

Package Leaflet: Information for the user

Catapres® Ampoules 150 micrograms in 1 ml Solution for Injection (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 Ampoules are and what they are used for
2. Before you receive CATAPRES Ampoules
3. How CATAPRES Ampoules will be given
4. Possible side effects
5. How to store CATAPRES Ampoules
6. Further information

1. WHAT CATAPRES AMPOULES ARE AND WHAT THEY ARE USED FOR

The name of your medicine is CATAPRES Ampoules 150 micrograms in 1 ml Solution for Injection (called CATAPRES Ampoules in this leaflet). Your medicine is a solution for injection.

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

CATAPRES is used to lower high blood pressure in cases of hypertensive crisis (a rapid rise in blood pressure that needs treating straight away).

2. BEFORE YOU RECEIVE CATAPRES AMPOULES

You should not be given CATAPRES Ampoules 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
- You are under 18 years old

You should not receive this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before having CATAPRES Ampoules.

Take special care with CATAPRES Ampoules

Check with your doctor or pharmacist before having 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')

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

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 obtained without a prescription and herbal medicines. This is because CATAPRES Ampoules can affect the way some other medicines work. Also some other medicines can affect the way CATAPRES Ampoules 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 and haloperidol

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 receiving CATAPRES Ampoules.

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, you will need to still receive CATAPRES Ampoules.

Having CATAPRES Ampoules with food and drink

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

Pregnancy and breast-feeding

You should not be given CATAPRES Ampoules 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.

Important information about some of the ingredients of CATAPRES Ampoules

CATAPRES Ampoules contain sodium chloride, the sodium content per 1 ml ampoule is less than 1 mmol (23 mg). The total sodium content if you are given 5 ampoules in 24 hours is less than 1 mmol (23 mg). This means that CATAPRES Ampoules are essentially sodium free.

3. HOW CATAPRES AMPOULES WILL BE GIVEN

CATAPRES Ampoules are usually given by a doctor or nurse. You will normally be given 1 to 2 CATAPRES Ampoules but over 24 hours up to 5 ampoules may be given.

Your doctor will start you on a low dose but may increase the dose if you need more medicine to control your blood pressure.

Receiving the injection

- CATAPRES Ampoules are slowly injected into a vein over 10-15 minutes
- CATAPRES Ampoules may be diluted with other solutions if needed

CATAPRES Ampoules are not recommended for children or adolescents under 18 years old.

If you have more CATAPRES Ampoules than you should

It is unlikely that you will be given too much of this medicine. However, tell the doctor or nurse if you think that you have been given too much.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, CATAPRES Ampoules 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 also 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 AMPOULES

Keep out of the reach and sight of children.

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

CATAPRES Ampoules should not be used after the expiry date which is stated on the ampoule label and carton. 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 Ampoules contain

- The active substance is clonidine hydrochloride. Each 1 ml ampoule contains 150 micrograms of clonidine hydrochloride
- The other ingredients in the injection are: sodium chloride, water for injections and hydrochloric acid

What CATAPRES Ampoules looks like and contents of the pack

CATAPRES Ampoules are clear glass ampoules containing a clear, colourless solution. CATAPRES Ampoules are supplied in cartons of 5 ampoules.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisations for CATAPRES Ampoules 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 ampoules are manufactured at

Delpharm Dijon
6 Boulevard de l'Europe
21800 Quetigny
France

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