

Package leaflet: Information for the user

Catapres® Tablets 100 micrograms (clonidine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What CATAPRES Tablets are and what they are used for
2. Before you take CATAPRES Tablets
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1. WHAT CATAPRES TABLETS ARE AND WHAT THEY ARE USED FOR

CATAPRES Tablets contain a medicine called clonidine. This belongs to a group of medicines called antihypertensives.

CATAPRES is used to lower high blood pressure (to treat hypertension).

2. BEFORE YOU TAKE CATAPRES TABLETS

Do not take CATAPRES if:

- You are pregnant, likely to get pregnant or are breast-feeding
- You are allergic (hypersensitive) to clonidine or any of the other ingredients of CATAPRES (see section 6: Further information)
- You have a slow heart rate due to heart problems

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 CATAPRES.

Take special care with CATAPRES

Check with your doctor or pharmacist before taking CATAPRES 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 CATAPRES.

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

Taking other medicines

Please 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 CATAPRES can affect the way some other medicines work. Also some other medicines can affect the way CATAPRES 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
- 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

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 frusemide
- 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

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

Tests

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

Operations

If you are going to have an operation, keep taking your CATAPRES Tablets. If you need to go into hospital, take the tablets with you.

Taking CATAPRES with food and drink

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

Pregnancy and breast-feeding

Do not take CATAPRES 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.

Important information about some of the ingredients of CATAPRES

CATAPRES contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE CATAPRES TABLETS

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

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.

Taking this medicine

- Take this medicine by mouth
- The usual starting dose is between 50 micrograms and 100 micrograms, three times a day
- If necessary, your doctor will gradually increase the dose
- Most people's blood pressure is controlled by taking between 300 micrograms and 1200 micrograms

CATAPRES is not recommended for children.

If you take more CATAPRES than you should

If you take more CATAPRES than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you, even if there are no tablets left.

If you forget to take CATAPRES

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 CATAPRES

Do not stop taking CATAPRES 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 CATAPRES, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

The side effects described below have been experienced by people taking CATAPRES. 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

Two cases of hepatitis (inflammation of the liver) have also been reported. This might show up in some blood tests. Your body may hold onto more water than usual (fluid retention).

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

5. HOW TO STORE CATAPRES TABLETS

Keep out of sight and reach of children.

The tablets should not be stored above 30°C and the blister strips should be kept in the outer carton.

Do not use CATAPRES after the expiry date which is stated on the packaging.

The expiry date refers to the last day of that month.

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 protect the environment.

6. FURTHER INFORMATION

What CATAPRES contains

- The active substance is clonidine hydrochloride. Each tablet contains 100 micrograms.
- The other ingredients are: lactose monohydrate, calcium hydrogen phosphate (anhydrous), maize starch, colloidal silica (anhydrous), povidone, modified starch (corn starch, oxidized) and stearic acid.

What CATAPRES looks like and contents of the pack

- CATAPRES 100 microgram tablets are white, round and flat with a bevelled edge. On one side, they have the code 01C written on both sides of the breakline.

CATAPRES tablets are available in blister packs of 100 tablets.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisations for CATAPRES are held by:

In the United Kingdom:

Glenwood GmbH
Pharmazeutische Erzeugnisse
Arabellastr. 17
81925 Munich
Germany

In Ireland:

Glenwood GmbH
Pharmazeutische Erzeugnisse
Arabellastr. 17
81925 Munich
Germany

and the tablets are manufactured at:
Delpharm Reims S.A.S., 10 Rue Colonel
Charbonneaux, 51100 Reims, France

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