Package leaflet: Information for the user

Moxamar 0,2 mg, filmomhulde tabletten
Moxamar 0,3 mg, filmomhulde tabletten
Moxamar 0,4 mg, filmomhulde tabletten

Active substance: moxonidine

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 /.../ is and what it is used for

/.../ is a centrally acting agent used to lower high blood pressure.

/.../ is used
- in the treatment of high blood pressure (primary or essential hypertension).

2. What you need to know before you take /.../

Do not take /.../
- if you are allergic to moxonidine or any of the other ingredients of this medicine (listed in section 6).
- if you have sick sinus syndrome (a kind of heart rhythm disorder) or sinoatrial block (a disturbance in the conduction [flow] of electrical impulses through the heart as they pass between the sinus node and the heart's upper chamber)
- if your heart rate is extremely slow (below 50 beats per minute at rest)
- if you have second or third-degree AV block (severe disturbances in the conduction [flow] of electrical impulses passing from the upper to the lower chambers of the heart)
- if you suffer from heart muscle weakness

Warnings and precautions

Talk to your doctor or pharmacist before taking /…/, if:
- you have first-degree AV block (moderate disturbances in the conduction [flow] of electrical impulses passing from the upper to the lower chambers of the heart).
- you are also being treated with a beta-blocker. In this case, when discontinuing treatment, the beta-blocker must be stopped first and then /.../ after a few days.

- you have a kidney dysfunction. In this case, the antihypertensive (blood pressure-lowering) effect of /.../ should be closely monitored, particularly at the start of treatment. Furthermore, caution should be exercised when adjusting the dose.

There is limited experience on the use of /.../ by patients who have a heart complaint (for example severe coronary artery disease or chest pain).

You should not suddenly stop taking /.../. The treatment should be stopped gradually over a period of two weeks (see also 3. "How to take /.../").

Children and adolescents

/.../ should not be used in children and adolescents below the age of 16, as there is insufficient experience with the use of /.../ in this age group.

Elderly

Your doctor should exercise caution when adjusting the dose.

Other medicines and /…/

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines. This is especially important if you are taking any of the following medicines:

Other antihypertensive agents (medicines used to lower the blood pressure)
The antihypertensive (blood pressure-lowering) effect can be increased.

Sleeping pills and tranquilisers
The effect of these drugs can be increased.

Benzodiazepines (certain type of sleeping pill/ tranquiliser)
The effect of these drugs can be increased.

So-called tricyclic antidepressants used to treat depression
The concomitant use with /.../ *tablets* should be avoided. The effect of these drugs can be increased.

/.../ with alcohol

Avoid the use of /.../ tablets with alcohol.

Pregnancy and breast-feeding

As there are insufficient data on the use of moxonidine in pregnant women, /.../ may only be used during pregnancy after the doctor has carefully considered the benefits and risks.

As moxonidine (the active substance) passes into breast milk, /.../ should not be given during breast-feeding.

Driving and using machines

To date, no studies on the effects on the ability to drive and use machines have been performed. However, sleepiness and dizziness have been reported. You should bear this in mind when performing such activities.

/…/ contains lactose.

Therefore, do not take this medicine until you have spoken to your doctor first, if you are known to have an intolerance to certain sugars.

3. How to take /.../

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

The recommended dose is

Moxonidine 0.2 mg film-coated tablets

Adults and elderly patients

Start of treatment:
1 film-coated tablet in the morning (equivalent to 0.2 mg moxonidine/day).

If the response is still unsatisfactory after 3 weeks:
2 film-coated tablets a day (either 2 film-coated tablets in the morning, or a divided dose of 1 film-coated tablet in the morning and 1 film-coated tablet in the evening) (equivalent to 0.4 mg moxonidine/day).

If the response is still unsatisfactory after a further 3 weeks:
0.3 mg moxonidine twice daily (equivalent to 0.6 mg moxonidine/day).
For this, there are more suitable dosage strengths available.

Maximum doses:
Maximum single dose: 0.4 mg moxonidine
Maximum total daily dose: 0.6 mg moxonidine

Patients with impaired kidney function
Moderate renal impairment (GFR more than 30 ml/min but less than 60 ml/min):
Maximum single dose: 0.2 mg moxonidine
Maximum total daily dose: 0.4 mg moxonidine

Severe renal impairment (GFR less than 30 ml/min):
Maximum single dose: 0.2 mg moxonidine
Maximum total daily dose: 0.3 mg moxonidine

Moxonidine 0.3 mg film-coated tablets

Adults and elderly patients:

Start of treatment:
0.2 mg moxonidine in the morning.
For this, there are more suitable dosage strengths available.

If the response is still unsatisfactory after 3 weeks:
0.4 mg moxonidine/day, either as a single dose or divided into two doses (morning and evening).
For this, there are more suitable dosage strengths available.

If the response is still unsatisfactory after a further 3 weeks:
1 film-coated tablet in the morning and 1 film-coated tablet in the evening (equivalent to 0.6 mg moxonidine/day).

Maximum doses:
Maximum single dose: 0.4 mg moxonidine
Maximum total daily dose: 0.6 mg moxonidine

Patients with impaired kidney function
Moderate renal impairment (GFR more than 30 ml/min but less than 60 ml/min):
Maximum single dose: 0.2 mg moxonidine
Maximum total daily dose: 0.4 mg moxonidine

Severe renal impairment (GFR less than 30 ml/min):
Maximum single dose: 0.2 mg moxonidine
Maximum total daily dose: 0.3 mg moxonidine

Moxonidine 0.4 mg film-coated tablets

Adults and elderly patients:

Start of treatment:
0.2 mg moxonidine in the morning.
For this, there are more suitable dosage strengths available.

