

Package leaflet: Information for the patient

Fortipine® LA 40mg Modified Release Tablets nifedipine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Fortipine® LA 40mg Modified Release Tablets; they contain nifedipine as the active ingredient. (They will be called Fortipine LA Tablets throughout this leaflet)

What is in this leaflet:

1. What Fortipine LA Tablets are and what they are used for
2. What you need to know before you take Fortipine LA Tablets
3. How to take Fortipine LA Tablets
4. Possible side effects
5. How to store Fortipine LA Tablets
6. Contents of the pack and other information

1. What Fortipine LA Tablets are and what they are used for

Fortipine LA Tablets contain the active substance nifedipine. This belongs to a group of medicines known as calcium antagonists. These work by opening up the blood vessels and increasing the flow of blood through them.

Fortipine LA Tablets are used:

- To stop the symptoms of angina. Angina is a chest pain caused by a narrowing of the arteries in the heart muscle.
- For the treatment of mild to moderate high blood pressure (hypertension).

2. What you need to know before you take Fortipine LA Tablets

Do not take Fortipine LA Tablets:

- if you are allergic to nifedipine or any of the other ingredients of this medicine (listed in section 6).
- if you have a severe problem with your heart which causes collapse and a sudden fall in your blood pressure
- if you have a severe constriction of the main blood vessel from the heart called aortic stenosis.
- if you suffer from a blood disease called porphyria.

- if you have suffered a heart attack in the last one month

Warnings and precautions

Talk to your doctor or pharmacist before taking Fortipine LA Tablets

- if you have any liver or kidney problems
- if you have heart problems which cause you to get breathless even with the slightest exercise
- if you suffer from low blood pressure causing dizziness or fainting on standing up
- if you are diabetic
- if you suffer from a severe form of increased blood pressure (hypertensive crisis)
- if you are pregnant/breast feeding

Children

Fortipine LA Tablets should not be given to children.

Other medicines and Fortipine LA Tablets:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. The effects of these medicines may change, especially if you are taking:

- Other medications for chest pains and/or high blood pressure
- Any other drug for the treatment of heart problems (especially Digoxin and Quinidine)
- Any drugs containing cimetidine (for the reduction of stomach acidity and treatment of ulcers)
- Medicines for treatment of tuberculosis (rifampicin)
- Anti psychotic drugs for treating mental disorders
- Muscle relaxants
- Medicines used in the treatment of epilepsy (Carbamezipine, phenytoin)
- Medicines to treat diabetes
- Cyclosporine used in organ transplantation

Fortipine LA Tablets with food and drink:

The tablets should be swallowed whole with a glass of water after eating. Do not break or chew the tablet.

Fortipine LA Tablets should not be taken with grapefruit juice.

Pregnancy and breast feeding:

Ask your doctor or pharmacist for advice before taking any medicine.

Fortipine LA Tablets should not be taken if you are pregnant, think you are pregnant or are planning to become pregnant, or if you are breast feeding.

Driving and using machines:

Fortipine LA Tablets may cause headaches, dizziness, tiredness and you may feel sick. If this occurs, do not drive or use machines.

Fortipine LA Tablets contains lactose:

This medicine also contains lactose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Fortipine LA Tablets

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

Fortipine LA Tablets are specially designed to release the active ingredient slowly.

The recommended dose is:

- one tablet (40mg) daily. However, your doctor may increase your dose to 2 tablets (80mg) once daily or 1 tablet (40mg) twice daily depending on your response.

The tablets should be swallowed whole with a glass of water after eating. Do not break or chew the tablet.

Use in children and adolescents

Fortipine LA Tablets are 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.

If you take more Fortipine LA Tablets than you should:

Taking too many Fortipine LA Tablets can cause a severe drop in blood pressure, a slow heart rate and unconsciousness. If you take more tablets than you should, contact your doctor or hospital immediately. Take any remaining tablets or this leaflet with you so the medical staff know exactly what you have taken.

If you forget to take your Fortipine LA Tablets:

If you forget to take a tablet, take it if you remember within 12 hours of your usual time. If more than 12 hours have passed, you should not take the missed tablet but should take your next tablet at the normal time when it is due.

