<MOXONIDINE 0.2, 0.3, 0.4 MG TABLETS name to be completed nationally>

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

IN THIS LEAFLET:

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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. BEFORE YOU TAKE MOXONIDINE

Do NOT take Moxonidine if you:
- are allergic (hypersensitive) to moxonidine or any of the other ingredients of this medicine
- 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 "2nd or 3rd degree AV-block"
- have, or have had, heart failure or other heart problems

Take special care with Moxonidine
Tell your doctor before you start to take this medicine if you:
- have a heart problem called "1st degree AV-block"
- have a severe coronary heart disease, or have angina (chest pain at rest)
- have poor circulation
- have kidney disease
- have been told you have cerebrovascular insufficiency (poor blood supply to the brain which means you are at a greater risk of stroke)
- are below 16 years of age
- have a rare hereditary problem of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption as you should not take this medicine .

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Taking other medicines

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Moxonidine with food and drink
Do not drink alcohol whilst taking Moxonidine.

Pregnancy and breast-feeding
Moxonidine is not recommended if you are pregnant, planning on becoming pregnant or are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines
Moxonidine may cause dizziness or drowsiness, if affected do not drive or operate machinery.

Important information about some of the ingredients of Moxonidine
Patients who are intolerant to **lactose** should note that Moxonidine tablets contain a small amount of 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 Moxonidine exactly as your doctor 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 usual dose is:
Adults (including the elderly):
Your treatment will normally start with one 200 microgram tablet, 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 one 200 microgram tablet as a single dose or more than 400 micrograms in total, a day.

Children under 16 yeas of age
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, 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Moxonidine 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 (affecting more than one person in 10):

- dry mouth
- drowsiness

Common (affecting fewer than one person in 10 but more than one person in 100):

- 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 (affecting fewer than one person in 100 but more than one person in 1,000):

- 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.

If any of the side effects get 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 store above 30°C. Keep blister in the outer carton in order to protect from light. Do not use Moxonidine after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month. 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 tablets contain:

- The active ingredient is moxonidine 200, 300 or 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 tablets look like and contents of the pack:

- The 200 microgram tablets are light pink, round, film-coated tablets.
- 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
<to be completed nationally>

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

Belgium	Moxonidine TEVA 0,2, 03, 04 mg filmomhulde tabletten
Netherlands	Moxinidine 0,2, 0,3, 0,4 PCH, filmomhulde tabletten
United Kingdom	Moxonidine 200, 300, 400 microgram tablets

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APPROVALS

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Nicola Prentice	Regulatory Affairs Approval	03-Jul-2012 11:06:52 AM