

Moxonidine 200 microgram Film-coated Tablets

Moxonidine 300 microgram Film-coated Tablets

Moxonidine 400 microgram Film-coated Tablets

Your medicine is known by the above names but will be referred to as Moxonidine throughout this:

Patient Information Leaflet

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 is **used to treat high blood pressure**.

This medicine effects the central nervous system. It works by making your blood vessels relax and widen. This helps to lower your blood pressure.

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 certain **heart stimulus disorders** known as
 - sick sinus syndrome
 - AV block 2nd and 3rd degree
- have a **pulse of less than 50 beats per minute at rest**
- have **heart failure**

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine.

Check with your doctor or pharmacist before taking your medicine if you:

- have a heart problem called “1st degree AV- block” or a high risk of developing AV-block
- have a severe heart problem such as angina or chest pain at rest
- 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.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine.

Children and adolescents

Due to insufficient knowledge, this medicine should not be used by children and adolescents under 16 years.

Other medicines and Moxonidine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- other medicines to lower your blood pressure. The blood pressure-lowering effect may be enhanced.
- beta-blockers (medicines to regulate heart rhythm). See “If you stop taking Moxonidine” in Section 3.
- tranquillisers, sedatives or sleeping tablets such as benzodiazepines. Moxonidine may increase the effect of these medicines.
- special medicines for depression, such as imipramine or amitriptyline (tricyclic antidepressants). Avoid using simultaneously with Moxonidine.
- Moxonidine is removed from your body by your kidneys through a 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 you are taking Moxonidine. This is because this medicine may increase the effects of alcohol.

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.

- Only take Moxonidine during **pregnancy if your doctor indicates that it is absolutely necessary**, as insufficient data is available.
- Moxonidine **should not be used if you are breast-feeding**, as it passes into mother’s milk. Your doctor may advise you to take another medicine if you want to breast-feed, or may ask you to stop breast-feeding.

Driving and using machines

You may feel sleepy or dizzy while taking this medicine. If this happens, talk to your doctor before driving or using any tools or machines. **If your attention is decreased, do not drive or operate machines.**

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.

The recommended dose is

- **Starting dose:** 200 mcg of moxonidine every morning
- **Dosage adjustment**
If necessary your doctor can increase the dose to 400 mcg of moxonidine after a 3 week interval (given as a single dose in the morning or divided into one dose in the morning and the second dose in the evening).
In case of insufficient response after a further 3 week treatment, the dose may be increased to a maximum daily dose of 600 mcg of Moxonidine (this dose must be divided into one dose in the morning and the second dose in the evening).
- **Maximum dose**
You should not take more than 400 mcg as a single dose or more than 600 mcg of moxonidine daily.
- **Patients with kidney problems**
Your doctor may tell you to take a lower dose if you have kidney problems.
- **Duration of use**
Your doctor will decide the duration of use.

Take tablets by mouth, whole and with a glass of water. You may take them prior to, with or after meals.

Use in children and adolescents

This medicine should not be given to children and adolescents under 16 years.

If you take more Moxonidine than you should

If you take more medicine than you should, contact your doctor immediately who will decide on further measures, or go to a hospital straight away. Take the medicine pack with you.

The following effects may happen:

- feeling sleepy (sedation, somnolence)
- headache
- feeling dizzy (vertigo)
- fall in blood pressure
- circulatory complaints such as unconsciousness when changing from lying to standing
- slow heart rate
- weakness
- feeling tired
- pain in the stomach (abdominal pain)
- dry mouth
- being sick (vomiting)
- a contradictory rise in blood pressure may occur in rare cases.

If you forget to take Moxonidine

Take the missed dose as soon as you remember, unless it is almost time for your next dose. In that case follow your usual schedule and skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Moxonidine

- Keep taking your tablets until your doctor decides that you should stop. Sudden medicine discontinuation may increase your blood pressure.
- If you need to stop, your doctor will lower your dose slowly over a few weeks. If you are taking more than one medicine for high blood pressure (such as beta-blockers), your doctor will tell you which medicine to stop first. This is so that your body can adjust slowly to the change.

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.

Stop taking Moxonidine and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- Serious allergic reaction which causes swelling of the face, throat, lips or mouth (angioedema). This is an uncommon side effect, affecting up to 1 in 100 people.

Other side effects include:

Very common, may affect more than 1 in 10 people

- dry mouth

Common, may affect up to 1 in 10 people

- headache
- a feeling of dizziness or “spinning”
- back pain
- rash or itching (pruritus)
- feeling sick (nausea) or being sick (vomiting)
- sleepiness or difficulty in sleeping
- diarrhoea
- indigestion
- weakness

Uncommon, may affect up to 1 in 100 people

- swelling in various body regions
- fall in blood pressure even with dizziness when changing position
- sudden fainting
- unusually slow heartbeat (bradycardia)
- ringing or noise in the ears (tinnitus)
- neck pain
- feeling nervous

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. 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 or search for MHRA Yellow Card in the

Google Play or **Apple App Store**. 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 blister and carton after “EXP”. The expiry date refers to the last day of that month.
- Do not store above 30 °C.
- Do not throw away 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.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6) Contents of the pack and other information

What Moxonidine contains

The **active substance** is **moxonidine**.

Each film-coated tablet contains either 200 micrograms, 300 micrograms or 400 micrograms of moxonidine.

The other ingredients are crospovidone, hypromellose, lactose monohydrate, macrogol 400, magnesium stearate, povidone K25, red iron oxide (E 172), titanium dioxide (E 171).

What Moxonidine looks like and contents of the pack

Moxonidine 200 micrograms film-coated tablets:

light pink, round, approximately 6 mm in diameter film-coated tablets, that are plain on both sides.

Moxonidine 300 micrograms film-coated tablets:

pink, round, approximately 6 mm in diameter film-coated tablets, that are plain on both sides.

Moxonidine 400 micrograms film-coated tablets:

dark pink, round, approximately 6 mm in diameter film-coated tablets, that are plain on both sides.

Pack size: 28 and 30 Film-coated Tablets.

PL 46420/0490 - Moxonidine 200 microgram Film-coated Tablets

PL 46420/0491 - Moxonidine 300 microgram Film-coated Tablets

PL 46420/0492 - Moxonidine 400 microgram Film-coated Tablets

POM

Who makes and repackages your medicine?

Your medicine is manufactured by Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, D-39179, Barleben, Germany.

Procured from within the EU and repackaged by the Product

Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

Leaflet date: 04.08.2023

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