Catapres® Ampoules

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Catapres?

Catapres contains the active ingredient clonidine hydrochloride. Catapres is used to lower high blood pressure, also called hypertension. Catapres works by relaxing and widening blood vessels and so helps to lower your blood pressure.

For more information, see Section <u>1. Why am I using</u> <u>Catapres?</u> in the full CMI.

2. What should I know before I am given Catapres Ampoules?

You should not be given Catapres if you have ever had an allergic reaction to clonidine hydrochloride or any of the ingredients listed at the end of the CMI.

Catapres should not be given to you if you have certain heart problems, such as irregular/slow heartbeat. Talk to your doctor if you have any other medical conditions, take any other medicines, or

are pregnant or plan to become pregnant or are breastfeeding.

This medicine should not be given to a child under the age of 18 years.

For more information, see Section 2. What should I know before I am given Catapres Ampoules? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Catapres and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How am I given Catapres Ampoules?

Your doctor will tell you what dose of Catapres
 Ampoules you will receive. Catapres Ampoules can
 be given as an injection into a muscle or as a slow
 injection into a vein.

More instructions can be found in Section <u>4. How are Catapres Ampoules given?</u> in the full CMI.

5. What should I know while I am being given Catapres Ampoules?

Things you should do

 Remind any doctor, dentist or pharmacist

	you visit that you are using Catapres.
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how Catapres affects you.
Drinking alcohol	 Alcohol may affect how well your medicine works. You may need different amounts of your medicine, or you may need to take different medicines.
Looking after your medicine	 Catapres Ampoules will be stored in the pharmacy or ward below 30°C.

For more information, see Section <u>5. What should I know while I am being given Catapres Ampoule?</u> in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Catapres. The more frequently reported side effects of Catapres are light-headedness when you stand up suddenly, drowsiness, dryness of the mouth, nausea and vomiting.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> effects? in the full CMI.

Catapres® Ampoules

Active ingredient: clonidine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Catapres. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Catapres.

Where to find information in this leaflet:

- 1. Why am I using Catapres Ampoules?
- 2. What should I know before I am given Catapres Ampoules?
- 3. What if I am taking other medicines?
- 4. How are Catapres Ampoules given?
- 5. What should I know while I am being given Catapres Ampoule?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Catapres Ampoules?

Catapres contains the active ingredient clonidine hydrochloride. Catapres works by relaxing and widening blood vessels and so helps to lower your blood pressure.

Catapres is used to lower high blood pressure, also called hypertension.

2. What should I know before I am given Catapres Ampoules?

Warnings

You should not be given Catapres if:

- you are allergic to clonidine hydrochloride, or any of the ingredients listed at the end of this leaflet.
 - Always check the ingredients to make sure you can use this medicine.
- if you have certain heart problems, such as irregular/ slow heartbeat.

Check with your doctor if you:

have or have had any of the following medical conditions:

- heart failure or any heart or circulation problem
- stroke, or transient ischaemic attack (TIA)
- mental depression
- sugar diabetes
- nerve damage, which may lead to weakness in the arms and legs
- constipation
- phaeochromocytoma (a rare tumour of the adrenal gland)

any problems with your kidneys.

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

You should not be given this medicine if you are pregnant.

It may affect your developing baby if you are given it during pregnancy.

Do not breast-feed if you are given this medicine.

The active ingredient in Catapres passes into breast milk and there is a possibility that your baby may be affected.

Children and adolescents

This medicine should not be given to a child under the age of 18 years.

Serious side effects have been observed when clonidine, the active ingredient in Catapres, is used with methylphenidate in children with ADHD. Therefore, Catapres in this combination is not recommended.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Catapres may interfere with each other. These include:

- other medicines for high blood pressure
- medicines for heart problems
- alcohol
- medicines used to control mood swings and some types of depression
- medicines used to relieve pain, swelling or other symptoms of inflammation

These medicines may interfere with Catapres and affect how it works.

You may need different amounts of your medicine, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Catapres.

4. How are Catapres Ampoules given?

How it is given

- Catapres Ampoules can be given as an injection into a muscle or as a slow injection into a vein.
- Catapres Ampoules must only be given by a doctor or nurse in a setting where appropriate equipment is readily available for diagnosis and patient monitoring.
- Catapres Ampoules should only be given to patients in a lying position.
- Your doctor will decide what dose of Catapres Ampoules you will receive.

If you are given too much Catapres

As Catapres Ampoules are given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Symptoms of an overdose may include slow heartbeat, drowsiness, temporarily stopping breathing and coma. Other signs include dizziness, weakness, lethargy, feeling cold, vomiting, looking pale, or having an irregular heartbeat.

You should immediately:

- Tell your doctor or nurse immediately if you experience any signs of overdose, or
- if you are not in hospital, go to the Emergency Department at your nearest hospital.
- phone the Poisons Information Centre

(in Australia by calling 13 11 26; in New Zealand by calling 0800 764 766)

You may need urgent medical attention.

5. What should I know while I am being given Catapres Ampoule?

Things you should do

Tell any other doctors, dentists, and pharmacists who treat you that you have been given Catapres.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Catapres affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may affect how well your medicine works. You may need different amounts of your medicine, or you may need to take different medicines.

Looking after your medicine

Catapres Ampoules will be stored in the pharmacy or ward below 30°C. Each ampoule can only be used once and unused contents of opened ampoules must be discarded.

When to discard your medicine

Catapres must not be used after the expiry date printed on the pack or ampoule or if the packaging is torn or shows signs of tampering.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

More frequently reported side effects

Side effects	What to do
 light-headedness when you stand up suddenly drowsiness dryness of the mouth nausea and vomiting 	Speak to your doctor if you have any of these side effects and they worry you.

Less frequently reported side effects

Side effects	What to do
 blurred vision dizziness confusion headache sleep disturbances mental depression irrational or abnormal thoughts irritability decreased sexual drive / impotence generally feeling unwell thinning of hair rash / hives / itching constipation dryness of the nose and eyes pain in the salivary glands tingling or numbness of the hands or feet larger breasts than normal, in men slow or irregular heartbeat 	Speak to your doctor if you have any of these side effects and they worry you.

Side effects	What to do
 blood glucose increased. 	
 occasional reports of abnormal liver function tests and cases of hepatitis have also been reported. 	

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Catapres Ampoules.

Tell your doctor or nurse if you notice anything unusual, during or after treatment with Catapres Ampoules.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Catapres Ampoule contains

Active ingredient (main ingredient)	Clonidine hydrochloride 150 micrograms in 1 mL of solution.
Other ingredients (inactive ingredients)	Sodium chloride, hydrochloric acid and water for injections.
Potential allergens	-

Do not take this medicine if you are allergic to any of these ingredients.

What Catapres Ampoule looks like

Catapres is the brand name of your medicine.

Catapres Ampoule is a clear, colourless solution. It comes in a glass ampoule. (AUST R 17919).

Who distributes Catapres Ampoule

Clinect Pty Ltd

120-132 Atlantic Drive

Keysborough, VIC 3173

Australia

Telephone: 1800 899 005

Catapres Ampoule are supplied in New Zealand by:

Clinect NZ Pty Limited

C/- Ebos Group Limited

108 Wrights Road

Christchurch 8024

New Zealand

Telephone: 0800 138 803

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