

Adipine™ MR 10 and Adipine™ MR 20 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.

What is in this leaflet

1. What Adipine™ MR is and what it is used for
2. What you need to know before you take Adipine™ MR
3. How to take Adipine™ MR
4. Possible side effects
5. How to store Adipine™ MR
6. Contents of the pack and other information

1. What Adipine™ MR is and what it is used for

Adipine™ MR contains the active substance nifedipine, which belongs to a group of medicines called *calcium antagonists*.

Adipine™ MR is used to treat high blood pressure or angina (chest pain).

For high blood pressure: Adipine™ MR works by relaxing and expanding the blood vessels. This makes the blood flow more easily and lowers blood pressure. Lower blood pressure reduces the strain on your heart.

For angina: Adipine™ MR works by relaxing and expanding the arteries supplying the heart. This allows more blood and oxygen to reach the heart and decreases the strain on it. Your angina attacks will be less severe and less frequent if there is less strain on the heart.

2. What you need to know before you take Adipine™ MR

Do NOT take Adipine™ MR

- **if you are allergic** to the active substance, to any other similar medicines (known as dihydropyridines) or to 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.** Adipine™ MR will not help relieve symptoms of angina quickly.
- **if you have unstable angina.**
- **if you are taking rifampicin**, an antibiotic.
- **if you have been told that you have a narrowing of the aortic heart valve** (stenosis).
- **if you have ever had a collapse** caused by a **heart problem** (cardiogenic shock), during which you became breathless, pale and had a cold sweat and dry mouth.
- **if your blood pressure continues to rise** despite treatment (malignant hypertension).
- If you have been told to **avoid lactose**, that you have a hereditary condition called **Lapp lactase deficiency** or **glucose-galactose malabsorption**.

Warnings and precautions

Talk to your doctor or pharmacist before taking Adipine™ MR.

Your doctor will take special care:

- **If you have low blood pressure** and you were prescribed Adipine™ MR for your angina. Your blood pressure may be decreased further by this treatment.
- **If you have a heart condition** where your heart cannot cope with increased strain (poor cardiac reserve).
- **If you are pregnant.**
- **If you are breastfeeding.** If you need to take Adipine™ MR, you should stop breastfeeding before you start to take this medicine.
- **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 Adipine™ MR.
- **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 Adipine™ MR.

Tell your doctor:

- **If your chest pain (angina)** gets worse (comes on more often or more severely) over a matter of hours or days. You may be advised not to take Adipine™ MR.
- **If you have chest pains after taking your first dose** of Adipine™ MR. Your doctor may wish to change your treatment.
- **If you notice increased breathlessness.**
- **If you notice swelling of the ankles.**

Tell your doctor before you take the next dose if any of these apply to you.

Also tell your doctor:

- **If you are giving a urine sample.** Adipine™ MR may interfere with the results of certain urine tests.
- **If you are a man who has been unable to father a child** by *in vitro* fertilisation. Drugs like Adipine™ MR have been shown to impair sperm function.

Children and adolescents

Adipine™ MR 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.

Other medicines and Adipine™ MR

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may affect the way Adipine™ MR 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).
- **Magnesium sulphate injections during pregnancy** (may cause a severe fall in blood pressure).
- **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).
- **Tacrolimus** (to prevent the rejection of transplanted organs).
- **Phenobarbital** (usually used to treat insomnia or anxiety).

Adipine™ MR with food and drink

You can take Adipine™ MR with or without food.

Do not drink grapefruit juice or eat grapefruit while taking Adipine™ MR.

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You may be able to use Adipine™ MR, but only after special consideration and agreement by your doctor.

Do not take Adipine™ MR if you are breast-feeding. If you need to take Adipine™ MR, you should stop breastfeeding before you start taking the tablets.

Driving and using machines

Adipine™ MR, 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 tablets, or if you have drunk alcohol.

Adipine™ MR contains milk sugar (lactose)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Adipine™ MR

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

Adults

Unless otherwise specified, the recommended starting dose is 10 mg Adipine™ MR every 12 hours. This may be increased to the maximum dose of 40 mg every 12 hours if necessary. Your doctor may increase or decrease the dose

depending on how well your blood pressure or angina is being controlled.

Older people

Lower doses may be prescribed for older people.

Hepatic impairment

If you have problems with your liver your doctor will monitor you carefully. A reduction in your nifedipine dose may be required

Use in children and adolescents

Adipine™ MR 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.

Method of administration

Swallow the tablets whole with a little water.

You can take Adipine™ MR either with or without food.

