Read all of this leaflet carefully before taking this medicine
- Keep this leaflet. You may need to read it again.
- If you any further questions ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or you notice any side effects, not listed in this leaflet, please tell your doctor.

In this leaflet
- What Manidipine is and what it is used for
- Before you take Manidipine
- How to take Manidipine
- Possible side effects
- How to store Manidipine
- Further information

1. WHAT MANIDIPINE IS AND WHAT IT IS USED FOR
Manidipine tablets contain 10 mg of the active ingredient manidipine, which belongs to a group of medicines called dihydropyridine calcium channel blocker.
Manidipine tablets contain 20 mg of the active ingredient manidipine, which belongs to a group of medicines called dihydropyridine calcium channel blocker.

Manidipine is indicated for the treatment of mild to moderate essential hypertension (high blood pressure).

Manidipine works by relaxing blood vessels, so that blood pressure is reduced.

2. BEFORE YOU TAKE MANIDIPINE
Do not use Manidipine
- If you are allergic (hypersensitive) to manidipine or to other calcium channel blockers or any of the other ingredients of manidipine tablets. (See section 6 for list of ingredients).
- If you suffer from unstable angina (chest pain not caused by stress or exercise or at night) or you have had a myocardial stroke within 4 weeks
- If you suffer from untreated congestive heart failure
- If you suffer from severe kidney failure (creatinine clearance <10ml/min)
- If you suffer from moderate to severe liver failure
- If you are a child

Take special care with Manidipine
- If you suffer from mild liver damage since the effects of manidipine may be increased (see section 3 “How to take manidipine”)
- If you are an elderly patient, reduction of the dose is required (see section 3 “How to take manidipine”)

- If you suffer from cardiac disease
- If you are taking some other medicinal products (see Taking other medicines).

**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, or medicines for any of the following conditions:

- High pressure such as diuretics and/or betablockers
- Viral and bacterial infections
- Mental disorders
- Irregular heart beat (such as amiodarone, quinidine, digozin)
- Allergies (such as terfenadine, astemizole)

**Taking Manidipine with food and drink**
Patients should not consume alcohol or grapefruit during treatment with manidipine.

**Pregnancy and breast feeding**
MANIDIPINE should not be used during pregnancy. The use of manidipine must be avoided during lactation. If manidipine treatment is necessary, breast-feeding must be discontinued.

**Fertility**
Changes in the head of spermatozoa which can impair fecundation have been reported in some patients treated by channel blockers.
Ask your doctor for advice before taking any medicine.

**Driving and using machines**
Please take care while driving and operating machinery since dizziness may be experienced.

**Important information of some of the ingredients**
MANIDIPINE 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 manidipine.

3. HOW TO TAKE MANIDIPINE
Always take manidipine exactly as your doctor has told you. You should check with your doctor if you are not sure.
If you feel that the action of Manidipine is too strong or too weak, talk to your doctor or pharmacist. Children should not take manidipine.

Your doctor will indicate the duration of their treatment. Do not stop the treatment until doctor say you.
Tablets are to be taken in the morning after breakfast with a little liquid and without chewing.
The usual starting dose is 10 mg once a day.
If after 2-4 weeks of treatment the antihypertensive effect of manidipine is insufficient, your doctor may increase the dosage to 20 mg once a day.

If you are elderly or you suffer with renal or liver dysfunction your doctor may prescribe you a lower dose (10 mg once a day).

**If you take more Manidipine than you should**
If you (or someone else) swallow a lot of the tablets at the same time, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. As occurs with other channel blockers, it is expected that an overdose would cause
excessive peripheral vasodilatation that leads to a lowering of blood pressure and increased heart rate.

**If you forget to take Manidipine**
If you miss a dose, take it as soon as possible and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

**If you stop taking Manidipine**
Before you stop taking Manidipine contact your doctor.

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

4. **POSSIBLE SIDE EFFECTS**
Like all medicines, manidipine can cause side effects, although not everybody gets them. The following side effects may occur when taking Manidipine.

*Common* (*≥ 1/100, < 1/10*):
- headache
- dizziness
- vertigo
- swelling caused by fluid retention
- palpitations
- hot flushes.

*Uncommon* (*≥1/1000 to < 1/100*):
- tingling sensations on the skin
- weakness or lack of energy
- rapid heartbeat
- shortness of breath
- nausea
- vomiting
- constipation
- dry mouth
- digestive disorders
- rash
- eczema
- increase of hepatic enzymes
- increase of renal parameters
(your doctor is aware of them).

*Rare* (*≥ 1/10000 to < 1/1000*):
- sleepiness
- drowsiness
- chest pain
- angina
- high blood pressure
- stomach ache
- abdominal pain
- redness of the skin
- itching and irritability.

*Very rare* (*<1/10000*):
- myocardial stroke
- inflammation of the gums
- overgrowth of the gums
which generally disappeared with the withdrawal of the treatment. In isolated cases patients with pre-existent angina may experience increased frequency, duration and severity of these incidents.

*Unknown*:
extrapyramidal syndrome has been reported with some calcium inhibitors.

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

5. **HOW TO STORE MANIDIPINE**
Keep out of the reach and sight of children.

Do not use manidipine after the expiry date which is stated on the carton. Exp. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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

6. **FURTHER INFORMATION**
What Manidipine 10mg contains:
The active substance is manidipine dihydrochloride 10 mg.
The other ingredients are lactose monohydrate, maize starch, low-substituted hydroxypropylcellulose, hydroxypropylcellulose, magnesium stearate, riboflavin.

What Manidipine 20mg contains:
The active substance is manidipine dihydrochloride 20 mg.
The other ingredients are lactose monohydrate, maize starch, low-substituted hydroxypropylcellulose, hydroxypropylcellulose, magnesium stearate, riboflavin.

What Manidipine looks like and contents of the pack
Manidipine is available in two strengths: 10 and 20 mg.

The 10 mg tablets are round convex, yellow coloured, with midline score line
The 20 mg tablets are oval convex, yellow coloured, with midline score line

Manidipine is available in the following packs:
10 mg 14, 28, 30, 56, 84, 90, 98, 112 tablets
20 mg 14, 28, 30, 56, 84, 90, 98, 112 tablets

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
To be completed nationally

Manufacturer
Abiogen Pharma SpA
Via Meucci 36, Ospedaletto
56014 Pisa - Italy