#### Package leaflet: Information for the user

# Clonidine hydrochloride 50micrograms/5ml Oral Solution

Clonidine hydrochloride

# 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, pharmacists or healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.
- The name of your medicine is Clonidine hydrochloride 50micrograms/5ml Oral Solution, but it will be referred to as 'Clonidine hydrochloride' throughout this leaflet.

#### What is in this leaflet

- 1. What is **Clonidine hydrochloride** and what is it used for
- 2. What you need to know before you take Clonidine hydrochloride
- 3. How to take Clonidine hydrochloride
- 4. Possible side effects
- 5. How to store **Clonidine hydrochloride**
- 6. Contents of the pack and other information

#### 1. What is Clonidine hydrochloride and what is it used for

Clonidine hydrochloride belongs to a group of medicines called vasodilators. Vasodilators widen the blood vessels, and this helps the blood to flow more easily.

Clonidine hydrochloride is used to prevent migraine attacks and similar types of headaches. It is also used to prevent hot flushes that may occur in women during the menopause (change of life).

# 2. What you need to know before you take Clonidine hydrochloride

#### Do not take Clonidine hydrochloride if:

- you are pregnant, likely to get pregnant or are breast-feeding
- you are allergic (hypersensitive) to clonidine or any of the other ingredients listed in section 6
- you have a slow heart rate due to heart problems
- you are already taking other medicines that contain clonidine.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor, pharmacists or healthcare professional before using Clonidine hydrochloride.

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#### Warnings and precautions

# Talk to your doctor, pharmacists or healthcare professional before taking Clonidine hydrochloride.

- you have Raynaud's disease (a problem with circulation to the fingers and toes) or other blood circulation problems, including circulation to the brain
- you have heart or kidney problems
- you have or have ever had depression
- you have constipation
- you have a nerve disorder that causes your hands and feet to feel different ('altered sensation').

If you are not sure if any of the above apply to you, talk to your doctor, pharmacists or healthcare professional before taking Clonidine hydrochloride.

As you may get dry eyes whilst taking this medicine, this may be a problem if you wear contact lenses.

#### Other medicines and Clonidine hydrochloride

Talk to your doctor, pharmacists or healthcare professional if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Clonidine hydrochloride can affect the way some other medicines work. Also some other medicines can affect the way Clonidine hydrochloride works.

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

- other medicines that make you drowsy
- medicines for depression such as imipramine or mirtazapine
- medicines for severe mental illness such as schizophrenia. These are also known as 'antipsychotics' and include chlorpromazine
- beta blockers such as atenolol
- water tablets ('diuretics') such as furosemide
- alpha blockers such as prazosin or doxazosin. These can also be used for prostate problems in men
- vasodilators such as diazoxide or sodium nitroprusside
- cardiac glycosides such as digoxin
- medicines to lower blood pressure.

If you are not sure if any of the above apply to you, talk to your doctor, pharmacists or healthcare professional before taking Clonidine hydrochloride.

#### Clonidine hydrochloride with food, drink and alcohol

You may feel drowsy while taking Clonidine hydrochloride. Drinking alcohol while taking Clonidine hydrochloride can make this worse.

#### Pregnancy and breast-feeding

Do not take Clonidine hydrochloride if you are pregnant, likely to get pregnant or are breast-feeding.

### Driving or using machines

You may feel drowsy, dizzy or could have some disturbances of vision. If affected, you should not drive, operate machinery or take part in any activities where these may put you or others at risk.

#### Clonidine hydrochloride contains:

Methyl hydroxybenzoate (E218) and Propyl hydroxybenzoate (E217), which may cause allergic reactions (possibly delayed).

#### 3. How to take Clonidine hydrochloride

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

#### Taking this medicine

- the usual starting dose is 5ml (50micrograms), two times a day
- if necessary, after two weeks, your doctor may increase the dose to 7.5ml (75micrograms), two times a day.

Clonidine hydrochloride is not recommended for children.

#### Route and method of administration

This medicinal product must be taken orally. Take Clonidine Oral Solution with a glass of water.

Use the measuring syringe provided in the pack to deliver the required dose.

