

Package leaflet: Information for the user

**Clonidine Hydrochloride
50 micrograms/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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Clonidine Hydrochloride 50 micrograms/5ml 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

Other medicines and Clonidine hydrochloride

Tell your doctor or pharmacist 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 nitropruside
 - 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 or pharmacist 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 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 oral solution contains benzoic acid (E210)

This medicine contains 3mg benzoic acid in each 5ml oral solution. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take Clonidine hydrochloride

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

Taking this medicine

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

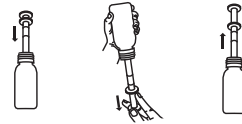
Clonidine hydrochloride is not recommended for children.

Route and method of administration

This medicinal product must be taken orally. Use the measuring syringe provided in the pack to deliver the required dose.

Using the dosing syringe

- When you use the medicine for the first time, place the adaptor in the neck of the bottle.
- Push the syringe firmly into the adaptor in the neck of the bottle.
- To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark on the syringe. Your doctor will tell you the right dose for you.
- Turn the bottle the right way up, remove the syringe from the adaptor by gently twisting the syringe.



- Place the end of the syringe into the mouth and gently press the plunger down to slowly and gently release the medicine.
- After use replace the bottle cap. Wash the syringe in warm water and allow to dry. Store out of reach of children.

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 this medicine, 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 heartbeat
- 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 heartbeat.

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 Yellow Card Scheme Website: 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 which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

Do not use your medicine if you notice that the container is damaged.

This medicine does not require any special storage conditions.

After first opening use within 30 days.

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 contains 50 micrograms of clonidine hydrochloride. The other ingredients are: benzoic acid (E 210), glycerol (E 422), xylitol (E 967), peppermint flavour, orthophosphoric acid (E 338) (to adjust pH) and purified water.

What Clonidine hydrochloride oral solution looks like and contents of the pack

This medicine is a clear colourless oral solution.

This medicine is available in 100ml amber glass bottles, sealed with a child-resistant, tamper-evident screw cap.

It comes with a syringe adaptor and a 10ml syringe with 0.5ml graduations.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This leaflet was last revised in May 2024

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