

Patient information leaflet for**DAPINELAT 30 & 60****PATIENT INFORMATION LEAFLET****SCHEDULING STATUS** S3**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

DAPINELAT 30 - Each extended release tablet contains 30 mg nifedipine

DAPINELAT 60 - Each extended release tablet contains 60 mg nifedipine

Sugar-free

Read all of this leaflet carefully before you start taking DAPINELAT.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or other health care provider.
- DAPINELAT 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 DAPINELAT is and what it is used for
2. What you need to know before you use DAPINELAT
3. How to use DAPINELAT
4. Possible side effects
5. How to store DAPINELAT
6. Contents of the pack and other information

1. What DAPINELAT is and what it is used for

DAPINELAT contains a medicine called nifedipine.

This belongs to a group of medicines called calcium antagonists.

DAPINELAT may be used to treat the following:

- high blood pressure or angina (chest pain)

2. What you need to know before you use DAPINELAT

Do not take DAPINELAT:

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- If you are allergic to nifedipine, any other similar medicines (known as dihydropyridines) or any of the other ingredients of this medicine (listed in section 6),
- If you have had a heart attack within the last month, if you get a sudden angina attack. Nifedipine will not help relieve symptoms of angina quickly, if you have unstable angina
- If you have ever had a collapse caused by a heart problem (cardiogenic shock)
- If you are taking rifampicin, an antibiotic
- If you have a liver disease that prevents your liver from working properly
- If you have an obstruction or narrowing in your intestines, or have had this in the past, had an obstruction in the gullet (the oesophagus - the tube connecting the throat to the stomach)
- If you have a “kock pouch” (a surgically constructed intestinal reservoir with an opening through the abdominal wall) in your gut
- If you have inflammation of the bowel or intestines, such as crohn’s disease
- If you are pregnant or breast-feeding
- If your blood pressure continues to rise despite treatment (malignant hypertension)
- If you have very low blood pressure (severe hypotension), in cases of manifest heart failure and if you have been told that you have a narrowing of the aortic heart valve (stenosis)

Do not have this medicine if any of the above applies to you. If you are not sure, talk to your doctor, nurse or pharmacist before you are given DAPINELAT.

Warnings and Precautions

Do not break, bite or chew your tablets

Tell your doctor or health care provider before taking this medicine

Take special care with DAPINELAT:

- If you have low blood pressure and you were prescribed DAPINELAT for your angina. Your blood pressure may be decreased further by this treatment
- If you are pregnant
- If you are breast-feeding. If you need to take DAPINELAT, you should stop breastfeeding before you start to take this medicine
- If your liver is not working properly. Your doctor may need to do some blood tests. You may also be given a lower dose of DAPINELAT.

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- If you are taking other medicines to treat high blood pressure (e.g. beta-blockers). If you are changing from a beta-blocker to nifedipine, you should gradually reduce your beta-blocker after discussion with your doctor
- If you have a heart condition where your heart cannot cope with increased strain (poor cardiac reserve)
- If you are a diabetic. The treatment for your diabetes may need to be adjusted. If you have any questions about this, ask your doctor.
- If you are on kidney dialysis. If you have a very high blood pressure and a low blood volume, you might experience a sudden drop in blood pressure when you take DAPINELAT.

Other medicines and DAPINELAT

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

This is because DAPINELAT can affect the way some other medicines work. Also some medicines can affect the way that DAPINELAT works.

Tell your doctor if you are taking:

- Other medicines to treat high blood pressure,
- rifampicin (an antibiotic),
- cimetidine (to treat stomach ulcers),
- digoxin, diltiazem, quinidine or beta-blockers (to treat heart conditions),
- quinupristin/dalfopristin (a combination antibiotic),
- phenytoin, carbamazepine or valproic acid (to treat epilepsy),
- cisapride (to treat reduced movements of the gullet and stomach),
- erythromycin (an antibiotic),
- ketoconazole, itraconazole or fluconazole (anti-fungal medicines),
- indinavir, nelfinavir, ritonavir, saquinavir or amprenavir (to treat HIV),
- fluoxetine or nefazodone (to treat depression),

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- tacrolimus (to prevent the rejection of transplanted organs),
- Phenobarbitone (usually used to treat insomnia or anxiety),
- magnesium sulphate injections during pregnancy (may cause a severe fall in blood pressure).

DAPINELAT with food and drink

Do not drink grapefruit juice or eat grapefruit while taking DAPINELAT.

Do not start taking DAPINELAT within 3 days of drinking grapefruit juice or eating grapefruit. Tell your doctor if you have had grapefruit or grapefruit juice in this time. Also, do not drink grapefruit juice or eat grapefruit whilst taking DAPINELAT.

Grapefruit juice is known to increase the blood levels of the active ingredient, nifedipine. This effect can last for at least 3 days.

Also tell your doctor:

If you are giving a urine sample. DAPINELAT may interfere with the results of certain urine tests.

If you are to have a barium contrast x-ray (barium meal). These tablets may affect the results of the test.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking DAPINELAT. You should not take DAPINELAT if you are pregnant.

Do not take DAPINELAT if you are breast-feeding. If you need to take DAPINELAT, you should stop breast-feeding before you start taking this medicine.

If you are a man who has been unable to father a child by *in vitro* fertilisation, medicines like DAPINELAT have been shown to impair sperm function.

Driving and using machines

DAPINELAT may make you feel dizzy, faint, extremely tired or have visual disturbances. Do not drive or operate machinery if you are affected in this way.

This may be more likely when you first start treatment, if you change medicine, or if you have drunk alcohol.

