

MONOPIN

4mg Film-coated tablets

LACIDIPINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What MONOPIN is and what it is used for
2. Before you take MONOPIN
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1. WHAT MONOPIN IS AND WHAT IS IT USED FOR

MONOPIN Tablets contains a medicine called lacidipine. This belongs to a group of medicines called 'calcium channels blockers'. Lacidipine Tablets helps to relax your blood vessels so that they get wider. This helps the blood to flow more easily and lowers the blood pressure.

MONOPIN Tablets taken regularly as prescribed by your doctor will help to lower your blood pressure (to treat hypertension).

2. BEFORE YOU TAKE MONOPIN

Do not take MONOPIN Tablets:

- If you are allergic (hypersensitive) to lacidipine, other calcium channel blocker medicines or any of the other ingredients of MONOPIN Tablets.
- If you have the heart problem 'aortic stenosis'. This is a narrowing of a valve in your heart, which restricts blood flow.
- If you have had a heart attack within the last month and in case of severe heart failure.
- You should stop taking lacidipine if you get chest pain (angina) or a fast, weak pulse, rapid shallow breathing, low blood pressure, cold clammy skin, blue lips or feel dizzy, faint, weak or sick

Do not take MONOPIN Tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking MONOPIN Tablets.

Take special care with MONOPIN Tablets:

Check with your doctor or pharmacist before taking your medicine:

- If you have an uneven heart beat or any other heart problems
- If you have or have ever had any liver problems

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Lacidipine Tablets can affect the way some other medicines work. Also some other medicines can affect the way MONOPIN Tablets works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines for high blood pressure
- Medicines for the treatment of fungal infections
- Medicines to control your heart beat (called 'anti-arrhythmics')
- Medicines for depression called 'tricyclic antidepressants'
- Antibiotics (eg. rifampicin)
- Medicines for the treatment of epilepsy
- Cimetidine – used for stomach problems
- Ciclosporin (eg immunosuppressive drugs administered to recipients of organ donors after a transplant)
- Steroids or tetracosactide (used for the treatment of inflammatory conditions such as asthma, ulcerative colitis or arthritis)

If you are having any blood tests, tell the person giving the test that you are taking this medicine. This is because MONOPIN Tablets can affect results relating to your liver.

Taking MONOPIN Tablets with food and drink

You can take this medicine on an empty stomach or with food.

Discuss with your doctor if it is appropriate for you to have alcohol whilst taking this medicine since alcohol may increase the effects of Lacidipine.

Do not take this medicine with grapefruit juice.

Pregnancy, fertility and breast-feeding

Do not take MONOPIN Tablets if you are pregnant, likely to become pregnant or are breast-feeding.

If you want to become pregnant, please contact your doctor or pharmacist before taking this medicine. This medicine may impair male fertility.

Driving and using machines

This medicine may cause dizziness. If you experience this side effect, do not drive vehicles or operate machines which require your attention.

Important information about some of the ingredients of MONOPIN Tablets

MONOPIN Tablets contain Lactose Monohydrate. If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE MONOPIN

Always take Lacidipine Tablets exactly as your doctor has told you. You should check with your doctor if you are not sure.

It is important to take the right number of tablets at the right time of day.

- The usual starting dose is 2 mg every morning.
- After 3-4 weeks this may be increased to 4 mg every morning.
- If necessary the dose may be increased again to 6 mg every morning which is the maximum daily dose.
- Swallow the tablets whole with a drink of water.
- Do not take with grapefruit juice.

If you take more MONOPIN Tablets than you should

If you take more of this medicine than you should talk to a doctor or go to a hospital straight away. Take the medicine pack with you, even if there are no tablets left.

Medical treatment can be necessary. Effects of overdose will likely cause irregular heartbeat, rapid shallow breathing, low blood pressure, cold humid skin or feeling dizzy, fainting, weakness or nausea.

If you forget to take MONOPIN Tablets

If you forget a dose in the morning, take it as soon as you remember it on the same day. However, if you remember the next day, take your normal dose on that morning. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, please contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, MONOPIN Tablets can cause side effects, although not everybody gets them.

Tell your doctor immediately if you have any of the following side effects:

- Chest pain (angina) including chest pain which gets worse.
- You become severely unwell with a rapid pulse, sweating, breathlessness and faintness. The frequency of adverse reactions listed below are classified as follows:
 - Very common: may affect more than 1 in 10 people
 - Common: may affect up to 1 in 10 people
 - Uncommon: may affect up to 1 in 100 people
 - Rare: may affect up to 1 in 1,000 people
 - Very rare: may affect up to 1 in 10,000
 - Not known: frequency cannot be estimated from the available data

Common

- Headache
- Dizziness
- Flushing
- Fast or irregular heart beat (palpitations),
- Upset stomach or nausea
- Rash, redness of the skin, itching
- An increase in the amount of urine
- Feeling weak
- Swelling particularly on the ankles,
- Changes in results of blood tests relating to your liver

Uncommon

- Chest pain (angina) including chest pain that is getting worse
- Low blood pressure for example feeling faint, fainting
- Swelling of the gums

Rare

- Angioedema (allergic reaction that causes swelling of the face)
- Skin rash with itching (hives/urticaria)
- Muscle cramps

Very rare

- Tremor
- Depression

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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.

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

5. HOW TO STORE MONOPIN

Keep out of the reach and sight of children.

Store in the original package in order to protect from light.

Do not take MONOPIN Tablets after the expiry date which is stated on the carton and the blister foil. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.