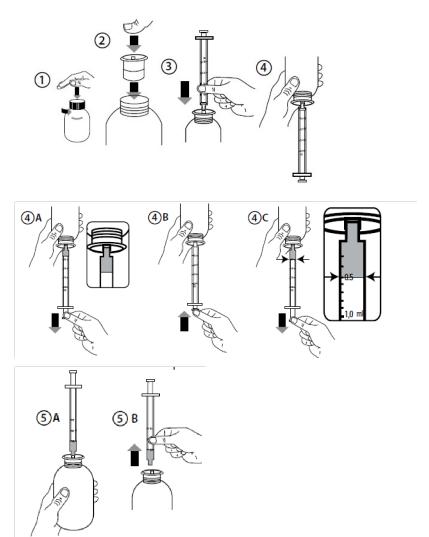
#### Measuring your dose

#### Instructions for use of the syringe

Use the oral syringe supplied in the pack as instructed:

- 1. To open the bottle, press the cap down and turn it anti-clockwise (Figure 1).
- 2. Put the syringe adaptor into the bottle neck (Figure 2).
- 3. Take the syringe and put it into the adaptor opening (Figure 3).
- 4. Turn the bottle upside down (Figure 4).
- 5. Fill the syringe with a small amount of solution by pulling the plunger down (Figure 4A). Then push the plunger upward to remove any possible bubbles (Figure 4B). Finally, pull the plunger down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor. The top flat edge of the piston should be in line with the graduation mark you are measuring to (Figure 4C).
- 6. Turn the bottle the right way up (Figure 5A).

- 7. Remove the syringe from the adaptor (Figure 5B).
- 8. Put the end of the syringe into your mouth and push the plunger slowly back in to take the medicine.
- 9. Wash the syringe with water and let it dry before you use it again.
- 10. Close the bottle with the plastic screw cap leave the syringe adaptor in the bottle.



#### If you take more Clonidine hydrochloride than you should

If you take more Clonidine hydrochloride than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you, even if there is no medicine left. This is so the doctor knows what you have taken.

# If you forget to take Clonidine hydrochloride

If you forget 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 Clonidine hydrochloride

Do not stop taking Clonidine hydrochloride without first talking to your doctor.

If you have any further questions on the use of Clonidine hydrochloride, ask your doctor, pharmacists or healthcare professional.

#### 4. Possible side effects

Like all medicines, Clonidine hydrochloride can cause side effects, although not everybody gets them.

The side effects described below have been experienced by people taking Clonidine hydrochloride. They are listed as either very common, common, uncommon, rare or not known.

# Very common (affects more than 1 in 10 people)

- dizziness, feeling tired and more relaxed than usual (sedation)
- feeling dizzy when you stand up (because your blood pressure has fallen sharply)
- dry mouth.

# Common (affects less than 1 in 10 people, more than 1 in 100 people)

- depression, sleeping problems
- headache
- constipation, feeling sick (nausea), pain below the ear (from the salivary gland), being sick (vomiting)
- erectile dysfunction
- fatigue.

#### Uncommon (affects less than 1 in 100 people, more than 1 in 1,000 people)

- problems with understanding what is happening around you, hallucinations, nightmares
- your hands and feet feeling different ('altered sensation')
- regular unusually slow heart beat
- Raynaud's phenomenon (a problem with circulation to the fingers and toes)
- itching, rash, urticaria (nettle rash)
- a feeling of discomfort and fatigue ('malaise').

#### Rare (affects less than 1 in 1,000 people, more than 1 in 10,000 people)

- breast growth ('gynaecomastia') in men
- dry eyes
- irregular heartbeat
- drying out of the lining of the nose
- pseudo-obstruction of the large bowel, which causes colicky pain, vomiting and constipation. Contact your doctor straight away if you have all these side effects.
- hair loss
- increase in your blood sugar.

#### Not known

- confusion, loss of libido
- blurred vision
- abnormally slow heart beat.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacists or healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website at: 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 Clonidine hydrochloride

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date (month, year) which is stated on the label after "EXP". The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not refrigerate or freeze.
- Do not use the medicine 1 month after it is first opened.

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- 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 Clonidine hydrochloride contains

The active substance is clonidine hydrochloride.

Each 5ml of oral solution contains 50micrograms of clonidine hydrochloride.

The other ingredients are: methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E217), sucralose (E955) and purified water.

#### What Clonidine hydrochloride looks like and contents of the pack

Clonidine hydrochloride is a clear colourless solution, supplied in an amber glass bottle, with a tamper evident, child resistant white plastic cap with a 10ml oral syringe with a syringe adaptor.

Clonidine hydrochloride oral solution is supplied in a bottle containing 100ml oral solution.

#### Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

This leaflet was last approved in October 2025