

Dosage form and strength: Each uncoated tablet contains amlodipine besilate equivalent to amlodipine 5mg and 10 mg respectively



APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

APRATE 5 mg (Tablet).

APRATE 10 mg (Tablet).

Amlodipine besilate.

APRATE is sugar-free

Read all of this leaflet carefully before you start taking APRATE

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist, nurse or other health care provider.
- **APRATE** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

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1. What APRATE is and what it is used for

APRATE belongs to a group of medicines called calcium channel blocking medicines (dihydropyridine calcium antagonists).

APRATE is used for the treatment of:

- **Treatment of angina pectoris.**

Treatment of mild-to moderate hypertension, alone or in combination with other antihypertensives.

2. What you need to know before you take [PRODUCT NAME]

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of APRATE with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Do not take APRATE:

- If you are hypersensitive (allergic) to amlodipine besilate or any of the other ingredients of **APRATE**.
- If you are hypersensitive (allergic) to dihydropyridines.
- if you suffer from severe hypotension (severe low blood pressure, symptoms include light headedness or dizziness)
- if you have previously experienced shock which could include cardiogenic shock (this is the term used when blood pressure becomes so low that your heart stops working properly and medical treatment is required)
- if you recently (within the past 28 days) suffered a heart attack
- if the blood flow from the left side of your heart is obstructed (e.g. aortic valve)

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narrowing)

- if you have unstable angina (chest pain which may occur when you are resting)
- if you are pregnant or breastfeeding your baby
- • if you are younger than 18 years of age

Warnings and precautions

Take special care with APRATE:

- If your doctor diagnosed you with severe high blood pressure.
- If you suffer from aortic stenosis with symptoms such as fatigue, feeling faint or fainting when exercising and shortness of breath.
- If you experience chest pain when taking **APRATE**.
- If you suffer from diabetes.
- If you need to undergo blood tests, as the use of BESYLOC may interfere with the results.
- If you have low blood pressure or other heart conditions
- if you are about to have a procedure where you would need general anaesthesia
- Elderly patients should start APRATE therapy at a lower dose.
- Dosage adjustments may be necessary in patients with kidney and liver disease
- Safety and efficacy in children has not been established.
- Safety in porphyria has not been established

Taking other medicines with APRATE:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines). See Do not take **APRATE**.

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Medicine that may influence **APRATE**:

- **APRATE** interacts with nitroglycerin, long-acting nitrates, beta-blockers or other antianginal agents
- aldesleukin used in the treatment of kidney cancer and skin melanoma or medicines used to treat mental conditions (antipsychotics), as this may increase the levels of **APRATE** in the blood
- grapefruit or grapefruit juice may increase the blood pressure lowering effects of **APRATE**
- medicines used to treat diabetes, as the doses of these medicines may need to be adjusted
- medicines that alter the heart rate, such as quinidine or procainamide
- certain medicines used to treat fits (carbamazepine, phenobarbital, phenytoin), as these may reduce the effect of **APRATE**
- sodium valproate (used for epilepsy), as this may increase **APRATE** blood levels. (Discuss with your doctor if you are unsure)
- medicines used to treat viral, fungal and bacterial infections (such as clarithromycin, erythromycin, ketoconazole, itraconazole or rifampicin), or St John's Wort (a herbal medicine used to treat anxiety), as these may lead to either increased or decreased levels of **APRATE** in the blood
- ritonavir used in the treatment of HIV infections, as this may lead to
- increased levels of **APRATE** in the blood
- dantrolene (a muscle relaxant) may affect potassium levels in the blood
- lithium, as this may result in toxic blood concentrations if used in combination with **APRATE**
- simvastatin (used to lower cholesterol), as this may result in increased levels of simvastatin in the blood. The simvastatin dose may need to be reduced.

Tell your doctor before you receive anaesthesia that you are taking **APRATE**

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APRATE with food and drink

APRATE can be taken with or without food.

Grapefruit and grapefruit juice should be avoided (see Other medicines and **APRATE**)

Pregnancy, breastfeeding and fertility

Safety of **APRATE** in pregnant and lactating women has not been established.

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.

Driving and using machines

APRATE can cause dizziness.

It is not always possible to predict to what extent **APRATE** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **APRATE** affects them.

APTRATE contains sodium.

APRATE contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take APRATE

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

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Always take APRATE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

The usual dose is:

Hypertension and Angina Pectoris:

Adults:

An initial dose of 5 mg **APRATE** orally once daily is recommended which may be increased to 10 mg once a day after 10-14 days of therapy if there is no improvement.

No dose reduction is required when adding APRATE to thiazide diuretics, beta-blockers, or angiotensin-converting enzyme inhibitors.