If the response is still unsatisfactory after 3 weeks:
1 film-coated tablet in the morning (equivalent to 0.4 mg moxonidine/day).

If the response is still unsatisfactory after a further 3 weeks:
0.3 mg moxonidine twice daily (equivalent to 0.6 mg moxonidine/day).
For this, there are more suitable dosage strengths available.

Maximum doses:
Maximum single dose: 0.4 mg moxonidine
Maximum total daily dose: 0.6 mg moxonidine

Patients with impaired kidney function
Moderate renal impairment (GFR more than 30 ml/min but less than 60 ml/min):
Maximum single dose: 0.2 mg moxonidine
Maximum total daily dose: 0.4 mg moxonidine

Severe renal impairment (GFR less than 30 ml/min):
Maximum single dose: 0.2 mg moxonidine
Maximum total daily dose: 0.3 mg moxonidine

Method of administration
Take /.../ before, during or after a meal with sufficient liquid (e.g. a glass of water).

If you have the impression that the effect of /.../ is too strong or too weak, talk to your doctor or pharmacist.

If you take more /.../ than you should

Signs of overdosage in small children may include:
Sedation, coma, hypotension (fall in blood pressure), constricted pupils, shortness of breath.

Signs of overdosage in adults may include:
Headache, Sedation, sleepiness, hypotension (fall in blood pressure), dizziness, feeling of weakness, abnormally slow heart rate, dry mouth, vomiting, tiredness and upper abdominal pain. In case of a severe overdose close monitoring of especially consciousness disturbances and difficulty in breathing is recommended.
You should tell your doctor if you experience any of these symptoms. He/she can then take appropriate action, e.g. measures to stabilise blood circulation.

If you forget to take /.../

Do not take a double dose to make up for a forgotten dose. Continue taking your tablets as you normally would.

If you stop taking /.../

The treatment should not be stopped suddenly.
Do not interrupt or stop treatment with /.../ of your own accord, unless expressly instructed to do so by your doctor.

Treatment with /.../ should be stopped gradually over a period of two 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, this medicine can cause side effects, although not everybody gets them.

The assessment of side effects is based on the following frequency data:

very common:	affects more than 1 user in 10
common:	affects 1 to 10 users in 100
uncommon:	affects 1 to 10 users in 1.000
rare:	affects 1 to 10 users in 10.000
very rare:	affects less than 1 user in 10.000
not known:	frequency cannot be estimated from the available data

There have been common reports of dry mouth, dizziness, feelings of weakness and sleepiness. These symptoms decrease after the first weeks of treatment.

Very Common
dry mouth

Common
difficulty in sleeping, altered thought processes, headache, dizziness, vertigo, sleepiness, diarrhoea, constipation, nausea, vomiting, indigestion, allergic skin reactions including rash and/or itching, back pain, weakness

Uncommon
breast enlargement in males, impotence and loss of sex drive, nervousness, fainting, tingling or numbness in the hands and feet, ringing in the ears, slower heart beat, low blood pressure (including orthostatic hypotension, being dizzy or fainting when standing suddenly caused by low blood pressure), angioedema (serious allergic reaction which causes swelling of the face or throat), neck pain, swelling of the tissue due to an accumulation of excess fluid (oedema).

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store /.../
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 strip and outer carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C.
Store in the original container in order to protect from light.

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 /.../contains

The active substance is moxonidine.

Moxonidine 0.2 mg film-coated tablets
1 film-coated tablet contains 0.2 mg moxonidine.

Moxonidine 0.3 mg film-coated tablets
1 film-coated tablet contains 0.3 mg moxonidine.

Moxonidine 0.4 mg film-coated tablets
1 film-coated tablet contains 0.4 mg moxonidine.

The other ingredients are:
Tablet core
Lactose monohydrate, crospovidone, povidone K 25, magnesium stearate (Ph.Eur.)
Tablet coating
Hypromellose, titanium dioxide (E171), macrogol 400, red iron oxide (E172).

What /.../ looks like and contents of the pack

Moxonidine 0.2 mg film-coated tablets
The tablets are round and light pink.

Moxonidine 0.3 mg film-coated tablets
The tablets are round and pink.

Moxonidine 0.4 mg film-coated tablets
The tablets are round and dark pink.

/.../ is available in packs with 10, 20, 28, 30, 50, 98, 100, 400 (20 x 20, 10 x 40 only as hospital pack) film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva Pharma B.V.
Swensweg 5
2031 GA Haarlem
Nederland

Manufacturer
Merckle GmbH
Ludwig-Merckle Strasse 3
89143 Blaubeuren-Weiler
Duitsland

Dit geneesmiddel is geregistreerd onder
Moxamar 0,2 mg, filmomhulde tabletten RVG 29252
Moxamar 0,3 mg, filmomhulde tabletten RVG 29253
Moxamar 0,4 mg, filmomhulde tabletten RVG 29254

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

NL/H/399/01-03/R/01

Netherland:	Moxonur 0,2 mg, filmomhulde tabletten
	Moxonur 0,3 mg, filmomhulde tabletten
	Moxonur 0,4 mg, filmomhulde tabletten
Austria:	Moxonidin „ratiopharm“ 0,2 mg Filmtabletten
	Moxonidin „ratiopharm“ 0,4 mg Filmtabletten
Germany:	Moxonidin AbZ 0,2 mg Filmtabletten
	Moxonidin AbZ 0,3 mg Filmtabletten
	Moxonidin AbZ 0,4 mg Filmtabletten

This leaflet was last revised in July 2015