

# Moxonidine 300 and 400 microgram tablets

moxonidine

## Package leaflet: Information for the user

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 drugs called anti-hypertensives that lower blood pressure. Moxonidine is used to treat high 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).
- if you have a slow heart rate or suffer from an abnormal heart rhythm or a change in the rate of the heart beat called "sick sinus syndrome" or "2<sup>nd</sup> or 3<sup>rd</sup> degree AV-block".
- if you have, or have had, heart failure or other heart problems.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Moxonidine

- if you have a heart problem called "1<sup>st</sup> degree AV-block"
- if you have a severe coronary heart disease, or have angina (chest pain at rest)
- if you have poor circulation
- if you have kidney disease
- if you are elderly as you may be more susceptible to the effects of blood pressure lowering drugs.

#### Children and adolescents

Do not give this medicine to children and adolescents under 16 years of age because it is unlikely to be safe.

#### Other medicines and Moxonidine

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

Talk to your doctor if you are taking any of the following:

- other medicines to lower your blood pressure. Moxonidine can increase the effect of these medicines
- beta-blockers, such as propranolol or atenolol, used to treat heart problems
- other medicines used to reduce blood pressure such as furosemide a diuretic, or captopril an angiotensin-converting enzyme inhibitor
- antidepressants such as imipramine or amitriptyline
- sleeping tablets such as zopiclone, tranquilizers such as nitrazepam, lorazepam or phenobarbital
- Moxonidine is removed from 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 food, drink and alcohol

The tablets can be taken with or without food.

Do not drink alcohol whilst taking Moxonidine. This is because the medicine can 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.

Talk to your doctor if you are pregnant or could become pregnant. Your doctor will usually advise you to stop taking Moxonidine. Your doctor may advise you to take another medicine instead of Moxonidine.

Moxonidine is not recommended for mothers who are breast-feeding. Your doctor may recommend that you take another medicine if you want to breast-feed or advise you not to continue breast-feeding.

#### Driving and using machines

Moxonidine may cause dizziness or drowsiness, if affected do not drive or operate machinery.

#### 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 medicinal product.

### 3 How to take Moxonidine

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

The tablets should be swallowed, preferably with a drink of water.

The recommended dose is:

#### Adults (including older people):

Your treatment will normally start with 200 micrograms, taken in the morning. After three weeks, your doctor may increase this dose to 400 micrograms daily, given in a single dose in the morning, or in divided doses in the morning and evening. After another three weeks, your doctor may need to increase this dose to 600 micrograms daily, given in divided doses (morning and evening). You should not take more than 400 micrograms as a single dose, or more than 600 micrograms in any one day.

#### Patients with kidney problems:

If you have moderate problems with your kidneys, you should not take more than 200 micrograms as a single dose or more than 400 micrograms in total, a day.

If you have severe problems with your kidneys you should not take more than 300 micrograms in total per day.

#### Use in children and adolescents

Moxonidine is not recommended for use in children.

#### If you take more Moxonidine than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause headache, sleepiness, dry mouth, loss of balance, dizziness, low blood pressure and slowing of the pulse, vomiting, feeling tired, weakness and pain in your stomach. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

#### **If you forget to take Moxonidine**

If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Moxonidine**

Do not suddenly stop taking Moxonidine. Your medicine should be reduced gradually over two weeks, your doctor will advise you on how and when to do this.

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 the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

The following side effects have been reported at the approximate frequencies shown:

**Very common** (may affect more than 1 in 10 people):

- dry mouth
- drowsiness

**Common** (may affect up to 1 in 10 people):

- headache
- dizziness (vertigo)
- flushing (vasodilation).
- weakness or loss of strength
- confusion
- sleep disturbances (difficulty sleeping – insomnia or feeling sleepy – somnolence)
- nausea (feeling sick), being sick (vomiting), stomach upsets (dyspepsia), diarrhoea
- rash or itching (pruritus)
- back pain

**Uncommon** (may affect up to 1 in 100 people):

- feeling nervous
- swelling, particularly of the lower legs and feet
- neck pain
- fainting
- unusually slow heart beat (bradycardia)
- low blood pressure, which may result in dizziness or light-headedness on standing
- circulatory disorders, which may produce numbness, coldness or pins-and-needles in the hands or feet
- ringing or noise in the ears (tinnitus)
- leg weakness
- anorexia
- painful neck glands
- dry, itchy or burning sensation in the eyes
- anxiety
- sexual problems such as impotence, or the development of breasts in men, or loss of sexual desire.

#### **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](http://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 store above 30°C.  
Keep blister in the outer carton in order to protect from light.

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 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**

- The active substance is moxonidine. Each tablet contains 300 micrograms or Each tablet contains 400 micrograms.
- The other ingredients are: lactose monohydrate, crospovidone, povidone K25 and magnesium stearate. The film coating contains hypromellose, titanium dioxide (E171), macrogol 400 and red iron oxide (E172).

#### **What Moxonidine looks like and contents of the pack**

- The 300 microgram tablets are pink, round, film-coated tablets.
- The 400 microgram tablets are dark pink, round, film-coated tablets.
- The product is available in packs of 10, 20, 28, 30, 50, 56, 98, 100 and 400 film-coated tablets.  
Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation holder:  
Teva UK Limited, Ridings Point,  
Whistler Drive, Castleford, WF10 5HX,  
United Kingdom.

Company responsible for  
manufacture: Merckle GmbH  
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