Your doctor will tell you how long your treatment with **APRATE** will last. Do not stop treatment early because your condition may worsen. If you have the impression that the effect of **APRATE** is too strong or too weak, tell your doctor or pharmacist.

If you take more APRATE than you should

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness. Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

There is no documented experience with APRATE over- dosage. Intravenous calcium gluconate may be of benefit in reversing the effects of calcium channel blockade. Since amlodipine is highly protein-bound, dialysis is not likely to be of

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benefit.

TREATMENT IS SYMPTOMATIC AND SUPPORTIVE.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

If you forget to take APRATE

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

If a dose is missed, the tablet should be taken as soon as the missed dose is remembered.

Two tablets should not be taken to make up for the missed dose.

4. Possible side effects

APRATE can have side effects.:

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

If any of the following happens, stop using **APRATE** 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

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- jaundice (yellow discolouration of the skin and eyes).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **APRATE**. 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:

- slow heartbeat (bradycardia) or rapid heartbeat (tachycardia), palpitations
- low blood pressure (hypotension) with symptoms such as fainting or lightheadedness
- high blood sugar levels (hyperglycaemia)
- hepatitis, a liver condition, with symptoms such as stomach pain, fever, nausea, vomiting or loss of appetite
- weakness, fatigue, weight loss, headache (symptoms of a condition called vasculitis)
- kidney problems (passing less urine than is normal for you)
- pancreatitis (inflammation of the pancreas with symptoms such as stomach pain, increased heart rate and fever)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache, dizziness and fatigue
- flushing
- nausea, stomach pain, change in bowel habits
- ankle swelling, swelling in any part of the body

Less frequent side effects:

- joint pain, back pain, muscle cramps or weakness

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- mood and/or sleep disorders, depression, anxiety
- reduced sense of touch or sensation (numbness)
- tingling sensation in hands, feet or lips (feeling of “pins and needles”)
- involuntary trembling (tremors), increased sweating
- blurred vision, worsening eyesight
- ringing in the ears (tinnitus)
- cough
- inflammation of the mucous membrane in the nose (rhinitis)

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects via the “ 6.04 Adverse Drug reaction Reporting Form found online under SAHPRA’s publications

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store APRATE

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 30 °C.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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6. Contents of the pack and other information

What APRATE contains

- The active substance is Amlodipine besilate.

APRATE:

Each tablet contains Amlodipine besilate equivalent to Amlodipine 5 mg.

APRATE:

Each tablet contains Amlodipine besilate equivalent to Amlodipine 10 mg.

The other ingredients are Cellulose, Microcrystalline; Calcium hydrogen phosphate, anhydrous Magnesium Stearate, and Sodium Starch Glycolate.

APRATE 5 mg:

1. PVC/PE/Aclar - Alu Blister Pack

Tablets are packed in 250 micron white opaque PVC film laminated with 25 micron PE coated with 23 micron Aclar and 25 microns printed aluminium foil.

Each blister contains 10 tablets.

Pack size: 30's— Each carton contains 3 blisters of 10 tablets each.

2. PVC/PVdC - Alu Blister Pack

Tablets are packed in white opaque 250 micron PVC film laminated with 90 gsm PVdC and 25 microns printed aluminium foil. Each blister contains 10 tablets.

Pack size: 30's — Each carton contains 3 blisters of 10 tablets each.

3. HDPE Container:

Tablets are packed in a HDPE container with a stock ribbed closure and induction sealing wad, in the following pack sizes:

Pack size: 30's

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APRATE 10 mg:

1. PVC/PE/Aclar -. Alu Blister Pack

Tablets are packed in 250 micron white opaque PVC film laminated with 25 micron PE coated with 23 micron Aclar and 25 microns printed aluminium foil. Each blister contains 10 tablets.

Pack size: 30's — Each carton contains 3 blisters of 10 tablets each.

2. PVC/PVdC - Alu Blister Pack

Tablets are packed in white opaque 250 micron PVC film laminated with 90 gsm PVdC and 25 microns printed aluminium foil. Each blister contains 10 tablets.

Pack size: 30's — Each carton contains 3 blisters of 10 tablets each.

3. HDPE Container:

Tablets are packed in a HDPE container with a stock ribbed closure and induction sealing wad, in the following pack sizes:

Pack size: 30's

What APRATE looks like and contents of the pack

APRATE 5 mg:

White to off white, flat, bevel edged, barrel shaped uncoated tablets, debossed with 'C' on one side and '58' on the other side.

APRATE 10 mg:

White to off white, flat, bevel edged, round shaped uncoated tablets, debossed with 'C' on one side and '59' on the other side.

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Holder of Certificate of Registration

Aurogen South Africa (Pty) Ltd

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