

<!DOCTYPE DOCUMENT SYSTEM "icon.dtd" []>

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edition="1996-97" section="company">

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<HEAD>

TPI 112040038/1 Patient Information Leaflet

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<BLOCK justified=center>

<EMPH weight="bold">

Adipine™ MR 10

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Adipine™ MR <CB n=1> <FIGURE></FIGURE>

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Please read this leaflet carefully because it contains important information on how to use this medication effectively and safely. If you have any questions or are not sure about anything do not hesitate to ask your doctor or pharmacist.

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<HEAD>

Adipine™ MR 10

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Active ingredient:

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nifedipine What is in your medicine Each tablet contains the active ingredient:

nifedipine 10 mg

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Excipients: lactose, microcrystalline cellulose, macrogol 6000, magnesium stearate, maize starch, hydroxypropylmethyl cellulose, polysorbate 80 (tween 80), talc, colourants E171, E172.

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Presentation and contents

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Apricot coated, round, slightly biconvex tablets. Adipine®; MR 10 is available in packs of 56 tablets.

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Adipine®; MR 10 is a medicine for the treatment of high blood pressure (hypertension) and for the prevention of coronary artery disease. It belongs to a group of drugs called calcium antagonists.

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STADA Arzneimittel AG Stadastrasse 2-18 61118 Bad Vilbel, FRG

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Trinity Pharmaceuticals Ltd Tuition House 27-37 St George's Road Wimbledon London SW19 4EU

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Why have I been prescribed Adipine®; MR 10?

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<BLOCK>

Adipine®; MR 10 has been prescribed by your doctor to treat your high blood pressure and/or to prevent angina pectoris (a heart condition due to lack of blood supply to the blood vessels of the heart).

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<HEAD weight="bold" >
When should I not take Adipine™ MR 10?
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<BLOCK>
Do not take Adipine™ MR 10 if you have previously had an allergic reaction to nifedipine, if you have a severe narrowing of the aortic valve (obstruction of one of the valves of the heart), if your BP is low and if you are pregnant or breast feeding
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<HEAD weight="bold" >
What special precautions should I take?
</HEAD>

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<HEAD slant="italic" >
Before starting treatment?
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<BLOCK>
You should remind your doctor about any other medicines you may be taking, such as other treatment for high blood pressure and angina pectoris, drugs for abnormal heart beats, antidepressant, anti-asthma (theophylline) and anti-ulcer drugs (cimetidine and ranitidine).
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<BLOCK>
You should remind your doctor of other problems you may have eg kidney or liver disease.
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Whilst taking Adipine™ MR 10?

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You should have your blood pressure checked regularly as your treatment may need to be adjusted.

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If you are diabetic, you should contact your doctor to see if any changes to your diabetic medicines need to be made.

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You should be very careful about driving or operating machinery since, when starting on Adipine™ MR 10 for the first time or when switching over from some other medication, you may experience dizziness, fatigue, marked fall in blood pressure and transient visual disturbances. Alcohol aggravates these symptoms.

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How many tablets, how often and how should I take Adipine™ MR 10?

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You should take the number of tablets prescribed by your doctor. Unless otherwise specified, the usual dose is one tablet twice daily. Your doctor may change the dose according to your response to the treatment.

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You should swallow the tablet(s) whole with some liquid after food. Do not bite, chew or break up the tablet(s).

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You should not take the next dose less than 4 hours after the first dose.

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For how long do I need to take Adipine™ MR 10?

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High blood pressure and angina pectoris require long term treatment. Your doctor will monitor your progress and determine the duration of your treatment. If you wish to stop Adipine™ MR 10 temporarily or permanently, you should consult your doctor.

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Discontinuation of Adipine™ MR 10 should be gradual, especially if you have been taking high doses.

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What should I do if I miss a dose?

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If you miss a dose and it is more than 4 hours before the next dose, then take your

usual treatment. If it is less than 4 hours, then you should wait till your next usual dosing time before taking the medication. You should never take a double dose to make up for the missed dose.

What undesirable effects may occur with the treatment?

At the start of treatment, worsening of angina pectoris may occur. Patients may experience headache, flushing or reddening of the skin associated with a feeling of warmth.

There have been reports of palpitations, fatigue, dizziness, swollen ankles due to fluid retention, tingling sensation in the arms or legs, muscle pain, finger tremors and minor transient visual disturbances. Rarely there have been reports of diarrhoea, nausea and a feeling of fullness.

Allergic skin reactions have been reported e.g. itching, hives and rashes, and rarely inflammation and peeling of the skin.

Rare reports have been made of abnormalities affecting the blood cells (reduced red and white cells and platelet counts) and of spontaneous bleeding. Swelling of the breasts have also been reported, especially in elderly men, and impairment of liver function and swelling of the gums have also known to occur; all of these have resolved on stopping treatment

Patients who are on kidney dialysis and have a very high blood pressure and a low blood volume may have a marked drop in their blood pressure. In those who have kidney impairment, their kidney function may deteriorate transiently.

Should you experience any effects not described above, please let your doctor know immediately.

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What should I do if an overdose has been taken?
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In case of an overdose, medical advice should be sought immediately.
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How should I store Adipine™ MR 10
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<BLOCK>
The tablets should be kept in the original container in a cool, dry place below 25°C.
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The expiry date of the medicine is printed on the package. Do not use this product after this expiry date.
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Keep out of reach of children.
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<EMPH weight="bold">
This medicine has been prescribed only for you. Do not give it to anyone else under any circumstances.
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Date of preparation or last revision:
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October 1995 ™Trade Mark applied for
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