



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 50micrograms/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

1. What Clonidine hydrochloride is and what it is 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 headache. 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 or pharmacist before using Clonidine hydrochloride.

Warning and precaution

Check with your doctor or pharmacist 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').

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.

Other medicines and Clonidine hydrochloride

Tell to 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 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 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 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 parahydroxybenzoate (E218), which may cause allergic reactions (possibly delayed).

3. How to take Clonidine hydrochloride

Always take Clonidine hydrochloride exactly as your doctor 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 (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. Use the measuring syringe provided in the pack to deliver the required dose.

Instructions for the use of syringe:

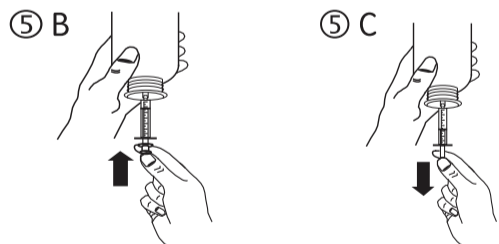
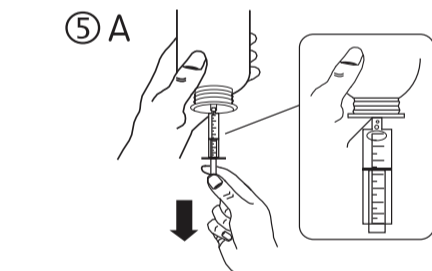
- a) Open the bottle: press the cap and turn it anticlockwise (figure 1). Separate the adaptor from the syringe (figure 2).



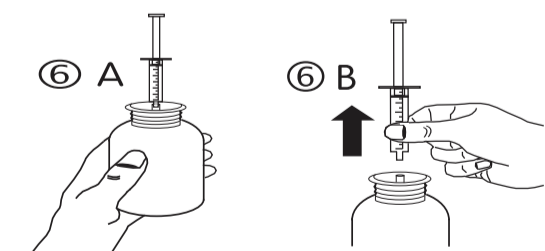
- b) Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



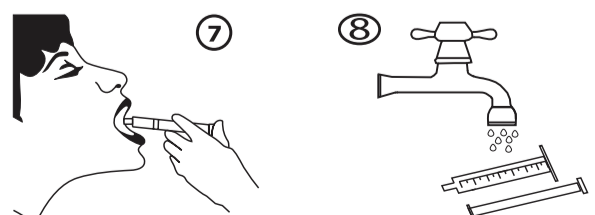
- c) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed 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). 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 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 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 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 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 to 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 parahydroxybenzoate (E218), sodium dihydrogen phosphate monohydrate, disodium hydrogen phosphate anhydrous, 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 0.5ml graduation mark for measuring and administering the dose and a syringe adaptor.

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

POM**Marketing Authorisation Holder:**

SyriMed,
Unit 4, Bradfield Road,
Ruislip, Middlesex,
HA4 0NU, UK

Manufacturer:

Galenica Pharmaceutical Industry S.A.
Asklipiou 4-6, Kryoneri, Attiki,
14568, Greece

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

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SyriMed

