

PACKAGE LEAFLET: INFORMATION FOR THE USER
Tensipine MR 10mg and 20mg 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 Tensipine MR is and what it is used for
2. What you need to know before you take Tensipine MR
3. How to take Tensipine MR
4. Possible side-effects
5. How to store Tensipine MR
6. Contents of the pack and other information

1. WHAT TENSIPINE MR IS AND WHAT IT IS USED FOR

Tensipine MR contains nifedipine, which belongs to a group of medicines called calcium antagonists. Tensipine MR is used to treat high blood pressure or angina (chest pain).

For high blood pressure: Tensipine 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: Tensipine 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 TENSIPINE MR

DO NOT take Tensipine MR:

- if you are allergic (hypersensitive) to nifedipine, any other similar medicines (known as *dihydropyridines*) or any of the other ingredients of Tensipine MR (listed in Section 6).
- if you have had a heart attack within the last month or if you suspect that you are having a heart attack.
- if you get a sudden angina attack. Tensipine MR will not help to relieve the symptoms of angina quickly.
- if you have unstable angina.
- if you are pregnant, think you may be pregnant, are planning to become pregnant or are breast-feeding.
- 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 the severity or frequency of your angina has rapidly worsened over a matter of hours or 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.

If you are unsure whether you may have any of these conditions, please ask your doctor.

Tensipine MR should **not** be given to children.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tensipine MR:

- if you have low blood pressure and you were prescribed Tensipine 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 breast-feeding. If you need to take Tensipine MR, you should stop breast-feeding before you start to take this medicine.
- if you are 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 high blood pressure and a low blood volume, you might experience a sudden drop in blood pressure when you take Tensipine 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 Tensipine 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 Tensipine MR.
- if you experience chest pains within 1 – 4 hours of taking your first dose of Tensipine MR. Contact your doctor **before you take the next dose**. Your treatment may be changed.
- if you suffer from a severe form of high blood pressure (malignant hypertension), Tensipine MR may not be suitable for you.
- if you notice increased breathlessness.
- if you notice swelling of the ankles.

Also tell your doctor:

- if you are having your urine tested. Inform the healthcare professional responsible that you are taking this medicine. It may interfere with the results of certain tests.
- if you are a man who has been unable to father a child by *in vitro* fertilisation. Drugs like Tensipine MR have been shown to impair sperm function.

Other medicines and Tensipine 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 Tensipine 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** (used 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 sulfate 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).

Taking Tensipine MR with food or drink

Tensipine MR can be taken with or without food.

Do not drink grapefruit juice or eat grapefruit while taking Tensipine MR.

Do not start taking Tensipine 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 Tensipine 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, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You may be able to use Tensipine MR after week 20 of your pregnancy, but only after special consideration and agreement by your doctor.

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

Driving and operating machinery

Tensipine 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.

Important information about some of the ingredients of Tensipine MR

This medicine contains lactose (a type 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.

Please read the back of this leaflet.

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3. HOW TO TAKE TENSIPINE MR

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

How to take:

- Swallow the tablets whole with a little water
- Continue to take the tablets for as long as your doctor has told you to
- Do not take this medicine with grapefruit juice.

Adults

The recommended dose is one 10mg tablet every 12 hours, but your doctor may want to increase your dose if your blood pressure or angina is not being controlled. If so, they will prescribe a 20mg tablet. The maximum dose is 40mg every 12 hours.

Elderly and adults with liver disease

Your doctor may want to prescribe a lower dose. Take the tablets as prescribed by your doctor.

Use in children and adolescents below 18 years of age

Tensipine 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.

If you take more Tensipine MR than you should

If you have taken more Tensipine MR than prescribed tell your doctor or go to the nearest hospital casualty department immediately and take your tablets or the box with you to show the doctor.

Taking more Tensipine MR tablets than prescribed may cause your blood pressure to become too low and your heartbeats to become irregular. It may also lead to nausea (feeling sick) and vomiting, a lack of energy, drowsiness, dizziness, confusion, flushing and possibly, even unconsciousness.

If you forget to take Tensipine MR

If you forget to take a dose at the right time, take it as soon as you remember and then go on as before. However, allow at least 12 hours before taking your next dose. **Do not take a double dose to make up for a forgotten tablet.**

If you stop taking Tensipine MR

Your doctor will monitor your progress and determine the duration of 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 about these tablets, ask your doctor or pharmacist.

4. POSSIBLE SIDE-EFFECTS

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

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
- chest pain (angina attacks) at the start of treatment.

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

Other side-effects include:

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 1 in 1,000 people)

- pins and needles
- inflammation of the gums, tender or swollen gums, bleeding gums
- itching on one particular location on the body
- loss of sensitivity or feeling in the hands.

Other side-effects (Frequency unknown)

- 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 (gaestoophageal 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.

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

Tell your doctor if any side-effects get serious, or if you notice any effects not listed in this leaflet.

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.

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

5. HOW TO STORE TENSIPINE MR

Keep out of the sight and reach of children.

Do not use Tensipine MR after the expiry date which is stated on the blister and carton after EXP.

The expiry date refers to the last day of that month.

Store in the original container and carton.

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 protect the environment.

6. FURTHER INFORMATION

What Tensipine MR contains

- The active substance in Tensipine MR is nifedipine. Tensipine MR 10 Tablets contain 10mg of nifedipine. Tensipine MR 20 Tablets contain 20mg of nifedipine.
- The other ingredients are microcrystalline cellulose, polysorbate 80, hydroxypropyl methylcellulose, lactose, maize starch, polyethylene glycol and magnesium stearate. Titanium dioxide (E171) and iron oxide (E172) are included as colouring agents.

What Tensipine MR looks like and contents of the pack

Tensipine MR are pink-grey coloured tablets with 'TMR' marked on one side and '10' or '20' marked on the other. They are supplied in calendar packs of 56 tablets. The foil has the days of the week printed on it to remind you when to take the tablets.

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PL 06831/0048 Tensipine MR 10

PL 06831/0049 Tensipine MR 20

Marketing Authorisation Holder and Manufacturer:

Genus Pharmaceuticals, Lintthwaite, Huddersfield, HD7 5QH, UK.

Manufacturer:

Bluepharma Industria Farmaceutica SA, Coimbra, Portugal.

This leaflet was last revised in September 2016.



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