

Fidocare XL 30 / 60, Prolonged-release tablets

Each tablet contains 30 mg or 60 mg nifedipine

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

Fidocare XL 30 prolonged-release tablets

Fidocare XL 60 prolonged-release tablets

Nifedipine

Sugar free.

Read all of this leaflet carefully before you start taking Fidocare XL.

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

1. What Fidocare XL is and what it is used for

Fidocare XL contains nifedipine, which belongs to a group of medicines called calcium antagonists.

Fidocare XL is used to treat:

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- high blood pressure or
- angina (chest pain)

2. What you need to know before you take Fidocare XL

Do not take Fidocare XL:

- If you are hypersensitive (allergic) to nifedipine, any other similar medicines (known as dihydropyridines) or any of the other ingredients of Fidocare XL (listed in section 6).
- If you have had a heart attack within the last month.
- If you get a sudden angina attack. Fidocare XL 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 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 suffer from inflammation of the bowel or intestines, such as Crohn's disease.
- If you are pregnant or breastfeeding.
- If your blood pressure continues to rise despite treatment (malignant hypertension).

Do not take Fidocare XL if any of the above applies to you. If you are not sure, talk to your doctor, nurse or pharmacist before you are given Fidocare XL.

Warnings and precautions

Take special care with Fidocare XL:

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- If you have low blood pressure and you were prescribed Fidocare XL for your angina. Your blood pressure may be decreased further by this treatment.
- If you have been diagnosed with heart failure or a narrowed heart valve (aortic stenosis), take extra precautions.
- If you are taking other medicines to treat high blood pressure (e.g. beta-blockers). If you are changing from a beta-blocker to Fidocare XL, 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 Fidocare XL.
- If you are giving a urine sample. Fidocare XL 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.

Children and adolescents

Fidocare XL is not intended to be used in children and adolescents under the age of 18 years.

Other medicines and Fidocare XL

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Tell your doctor if you are taking:

- other medicines to treat high blood pressure
- rifampicin (an antibiotic) (see ‘Do not take Fidocare XL’)
- cimetidine (to treat stomach ulcers)
- digoxin, diltiazem, quinidine or beta-blockers (to treat heart conditions)

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- quinupristin/dalfopristin (a combination antibiotic)
- phenytoin, carbamazepine or valproic acid (to treat epilepsy)
- cisapride (to treat reduced movements of the oesophagus and stomach)
- erythromycin (an antibiotic)
- ketoconazole, itraconazole or fluconazole (antifungal medicines)
- indinavir, nelfinavir, ritonavir, saquinavir or amprenavir (to treat HIV)
- fluoxetine or nefazodone (to treat depression)
- 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).

Fidocare XL with food and drink

Do not drink grapefruit juice or eat grapefruit while taking Fidocare XL.

Do not start taking Fidocare XL 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 Fidocare XL. Grapefruit juice is known to increase the blood levels of the active ingredient, nifedipine. This effect can last for at least 3 days.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before taking Fidocare XL.

Do not take Fidocare XL if you are pregnant.

Do not take Fidocare XL if you are breastfeeding. If you need to take Fidocare XL, you should stop breastfeeding 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 Fidocare XL have

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been shown to impair sperm function.

Driving and using machines

Fidocare XL 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 ingested alcohol.

Fidocare XL contains sodium

Fidocare XL 30 contains 9,52 mg of sodium and Fidocare XL 60 contains 19,04 mg of sodium.

Increasing the daily dose to 90 mg nifedipine results in an intake of 28,56 mg sodium. This is equivalent to 1,43 % of the WHO recommended maximum daily dietary intake of 2 g sodium for an adult.

Tell your doctor if you are on a low-salt diet.

3. How to take Fidocare XL

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

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

If you have the impression that the effect of Fidocare XL is too strong or too weak, talk to your doctor or pharmacist.

The tablets should be swallowed whole with a glass of water, either with or without food. The tablets should be taken at approximately 24-hour intervals, i.e. at the same time each day, preferably during the morning. Fidocare XL must be swallowed whole; under no circumstances should they be bitten, chewed or broken up.

Do not take the tablets with grapefruit juice.

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Fidocare XL 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.

Use in elderly

No dose adjustment 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

Fidocare XL 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 problems

Fidocare XL should not be administered to patients with liver problems.

If you take more Fidocare XL 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 heartbeat 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.

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If you forget to take Fidocare XL

Take your normal dose immediately and continue taking your tablets at the usual time of day, waiting at least 12 hours before taking the next dose.

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

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Fidocare XL can have side effects.

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

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

- allergic reactions causing swelling under the skin (possibly severe and including swelling of the larynx that may result in a life-threatening outcome), itching (possibly severe), a rash or hives
- fast heartbeat (tachycardia)
- shortness of breath (frequency not known) or difficulty breathing
- a skin reaction or blistering/peeling of the skin and/or mucosal reactions (in the mouth/nose or at the penis/vagina) (called toxic epidermal necrolysis)
- yellowing of your skin and eyes (also called jaundice).

These are all very serious side effects. If you have them, you may have had a serious reaction to Fidocare XL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

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- headache
- pain in eye
- swelling particularly of the ankles and legs
- flushing
- a general feeling of being unwell
- constipation.

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)
- 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

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- heartburn or indigestion (gastroesophageal sphincter insufficiency)
- temporary increase in certain liver enzymes
- 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)
- sudden generalised allergic reaction including very rarely life-threatening shock
- increased blood sugar (hyperglycaemia)
- decreased skin sensitivity (hypoaesthesia)
- 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
- sensitivity to light (photosensitivity allergic reaction)
- enlargement of a man's breasts (gynaecomastia).

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of Fidocare XL.

5. How to store Fidocare XL

- Store at or below 25 °C.
- Protect from light and moisture.
- Keep the blister strips in the outer carton and keep the carton closed until required for use.
- Store all medicines out of reach of children.
- Do not use the tablets after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information**What Fidocare XL contains:**

Fidocare XL 30: The active substance is nifedipine 30 mg per prolonged-release tablet.

Fidocare XL 60: The active substance is nifedipine 60 mg per prolonged-release tablet.

The other ingredients are: Cellulose acetate, colloidal silicon dioxide, ferric oxide red (colourant), hypromellose, magnesium stearate, Opacode black (colourant), Opadry brown (consisting of hypromellose, iron oxide red (colourant), iron oxide yellow (colourant), polyethylene glycol and titanium dioxide (colourant)), polyethylene glycol, polyethylene oxide, potassium chloride, sodium chloride.

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What Fidocare XL looks like and contents of the pack

Fidocare XL 30: Brown coloured, round biconvex film coated tablet free from cracks, plain on one side & laser drilled hole on other side.

Fidocare XL 60: Brown coloured, round biconvex film coated tablet free from cracks, plain on one side & laser drilled hole on other side.

10 tablets in an aluminium PVC blister; 3 such blisters with product insert into a carton.

30 tablets per carton.

Holder of the certificate of registration

Biotech Laboratories (Pty) Ltd

Ground Floor, Block K West, Central Park

400 16th Road, Randjespark

Midrand, 1685

Tel: +27 (0) 11 848 3050

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Access to the corresponding Professional Information

The Professional Information is available from Biotech Laboratories (Pty) Ltd. To request a digital copy please email info@biotechlabs.co.za.