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

If you stop taking Fortipine LA Tablets:

Do not stop taking your tablets suddenly as your condition may get worse. Consult your doctor first.

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

4. Possible side effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

Stop taking Fortipine LA Tablets and tell your doctor immediately if you experience:

- Severe, sudden generalised allergic reaction including very rarely life-threatening shock (e.g. difficulty in breathing, drop of blood pressure, fast pulse), swelling (including potentially life-threatening swelling of the airway)

- other allergic reactions causing swelling under the skin (possibly severe and including swelling of the larynx that may result in a life-threatening outcome)
- fast heart beat (*tachycardia*)
- shortness of breath or difficulty breathing
- Mild to moderate allergic reactions
- Itching (possibly severe), a rash or hives

Contact your doctor immediately before you continue treatment 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) as these may be signs of a severe reaction (Toxic Epidermal Necrolysis)

Other side effects may include:

Common side effects (*These may affect up to 1 in 10 people*)

- Headache
- General feeling of being unwell
- Constipation
- Redness of skin (flushing)
- Swelling of ankles and legs

Uncommon side effects (*These may affect up to 1 in 100 people*)

- Increase in the need to pass water (urinate)
- Painful or difficult urination
- Trembling
- Low blood pressure when standing up (symptoms include fainting, dizziness, light headedness, occasional palpitations, blurred vision and sometimes confusion)
- Anxiety or nervousness
- Erythema (localized redness of skin)
- Fainting
- Giddiness or sensation of spinning (vertigo)
- Dizziness
- Sleep disorders
- Migraine
- Blurred vision
- Feeling that the heart is pounding (palpitations)
- Bleeding from nose,
- Nose block
- Pain in abdomen
- Indigestion or upset stomach
- Wind (flatulence)
- Dry mouth
- Feeling sick (nausea)
- Temporary increase in certain liver enzymes
- Muscle cramps
- Joint swelling
- Inability to achieve or maintain an erection (impotence)

- Unspecific pain
- Chills

Rare side effects (*These may affect up to 1 in 1000 people*)

- Numbness and tingling sensations in fingers (pins and needles),
- inflammation of the gums, tender or swollen gums, bleeding gums.

Not known (*frequency cannot be estimated from the available data*)

- A reduction in the number of white blood cells (leucopenia)
- A more severe decrease in a specific class of white blood cell (agranulocytosis)
- Increased glucose in blood (hyperglycemia)
- Decreased skin sensitivity (hypoesthesia)
- Drowsiness (somnia)
- Eye pain
- Stomach pain or distress caused by a mass of foreign material found in the stomach which may require surgery for removal
- Difficulty in swallowing
- Obstruction of gut
- Being sick (vomiting)
- Yellowing of the whites of the eyes or skin (jaundice)
- Small, raised areas of bleeding in the skin (palpable purpura)
- Pain in joints
- Muscle pain
- Skin rash on exposure to light
- Ulcers in gut
- Difficulty in breathing
- Chest pain
- Heartburn or indigestion (gastroesophageal sphincter insufficiency)
- Shortness of breath

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fortipine LA Tablets

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

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month

- Store in a dry place in the original package in order to protect from light. The tablet must not be removed from its blister until it is about to be taken.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fortipine LA Contains

- The active substance is nifedipine. Each tablet contains 40mg nifedipine.
- The other ingredients are
Core-microcrystalline cellulose, cellulose, Methylhydroxypropylcellulose (Hypromellose 2208/4000 mPas), lactose, magnesium stearate, colloidal anhydrous silica;
Film-coat- Methylhydroxypropylcellulose Hypromellose 15 mPas), Macrogol 400 (polyethylene glycol 400), Macrogol 6000 (polyethylene glycol 6000), Ferric oxide red (E172), titanium dioxide (E171), talc.

What Fortipine LA Tablets look like and contents of the pack

Fortipine LA 40mg Modified Release Tablets are red brownish modified release tablets.

Fortipine LA 40mg Modified Release Tablets come in blister strips which are in cartons of 30 tablets.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in September 2023.

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