

Physiotens[®]

film-coated tablets

200 micrograms, 300 micrograms and
400 micrograms
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 Physiotens is and what it is used for
2. What you need to know before you take Physiotens
3. How to take Physiotens
4. Possible side effects
5. How to store Physiotens
6. Contents of the pack and other information

1. What Physiotens is and what it is used for

Physiotens contains a medicine called moxonidine. This medicine belongs to a group of medicines called “anti-hypertensives”.

Physiotens is used to treat high blood pressure (hypertension). 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 Physiotens

Do not take Physiotens if:

- you are allergic (hypersensitive) to moxonidine or any of the other ingredients of Physiotens (listed in Section 6)
- you have a slow heart rate caused by a heart problem called “sick sinus syndrome” or “2nd or 3rd degree AV-block”
- you have heart failure.
- you have serious kidney problems

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Physiotens if:

- you have a heart problem called “1st degree AV-block”
- you have a severe heart problem such as angina or chest pain at rest
- you have kidney problems. Your doctor may need to adjust your dose.

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

Other medicines and Physiotens

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

without a prescription, including herbal medicines. This is because Physiotens can affect the way some other medicines work. Also some other medicines can affect the way Physiotens works.

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

- other medicines to lower your blood pressure. Physiotens may increase the effect of these medicines
- medicines for depression such as imipramine or amitriptyline
- tranquillisers, sedatives or sleeping tablets such as benzodiazepines
- beta-blockers (see “If you stop taking Physiotens” in Section 3)
- Physiotens 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 Physiotens works.

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

Physiotens with food, drink and alcohol

- You can take the tablets with or without food.
- Do not drink alcohol while you are taking Physiotens. This is because Physiotens may increase the effects of alcohol.

Pregnancy and breast-feeding

- Tell your doctor if you are pregnant or might become pregnant. Your doctor will normally advise you to stop taking Physiotens. Your doctor will advise you to take another medicine instead of Physiotens.
- Tell your doctor if you are breast-feeding or about to start breast-feeding. Physiotens is not recommended for mothers who are breast-feeding. Your doctor may advise you to take another medicine if you want to breast-feed, or may ask you to stop breast-feeding.

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

Driving and using machines

You may feel sleepy or dizzy while taking Physiotens. If this happens, talk to your doctor before driving or using any tools or machines.

Physiotens 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 Physiotens

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

Taking this medicine

- Swallow the tablets whole with a glass of water.
- Try to take your tablets around the same time each day. This will help you remember to take them.

How much to take

The usual starting dose is 200 micrograms a day.

- Your doctor may increase this dose to up to 600 micrograms a day. You should not take more than 400 micrograms as a single dose or more than 600 micrograms in any one day.
- If your doctor has told you to take 600 micrograms a day, this should be split in two (300 micrograms in the morning and 300 micrograms in the evening).
- Your doctor may tell you to take a lower dose if you have kidney problems.

Use in children and adolescents

Physiotens should not be given to children and adolescents under 18 years.

If you take more Physiotens than you should

If you take more Physiotens than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you. The following effects may happen: headache, feeling sleepy (somnolence, sedation), fall in blood pressure (hypotension), slow heart rate (bradycardia), feeling dizzy (vertigo), dry mouth, being sick (vomiting), feeling tired (fatigue), weakness and pain in your stomach (abdominal pain).

If you forget to take Physiotens

- If you forget to take a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Physiotens

- Keep taking your tablets until your doctor decides that you should stop.
- 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Physiotens can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

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

- swelling of the face, lips or mouth (angioedema). This is uncommon, affecting less than 1 in 100 people.

Other side effects include:

Very Common (affects more than 1 in 10 people)

- dry mouth.

Common (affects less than 1 in 10 people)

- back pain
- headache
- weakness (asthenia)
- feeling dizzy (vertigo)
- rash or itching (pruritus)
- difficulty sleeping (insomnia), feeling sleepy (somnolence)
- feeling sick (nausea), diarrhoea, being sick (vomiting), indigestion (dyspepsia).

Uncommon (affects less than 1 in 100 people)

- neck pain
- feeling nervous
- fainting (syncope)
- swelling (oedema)
- ringing or noise in the ears (tinnitus)
- unusually slow heartbeat (bradycardia)
- low blood pressure, including low blood pressure when standing up.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national report systems listed below.

In the UK:

The Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard

In Malta:

ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Physiotens

Keep out of the sight and reach of children. Do not store above 25°C. Do not use Physiotens after the expiry date which is stated on the carton and blister strips. 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. Contents of the pack and other information

What Physiotens contains

- Each tablet contains 200 micrograms, 300 micrograms or 400 micrograms of moxonidine, the active substance.
- The other ingredients are lactose, crospovidone, povidone, magnesium stearate, hypromellose, ethylcellulose, talc, polyethylene glycol 6000, red ferric oxide (E172) and titanium dioxide (E171).

What Physiotens looks like and contents of the pack

The 200 microgram tablets are round, pale pink and are marked 0.2.

The 300 microgram tablets are round, pale red and are marked 0.3.

The 400 microgram tablets are round, dull red and are marked 0.4.

Physiotens tablets come in packs of 14, 28 or 84 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisations for Physiotens are held by:

UK:
Mylan Products Ltd.
20 Station Close
Potters Bar
Herts, EN6 1TL, UK

Malta:
Mylan IRE Healthcare Limited,
Unit 35/36,
Grange Parade,
Baldoye Industrial Estate,
Dublin 13,
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The manufacturer is:
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