

## Package Leaflet: Information for the user

### Physiotens® 200 micrograms Film-Coated Tablets (moxonidine)

Your medicine is available as Physiotens 200 micrograms Film-Coated Tablets, but will be referred to as Physiotens throughout the leaflet.

Other strengths of Physiotens Tablets are also available: 300 micrograms and 400 micrograms.

### 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 "2<sup>nd</sup> or 3<sup>rd</sup> 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 "1<sup>st</sup> 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 monohydrate

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 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 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.
- If your doctor tells you to stop taking this medicine, return any unused tablets to your pharmacist (chemist) for safe disposal. Only keep this medicine if your doctor tells you to.
- If the medicine becomes discoloured or show any signs of deterioration, you should seek the advice of your doctor or pharmacist.
- 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**

- The active substance is moxonidine. Each tablet contains 200 micrograms of moxonidine.
- The other ingredients are lactose monohydrate, povidone, crospovidone, magnesium stearate, hypromellose, ethylcellulose, macrogol 6000, talc, red iron oxide (E172) and titanium dioxide (E171).

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

Physiotens Tablets are pale pink, round, biconvex, film-coated tablets imprinted '0,2' on one face and plain on the reverse.

Your medicine is available in blister packs of 28 tablets.

### **Manufacturer**

Manufactured by: Mylan Laboratories SAS, Route de Belleville, Lieu-dit "Maillard", 01400 Chatillon sur Chalaronne, France.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: Doncaster Pharma Limited, Crompton Road, Doncaster, DN2 4PW, UK.

PL: 56830/0043

POM

Leaflet revision and issue date: 23.08.22

Trademark Owner: BGP Products Operations GmbH.

**Blind or partially sighted?  
Is this leaflet hard to see or read?**

**Call +44 (0) 1302 365000  
(Regulatory)**

**Please be ready to give the following information:**

**Product name:**

**Physiotens 200 micrograms  
Film-Coated Tablets**

**Reference No: 56830/0043**

## Package Leaflet: Information for the user

### Moxonidine 200 micrograms Film-Coated Tablets

Your medicine is available as Moxonidine 200 micrograms Film-Coated Tablets, but will be referred to as Moxonidine Tablets throughout the leaflet.

Other strengths of Moxonidine Tablets are also available: 300 micrograms and 400 micrograms.

#### 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 Tablets are and what these are used for
2. What you need to know before you take Moxonidine Tablets
3. How to take Moxonidine Tablets
4. Possible side effects
5. How to store Moxonidine Tablets
6. Contents of the pack and other information

#### 1. What Moxonidine Tablets are and what these are used for

Moxonidine Tablets contain a medicine called moxonidine. This medicine belongs to a group of medicines called "anti-hypertensives".

Moxonidine Tablets are 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 Moxonidine Tablets

##### Do not take Moxonidine Tablets if:

- you are allergic (hypersensitive) to moxonidine or any of the other ingredients of Moxonidine Tablets (listed in Section 6)

- you have a slow heart rate caused by a heart problem called "sick sinus syndrome" or "2<sup>nd</sup> or 3<sup>rd</sup> degree AV-block"
- you have heart failure
- you have serious kidney problems.

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

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Moxonidine Tablets if:

- you have a heart problem called "1<sup>st</sup> 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 Moxonidine Tablets.

##### Other medicines and Moxonidine Tablets

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 Moxonidine Tablets can affect the way some other medicines work. Also some other medicines can affect the way Moxonidine Tablets work.

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

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

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

##### Moxonidine Tablets 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 Moxonidine Tablets 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 Moxonidine Tablets. Your doctor will advise you to take another medicine instead of Moxonidine Tablets
- Tell your doctor if you are breast-feeding or about to start breast-feeding. Moxonidine Tablets are 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 Moxonidine Tablets. If this happens, talk to your doctor before driving or using any tools or machines.

##### Moxonidine Tablets contains lactose monohydrate

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 Tablets

Always take Moxonidine Tablets 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

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

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

If you take more Moxonidine Tablets 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 (somnia, 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 Moxonidine Tablets**

- 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 Moxonidine Tablets**

- 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, Moxonidine Tablets can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

### **Stop taking Moxonidine Tablets 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 (somnia)
- 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 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 Tablets**

- **Keep out of the sight and reach of children.**
- Do not store above 25°C.
- Do not use Moxonidine Tablets after the expiry date which is stated on the carton and blister strips. The expiry date refers to the last day of that month.
- If your doctor tells you to stop taking this medicine, return any unused tablets to your pharmacist (chemist) for safe disposal. Only keep this medicine if your doctor tells you to.
- If the medicine becomes discoloured or show any signs of deterioration, you should seek the advice of your doctor or pharmacist.
- 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 Moxonidine Tablets contains**

- The active substance is moxonidine. Each tablet contains 200 micrograms of moxonidine.
- The other ingredients are lactose monohydrate, povidone, crospovidone, magnesium stearate, hypromellose, ethylcellulose, macrogol 6000, talc, red iron oxide (E172) and titanium dioxide (E171).

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

Moxonidine Tablets are pale pink, round, biconvex, film-coated tablets imprinted '0,2' on one face and plain on the reverse.

Your medicine is available in blister packs of 28 tablets.

### **Manufacturer**

Manufactured by: Mylan Laboratories SAS, Route de Belleville, Lieu-dit "Maillard", 01400 Chatillon sur Chalaronne, France.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: Doncaster Pharma Limited, Crompton Road, Doncaster, DN2 4PW, UK.

PL: 56830/0043

POM

Leaflet revision and issue date: 23.08.22

Blind or partially sighted?  
Is this leaflet hard to see or read?  
Call +44 (0) 1302 365000  
(Regulatory)

Please be ready to give the following information:  
Product name:  
Moxonidine 200 micrograms  
Film-Coated Tablets  
Reference No: 56830/0043