Package leaflet: Information for the patient

Moxonidine 0.2 mg Film-coated Tablets
Moxonidine 0.3 mg Film-coated Tablets
Moxonidine 0.4 mg Film-coated Tablets

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

Do not take Moxonidine if you:
- are allergic to moxonidine or any of the other ingredients of this medicine (listed in section 6)
- have a slow heart rate (below 50 beats/minute at rest) or suffer from an abnormal heart rhythm or a change in the rate of the heart beat (called “sick-sinus syndrome” or “second or third degree AV-block”)
- have heart function insufficiency.

Warnings and precautions

Talk to your doctor or pharmacist before taking moxonidine if you:
- have a type of irregular heart beat called “1st degree AV-block” or a high risk of developing AV-block
- have severe coronary artery disease or chest pain (unstable angina pectoris)
- have kidney problems. Your doctor may need to adjust your dose
- are elderly. Your doctor may start you on the lowest dose and increase it gradually.

Children and adolescents
This medicine should not be given to children and adolescents under 18 years old.

Other medicines and Moxonidine
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, especially any of the following:

- beta-blockers such as propranolol or atenolol, used to treat heart problems (see "If you stop taking Moxonidine" in section 3)
- other medicines used to reduce blood pressure such as furosemide (a diuretic), captopril (an angiotensin-converting enzyme inhibitor) or tolazoline (an alpha-blocker)
- medicines used to treat anxiety such as benzodiazepines (e.g. diazepam, lorazepam) and depression (e.g. amitriptyline)
- sleeping tablets and tranquilisers
- moxonidine is removed from the body by kidneys through the process called "tubular excretion". Other medicines removed from the kidneys in the same way could affect how moxonidine works.

Moxonidine with alcohol
Do not drink alcohol while taking this medicine.

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.

This product should not be used during pregnancy unless clearly necessary. Moxonidine has been shown to pass in to breast milk and should therefore not be used during breast-feeding. If therapy with moxonidine is considered absolutely necessary, the breast-feeding shall be stopped.

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

Moxonidine contains 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 Moxonidine
Always take this medicine exactly as your doctor has told you. 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 recommended dose is:

Use in adults (including the elderly)
The recommended starting dose is one 0.2 mg tablet taken in the morning. After three weeks, your doctor may increase this to 0.4 mg of moxonidine (given as a single dose in the morning or as 0.2 mg in the morning and 0.2 mg in the evening). If needed, after another three weeks, the dose may be increased to the maximum daily dose of 0.6 mg (given as a divided dose in the morning and evening).

Use in patients with kidney problems
You may be more sensitive to the effects of Moxonidine.
A single dose should not be more than 0.2 mg and the maximum daily dose is 0.4 mg of Moxonidine. If you have severe kidney problems, the maximum daily dose is 0.3 mg of Moxonidine.

Use in children and adolescents
Moxonidine **should not** be given to children and adolescents under 18 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 headache, feeling sleepy (somnolence, sedation), fall in blood pressure (hypotension), feeling dizzy, unusual weakness (asthenia), slow heart rate (bradycardia), dry mouth, being sick (vomiting), feeling tired and pain in the stomach (abdominal pain).

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 are taking Moxonidine and a beta-blocker (e.g propranolol) at the same time, treatment with the beta-blocker 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.

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.

If any of the following happens, **stop taking Moxonidine and tell your doctor immediately** or go to your nearest hospital emergency department.

Uncommon (may affect up to 1 in 100 people):
- Difficulty in breathing, tightness of the chest, swelling of the face, lips, mouth, throat or tongue, or skin rashes. You may be experiencing an allergic reaction to the medicine.

Very rare (may affect up to 1 in 10,000 people):
- 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.

In decreasing order of frequency, other side effects can include:

Very common (may affect more than 1 in 10 people):
- dry mouth.

Common (may affect up to 1 in 10 people):
- headache
- feeling dizzy/vertigo
- back pain
- abnormal thinking
- sleep problems, difficulty sleeping (insomnia), feeling sleepy (somnolence)
- rash/itching

- feeling sick (nausea), stomach upset, indigestion, constipation, diarrhoea, being sick (vomiting)
- feeling flushed
- weakness (asthenia).

Uncommon (may affect up to 1 in 100 people):
- feeling anxious or nervous,
- swelling of different parts of the body (e.g hands or ankles), fluid retention, leg weakness,
- fainting,
- drowsiness,
- loss of appetite (anorexia),
- neck pain, painful parotid glands (glands below the ears),
- low blood pressure, including low blood pressure when standing up,
- ringing or noise in the ears,
- dry itchy or burning eyes,
- pins and needles or abnormal sensations (paraesthesia) in the extremities,
- painful or cold fingers or toes and other circulation problems,
- swollen breasts in male patients,
- inability to get or maintain an erection, loss of sexual drive,
- slow heart beat.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any 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 Moxonidine

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date, which is stated on the label or carton after 'EXP'. The expiry date refers to the last day of that month. Do not store this medicine above 30°C.
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 Moxonidine contains
- Each tablet contains 0.2 mg, 0.3 mg or 0.4 mg of the active substance moxonidine.
- The other ingredients are lactose monohydrate, crospovidone (Type A), povidone K-25 and magnesium stearate. The coating contains hypromellose, titanium dioxide (E171), macrogol 400 and red iron oxide (E172).

What Moxonidine looks like and contents of the pack
Your medicine comes as a round film-coated tablet.
The 0.2 mg tablets are light pink, the 0.3 mg tablets are pink and the 0.4 mg tablets are dark pink.
Moxonidine is available in blister packs of 10, 28, 28 x 1, 30, 50, 98 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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