

Package leaflet: Information for the patient

Clonidine hydrochloride 100 micrograms/ 5 ml Oral Solution

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.

The name of your medicine is Clonidine hydrochloride 100 micrograms/ 5 ml Oral Solution but it will be referred to as 'Clonidine hydrochloride' throughout this leaflet.

What is in this leaflet

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

Clonidine hydrochloride belongs to a group of medicines known as antihypertensives. It is used in adults to reduce blood pressure (to treat hypertension).

You must talk to a doctor if you do not feel better or if you feel worse when taking this medicine.

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

Do not take Clonidine hydrochloride:

- If you are allergic (hypersensitive) to clonidine or any of the other ingredients of this medicine (listed in section 6).
- This medicine should not be used by children and adolescents below 18 years of age
- If you have a slow heart rate due to heart problems
- If 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 or pharmacist before using Clonidine hydrochloride.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Clonidine hydrochloride if:

- 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') or low blood pressure when you stand up.

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

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

Children and adolescents

This medicine should not be used in children or adolescents under 18 years of age.

Other medicines and Clonidine hydrochloride

Tell to your doctor or pharmacist if you are taking or have recently taken or might take 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
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen
- Antidepressants such as imipramine or mirtazapine
- Medicines for severe mental illness such as schizophrenia. These are also known as 'antipsychotics' and include chlorpromazine

Please also tell your doctor or pharmacist if you are taking any of the following medicines for high blood pressure or other heart problems:

- 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
- Calcium antagonists such as verapamil or diltiazem hydrochloride
- ACE inhibitors such as captopril or lisinopril
- Digitalis glycosides such as digoxin
- Any other medicines used to lower blood pressure.

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

Tests

If you are having any blood tests, tell the person giving the test that you are taking this medicine. This is because Clonidine hydrochloride can affect results relating to your liver.

Operations

If you are going to have an operation, keep taking your Clonidine hydrochloride unless your doctor tells you otherwise. If you need to go into hospital, take the bottle of oral solution with you.

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Taking Clonidine hydrochloride is not recommended if you are pregnant or breast-feeding.

Driving and 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 parahydroxybenzoate (E218), which may cause allergic reactions (possibly delayed).
Sodium: This medicine contains less than 1mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

3. How to take Clonidine hydrochloride

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

Taking this medicine

Your doctor will start you on a low dose and gradually increase it. This will depend on how well your medicine works to control your blood pressure.

- The usual starting dose is between 2.5 ml (50 micrograms) and 5 ml (100 micrograms) of oral solution, three times a day
- If necessary, your doctor may increase the dose
- Most people's blood pressure is controlled by taking between 15 ml (300 micrograms) and 60 ml (1200 micrograms) of oral solution daily, in divided doses

Children and adolescents

This medicine is not recommended for use in children and adolescents below 18 years

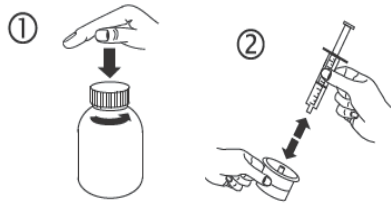
Route and method of administration

This medicine must be taken orally.

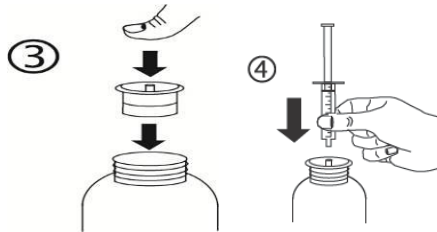
Use the measuring syringe provided in the pack to deliver the required dose.

Instructions for the use of syringe:

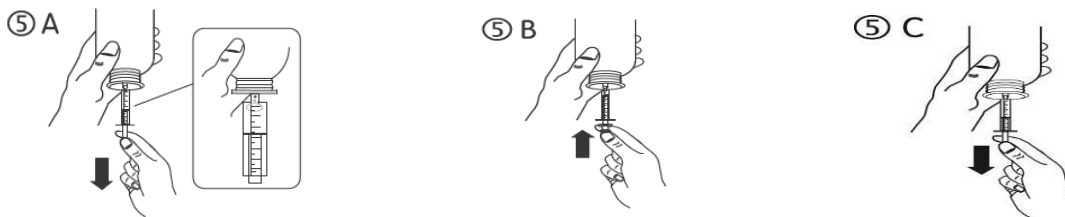
- a) Open the bottle: press the cap and turn it anticlockwise (figure 1). Separate the adaptor from the syringe (figure 2).



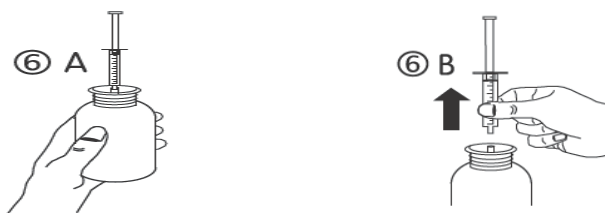
b) Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



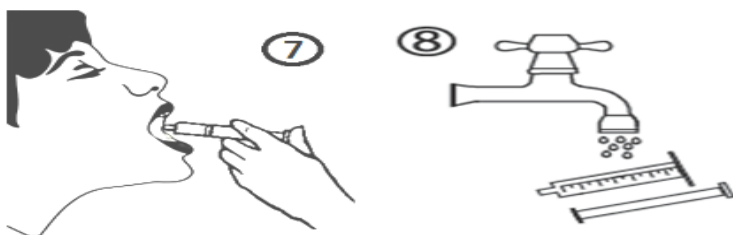
c) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



d) Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



e) Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard. Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).



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 been using this medicine for a long time, you may feel agitated when you stop taking it. This is called a 'withdrawal effect'.

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

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance Website: www.hpra.ie. 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 which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage condition.
- Do not refrigerate or freeze.
- Discard 30 days after first opening.
- Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- 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 contains

The active substance is clonidine hydrochloride.

Each 5 ml of oral solution contains 100 micrograms of clonidine hydrochloride.

The other ingredients are: methyl parahydroxybenzoate (E218), sodium dihydrogen phosphate monohydrate (E339), disodium phosphate (E339), 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 10 ml oral syringe with 0.25 ml graduation mark for measuring and administering the dose and a syringe adaptor.

Clonidine hydrochloride is supplied in a bottle containing 150 ml oral solution.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

Syri Pharma Limited t/a Thame Laboratories
Floor 0, 1 WML,
1 Windmill Lane
Dublin 2, D02 F206, Ireland

Manufacturer:

Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park,
Paola PLA 3000, Malta

This medicine is authorised in the Member States of the European Economic Area under the following name:

IE: Clonidine hydrochloride 100 mcg/ 5 ml Oral Solution

MT: Clonidine hydrochloride 100 mcg/ 5 ml Oral Solution

If this leaflet is hard to see or read, please call +353 1437 0882 for help.

This leaflet was last revised in 07/2025