Do not take them with grapefruit juice.

Duration of treatment

Continue to take the tablets for as long as your doctor has told you to.

If you take more Adipine™ MR than you should Get medical help immediately. If possible, take your tablets or the box with you to show the doctor.

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.

If you forget to take Adipine™ MR

Take your normal dose immediately and continue taking your tablets as prescribed, waiting 12 hours before taking your next dose.

Do not take a double dose to make up for the missed dose.

If you stop taking Adipine™ MR

High blood pressure and angina pectoris require longterm treatment. Your doctor will monitor your progress and determine the duration of your treatment. If you wish to stop taking these tablets temporarily or permanently, you should consult your doctor. It is important to reduce the dose gradually, especially if you have been taking high doses.

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. For the assessment of the side effects the following frequency rating was used:

Serious side effects

If you notice:

- 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 and do not take the next dose as these may be the first signs of allergic reaction which may become severe.

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*).

Contact your doctor immediately before you continue treatment as these may be signs of a severe reaction.

Less serious side effects

Apart from the side effects listed above, these are the other side effects of Nifedipine, starting with the more common ones:

Common (may affect up to 1 in 10 people):

- headache
- flushing
- general feeling of being unwell
- constipation
- swelling, particularly of the ankles and legs

Uncommon (may affect up to 1 in 100 people):

- stomach pain (*abdominal pain*)
- unspecific pain
- chills
- low blood pressure when standing up (symptoms include fainting, dizziness, light headedness, occasional palpitations, blurred vision and sometimes confusion)
- fainting
- irregular heartbeat (*palpitations*)
- dry mouth
- indigestion or upset stomach
- wind (*flatulence*)
- feeling sick (*nausea*)
- muscle cramps
- joint swelling
- sleep disorders

- anxiety or nervousness
- reddening of the skin
- nose bleeds
- nasal congestion
- sensation of spinning or whirling motion (*vertigo*)
- migraine
- dizziness
- trembling
- increase in the need to pass water (*urinate*)
- painful or difficult urination
- inability to achieve or maintain an erection (impotence)
- blurred vision
- temporary increase in certain liver enzymes

Rare (may affect up to 1 in 1,000 people):

- pins and needles
- inflammation of the gums, tender or swollen gums, bleeding gums

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

- vomiting
- a reduction in the number of white blood cells (*leucopenia*)
- a more severe decrease in a specific class of white blood cell (*agranulocytosis*)
- increased blood sugar (*hyperglycaemia*)
- decreased skin sensitivity (*hypoesthesia*)
- drowsiness (*somnolence*)
- eye pain
- chest pain (*angina pectoris*)
- heartburn or indigestion (*gastroesophageal sphincter insufficiency*)
- yellowing of the whites of the eyes or skin (*jaundice*)
- sensitivity to light (*photosensitivity allergic reaction*)
- small, raised areas of bleeding in the skin (*palpable purpura*)
- joint pain
- muscle pain
- shortness of breath

All of these symptoms usually go away when treatment with Adipine™ MR is stopped.

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 YellowCard Scheme at www.mhra.gov.uk/yellowcard.

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

5. How to store Adipine™ MR

Keep this medicine out of sight and reach of children.

Do not take 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 the original package in a cool, dry place below 25°C.

Nifedipine is light-sensitive. Once you remove the tablets from the packaging, you should not expose them to intensive light for prolonged periods of time.

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 Adipine™ MR contains

- The active substance is nifedipine.

Each Adipine™ MR 10 tablet contains 10 mg of nifedipine.

Each Adipine™ MR 20 tablet contains 20 mg of nifedipine.

- The other ingredients are lactose, microcrystalline cellulose, macrogol 6000, magnesium stearate, maize starch, hydroxypropylmethyl cellulose, polysorbate 80 (tween 80), talc, titanium dioxide (E171), red iron oxide (E172).

What Adipine™ MR looks like and contents of the pack

Adipine™ MR 10 and Adipine™ MR 20 modified release tablets are pink-coated round, slightly biconvex tablets with smooth surface.

Adipine™ MR 10 and Adipine™ MR 20 are available in packs containing 10, 20, 30, 50, 56, 60 or 100 tablets.

Blister packages are made of aluminium foil and PVC film.

Not all packaging sizes may be marketed.

Marketing Authorisation Holder And Manufacturer

STADA,
Linthwaite, Huddersfield, HD7 5QH, UK

Distributor

Chiesi Limited,
333 Styal Road, Manchester, M22 5LG, UK.

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