



MercuryPharma

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 or nurse.
- 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.

### What is in this leaflet:

1. What Fortipine LA 40mg Modified Release Tablets are and what they are used for
2. What you need to know before you take Fortipine LA 40mg Modified Release Tablets
3. How to take Fortipine LA 40mg Modified Release Tablets
4. Possible side effects
5. How to store Fortipine LA 40mg Modified Release Tablets
6. Contents of the pack and other information

### 1. WHAT FORTIPINE LA 40MG MODIFIED RELEASE TABLETS ARE AND WHAT THEY ARE USED FOR

Fortipine LA 40mg Modified Release 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 40mg Modified Release 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 40MG MODIFIED RELEASE TABLETS

#### DO NOT take Fortipine LA 40mg Modified Release Tablets if:

- You know that you are allergic to nifedipine or any of the other ingredients of Fortipine LA 40mg Modified Release Tablets (listed at the end of this leaflet)
- You have a severe problem with your heart which causes collapse and a sudden fall in your blood pressure
- You have a severe constriction of the main blood vessel from the heart called aortic stenosis
- You suffer from a blood disease called porphyria
- You have suffered a heart attack in the last one month.

Fortipine LA 40mg Modified Release Tablets should not be given to children.

#### Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Fortipine LA 40mg Modified Release Tablets

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

#### Other medicines and Fortipine LA 40mg Modified Release Tablets:

Please tell your doctor or pharmacist if you are taking or have recently taken 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.

#### Pregnancy and breast feeding:

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

Fortipine LA 40mg Modified Release 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 40mg Modified Release Tablets may cause headaches, dizziness, tiredness and you may feel sick. If this occurs, do not drive or use machines.

#### Taking 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 40mg Modified Release Tablets should not be taken with grapefruit juice.

#### Fortipine LA 40mg Modified Release 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 40MG MODIFIED RELEASE 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 40mg Modified Release 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.

#### Children

Fortipine LA 40mg Modified Release 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 40mg Modified Release Tablets than you should:

Taking too many Fortipine LA 40mg Modified Release 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 40mg Modified Release 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.

#### If you stop taking Fortipine LA 40mg Modified Release 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 or nurse.

### 4. POSSIBLE SIDE EFFECTS

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

#### Stop taking Fortipine LA 40mg Modified Release 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

- Headache
- General feeling of being unwell
- Constipation

##### Uncommon side effects

- 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 (palpations)

##### Rare cases

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

##### Frequency not known

- 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 (hypoaesthesia)
- Drowsiness (sommolence)
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 40MG MODIFIED RELEASE 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 pack. 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

The active substance is nifedipine. Each tablet contains 40mg nifedipine.

The other ingredients are microcrystalline cellulose, hypromellose, lactose monohydrate, magnesium stearate, colloidal anhydrous silica, polyethylene glycol 400, polyethylene glycol 6000, red iron oxide (E172), titanium dioxide (E171), talc.

#### What Fortipine LA 40mg Modified Release 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:

Mercury Pharmaceuticals Ltd., Capital House, 85 King William Street, London EC4N 7BL, UK

This leaflet was last revised in April 2019.

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