CALCIBLOK contains sodium

- Each 30 mg tablet contains 24,2 mg sodium, equivalent to 1,21 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

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- Each 60 mg tablet contains 48,4 mg sodium, equivalent to 2,42 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

3. How to use DAPINELAT**How DAPINELAT is given**

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

Always take DAPINELAT exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

DAPINELAT is specially formulated so that you only have to take one dose each day.

Dose for high blood pressure: the usual dose is 1 tablet, once a day.

Dose for angina: the dose depends on your individual requirements.

Your doctor will decide how much you should take. Your doctor will tell you how long your treatment with DAPINELAT will last. Do not stop treatment early because. If you have the impression that the effect of DAPINELAT is too strong or too weak, tell your doctor or pharmacist.

The tablets should be swallowed whole with a glass of water, either with or without food. Taking your tablets at the same time each day will have the best effect on your blood pressure, preferably during the morning. It will also help you remember when to take the tablets, DAPINELAT must be swallowed whole; under no circumstances should they be bitten, chewed or broken up.

Do not take them with grapefruit juice.

Use in elderly

No dose adaptation in elderly people above 65 years is necessary.

Use in adults and the elderly with kidney problems

No dosage adjustment is required in patients with kidney problems.

Use in children and adolescents

DAPINELAT is not recommended for use in children and adolescents below 18 years of age, because there are only limited data on the safety and efficacy in this population.

Use in patients with liver impairment

DAPINELAT should not be administered to patients with liver impairment.

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If you missed a dose of DAPINELAT

Do not take / receive a double dose to make up for forgotten individual doses. If you have any further questions on the use of this medicine, ask your doctor.

If you take more DAPINELAT than you should

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

Taking too many tablets may cause your blood pressure to become too low and your heartbeats to speed up or slow down. It may also lead to an increase in your blood sugar level or an increase in the acidity of your blood, swelling in the lungs, low blood oxygen levels and disturbances in consciousness, possibly leading to unconsciousness.

4. Possible side effects

DAPINELAT can have side effects.

Not all side effects reported for DAPINELAT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking DAPINELAT and tell your doctor immediately or go to the casualty department at your nearest hospital:

allergic reactions causing swelling under the skin including swelling of the larynx that may result in a life-threatening outcome, itching, a rash or hives,

fast heart beat (tachycardia),

shortness of breath (frequency not known) or difficulty breathing,

If you develop a skin reaction or blistering / peeling of the skin and/or mucosal reactions (in the mouth/nose or at the penis/vagina) (Toxic Epidermal Necrolysis).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DAPINELAT. You may need urgent medical attention.

Tell your doctor if you notice any of the following side effects.

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Frequent side effects:

Headache

Pain in eye

Swelling particularly of the ankles and legs, flushing

Constipation

Feeling unwell

Less frequent side effects:

Anxiety or nervousness, sleep disorders, sensation of spinning or whirling motion (vertigo), migraine, dizziness, trembling, abnormal sensation (dysesthesia), drowsiness (somnolence), visual disturbances, blurred vision, irregular heartbeat (palpitations), fast heart beat (tachycardia), chest pain (angina), fall in blood pressure, fainting (syncope), nose bleeds, nasal congestion, stomach pain (abdominal pain), feeling sick (nausea), indigestion or upset stomach, wind (flatulence), dry mouth, inflammation of the gums, tender or swollen gums, bleeding gums, heartburn or indigestion (gastroesophageal sphincter insufficiency), temporary increase in certain liver enzymes, small, redness of skin, raised areas of bleeding in the skin (palpable purpura), muscle cramps, joint swelling, increase in the need to pass water, painful or difficult urination, inability to achieve or maintain an erection, unspecific pain, chills.

Other side effects (Frequency unknown):

A more severe decrease in a specific class of white blood cell (agranulocytosis), a reduction in the number of white blood cells (leucopenia), severe, sudden generalised allergic reaction including very rarely life-threatening shock, increased blood sugar (hyperglycaemia), decreased skin sensitivity (hypoesthesia), difficulty in breathing, swelling in lungs, stomach pain or distress caused by a mass of foreign material found in the stomach which may require surgery for removal, difficulty swallowing, abdominal pain, caused by obstruction of the gut or ulcers in the gut, vomiting, yellowing of the whites of the eyes or skin (jaundice), sensitivity to light (photosensitivity allergic reaction), enlargement of a man's breasts (gynaecomastia)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via

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the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

5. How to store DAPINELAT

Keep this medicine out of the sight and reach of children.

Store at or below 25 °C.

Not to be removed from the outer carton until required for use.

6. Contents of the pack and other information

DAPINELAT tablets contain the active ingredient, nifedipine.

Excipients:

Polyethylene oxide (polyox),

hypromellose type 2910 (methocel premium E5LV),

potassium chloride,

magnesium stearate,

colloidal silicon dioxide,

sodium chloride,

ferric oxide red,

cellulose acetate,

polyethylene glycol 4000,

hypromellose type 2208 (methocel E3 LV),

opadry brown 03B86636 (HPMC 2910/hypromellose, titanium dioxide, macrogol/PEG, iron oxide red, iron oxide yellow).

Each 30 mg tablet contains 24,2 mg sodium (main component of cooking/table salt). This is equivalent to 1,21 % of the recommended maximum daily dietary intake of sodium for an adult.

Each 60 mg tablet contains 48,4 mg sodium (main component of cooking/table salt). This is equivalent to 2,42 % of the recommended maximum daily dietary intake of sodium for an adult.

Marketing authorisation holder

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