

PACKAGE LEAFLET: INFORMATION FOR THE USER

Moxonidine 200 micrograms film-coated Tablets

Moxonidine 300 micrograms film-coated Tablets

Moxonidine 400 micrograms film-coated Tablets

(moxonidine)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any side effect gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Moxonidine is and what it is used for
2. Before you take Moxonidine
3. How to take Moxonidine
4. Possible side effects
5. How to store Moxonidine
6. Further information

1. WHAT MOXONIDINE IS AND WHAT IT IS USED FOR

Moxonidine belongs to a group of medicines called anti-hypertensives, which reduce blood pressure.

Moxonidine is used to treat high blood pressure (hypertension).

2. BEFORE YOU TAKE MOXONIDINE

Do not take Moxonidine if you

- are allergic (hypersensitive) to Moxonidine or any of the other ingredients in this medicine (see Section 6 .Further Information.).
- have suffered in the past from a severe allergic reaction (called angioedema) causing itching,
- wheezing or swelling of the face and tongue, which in some cases can lead to difficulty swallowing
- or breathing
- have a heart condition eg. heart failure, a slow beating heart or abnormal heart rhythm
- suffer from angina or hardened arteries
- have severe liver or kidney problems.

Take special care with Moxonidine

You should tell your doctor before taking this medicine if you:

- are pregnant or might become pregnant
- are breastfeeding
- have leg cramps caused by poor blood circulation
- suffer from blood circulation problems eg. Raynaud.s phenomenon
- are recovering from a heart attack or stroke
- have Parkinson.s disease
- have epilepsy
- have glaucoma (high pressure in the eye)
- are depressed
- are under 16 years old.

If you are taking Moxonidine and a beta-blocker (e.g propranolol) at the same time, treatment with the betablocker should be stopped a few days before treatment with Moxonidine is stopped. This is because stopping both treatments at the same time could result in an increased blood pressure.

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 the following:

- other medicine to lower blood pressure (e.g tolazoline)
- digoxin, to treat a heart condition
- tranquilisers and medicines used to treat anxiety such as diazepam, lorazepam
- sleeping pills
- sedatives such as benzodiazepines
- medicine to treat depression such as amitriptyline
- anti-diabetic medicine such as insulin, sulfonylurea eg. gliclazide
- medicine to treat gout eg. allopurinol, colchicine, probenecid
- cholesterol-lowering medicine
- anti-ulcer medicine
- medicine to treat aches and pains of joints
- thyroid medicine.

Taking Moxonidine with food and drink

This medicine may be taken before, during or after a meal. **Do not** drink alcohol while taking this medicine.

Pregnancy and breast-feeding

Moxonidine **should not** be taken by pregnant or breast-feeding mothers as it could harm the baby. If you become pregnant while taking this medicine, **tell your doctor straight away**. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or operate machinery if you feel dizzy or drowsy while taking this medicine.

Important information about some of the ingredients of Moxonidine

This medicine contains **lactose monohydrate**. If your doctor has told you that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. HOW TO TAKE MOXONIDINE

Always take Moxonidine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Swallow your tablets with a glass of water
- Take before, during or after a meal.

The usual dose is:

Adults (including the elderly)

The usual starting dose is one 200 microgram tablet taken in the morning. After three weeks, your doctor may increase this to 400 micrograms of moxonidine (given as a single dose in the morning or as 200 micrograms in the morning and 200 micrograms in the evening). If needed, after another three weeks, the dose may be increased to the maximum daily dose of 600 micrograms (given as a divided dose in the morning and evening).

Patients with kidney problems

You may be more sensitive to the effects of Moxonidine. A single dose should not be more than 200 micrograms and the maximum daily dose is 400 micrograms of Moxonidine.

Children

Moxonidine **should not** be given to children under 16 years old.

If you take more Moxonidine than you should

Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you. Symptoms of overdose include feeling light-headed or faint.

If you forget to take Moxonidine

Take it as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Moxonidine

Do not suddenly stop taking Moxonidine as this may cause serious changes in your blood pressure. Speak to your doctor first. Your doctor will slowly reduce the dose over 2 weeks. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

If any of the following happen, **stop taking Moxonidine and tell your doctor immediately** or go to your nearest hospital emergency department. You may be experiencing an allergic reaction to the tablets.

- Difficulty in breathing, tightness of the chest, swelling of the face, throat or tongue, or skin rashes
- Liver problems, dark urine, pale stools, yellowing of the skin or whites of the eyes.

These side effects are serious. You may need urgent medical attention.

Other side effects:

Very common side effects (affecting more than 1 in 10 people):

- dry mouth
- headache
- feeling dizzy or drowsy.

These effects are more likely at the start of treatment.

Common side effects (affecting fewer than 1 in 10 people):

- mood changes
- sleep problems
- feeling sick or weak, stomach upset, constipation
- feeling flushed.

Uncommon side effects (affecting fewer than 1 in 100 people):

- feeling depressed or anxious
- drowsy
- swollen hands or ankles, fluid retention, leg weakness
- feeling faint
- loss of appetite
- earache
- changes in urine function
- allergic skin reactions
- dry itchy or burning eyes
- dizziness on standing
- tingling or numbness in the fingers and toes
- painful or cold fingers or toes and other circulation problems
- swollen breasts
- impotence and loss of libido.
- angioedema (severe allergic reaction)

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

5. HOW TO STORE MOXONIDINE

Keep out of the reach and sight of children.

Do not use Moxonidine after the expiry date, which is shown on the label or carton. The expiry date refers to the last day of that month.

Don't store this medicine above 30°C.

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.

6. FURTHER INFORMATION

What Moxonidine contains

- The active substance is 200 micrograms, 300 micrograms or 400 micrograms of moxonidine.
- The other ingredients are lactose monohydrate, crospovidone, povidone and magnesium stearate. The coating contains hypromellose, titanium dioxide (E171), macrogol and red iron oxide (E172).

What Moxonidine looks like and contents of the pack

Your medicine comes as a round coated tablet.

The 200 microgram tablets are light pink, the 300 microgram tablets are pink and the 400 microgram tablets are dark pink.

Moxonidine is available in blister packs of 10, 28, 30, 50, 100 and 98 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

<To be completed Nationally>

Generics [UK] Ltd.

Station Close

Potters Bar

Hertfordshire EN6 1TL

United Kingdom

Manufacturer

<To be completed Nationally>

Chanelle Medical, IDA Industrial Estate, Loughrea, Co. Galway, Ireland

Generics [UK] Ltd., Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

McDermott Laboratories T/a Gerard laboratories, 35/36Baldoye Industrial Estate, Dublin, Ireland

Mylan dura GmbH, Wittichstr. 6, D. 64295 Darmstadt, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

<To be completed Nationally>

Austria - Moxonidin .Arcana. Filmtabletten

Belgium - Moxonidine Mylan

Germany - Moxodura Filmtabletten

Luxembourg - Moxonidine Mylan

The Netherlands - Moxonidin Mylan

The United Kingdom - Moxonidine Film-coated tablets

This leaflet was last approved in {MM/YYYY}.