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 is also used to prevent migraine headache and to relieve symptoms of menopausal flushing.

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 use Catapres?

Do not use if you have ever had an allergic reaction to clonidine hydrochloride or any of the ingredients listed at the end of the CMI.

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.

For more information, see Section <u>2. What should I know</u> <u>before I use Catapres?</u> 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 <u>3. What if I am</u> <u>taking other medicines?</u> in the full CMI.

4. How do I use Catapres?

- Your doctor will tell you how much of your medicine you need to take every day. This depends on your condition and whether you are taking other medicines.
- Swallow the tablets with a full glass of water.

More instructions can be found in Section <u>4. How do I</u> <u>use Catapres?</u> in the full CMI.

5. What should I know while using Catapres?

Things you should do	 Remind any doctor,
	dentist or pharmacist

	 you visit that you are using Catapres. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Catapres. It may affect other medicines used during surgery. If you become pregnant while taking Catapres, tell your doctor immediately.
Things you should not do	 Do not stop taking your medicine or lower the dosage without checking with your doctor. Do not take Catapres to treat any other complaints unless your doctor tells you to.
Driving or using machines	 Be careful driving or operating machinery until you know how Catapres affects you. Catapres, like other medicines used to treat high blood pressure, may cause dizziness or drowsiness in some people.

Looking after your medicine• Keep your tablets in t blister strip until it is t	
 to take them. Keep your tablets in a cool dry place where temperature stays be 30°C. 	ime a the

For more information, see Section <u>5. What should I know</u> while using Catapres? 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 lightheadedness 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> <u>effects?</u> in the full CMI.

Catapres[®] 100

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?
- 2. What should I know before I use Catapres?
- 3. What if I am taking other medicines?
- 4. How do I use Catapres?
- 5. What should I know while using Catapres?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Catapres?

Catapres contains the active ingredient clonidine hydrochloride. Catapres lowers high blood pressure, also called hypertension. 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.

Catapres is also used to prevent migraine headache and to relieve symptoms of menopausal flushing.

2. What should I know before I use Catapres?

Warnings

Do not use 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 the rare hereditary condition of galactose intolerance.
- 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. Are there any side effects</u>?

Pregnancy and breastfeeding

Do not take Catapres if you are pregnant.

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

Do not breast-feed if you are taking 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

Do not give Catapres 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 do I use Catapres?

How much to take

- Your doctor will tell you how much of your medicine you need to take every day. This depends on your condition and whether you are taking other medicines.
- The usual starting dose for high blood pressure is 50 micrograms (half a tablet), two or three times a day. Your doctor may increase the daily dosage by half-tablet increments, depending on how your blood pressure responds.
- For migraine and menopausal flushing the usual starting dose is 25 micrograms two times a day. Your doctor may increase this to 50 micrograms two times a day. If necessary, your doctor may increase this to a total daily dose of 150 micrograms.
- Swallow the tablets with a full glass of water.
- Follow the instructions provided and use Catapres until your doctor tells you to stop.

When to take Catapres

- Catapres should be taken at about the same time each day.
- Continue taking Catapres for as long as your doctor tells you.
- Catapres helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

- If your doctor tells you to stop taking Catapres, you should reduce the dose of medicine gradually over a period of a week or more.
- This is to avoid a sudden increase in your blood pressure.

If you forget to use Catapres

Catapres should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

- If you are not sure what to do, ask your doctor or pharmacist.
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much Catapres

If you think that you have used too much Catapres, you may need urgent medical attention. Signs of 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:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Catapres?

Things you should do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Catapres.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Catapres.

It may affect other medicines used during surgery.

Have your blood pressure checked as instructed by your doctor, to make sure Catapres is working.

Tell your doctor if, for any reason, you have not taken Catapres exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Call your doctor straight away if you:

 If you become pregnant while taking Catapres
 Remind any doctor, dentist or pharmacist you visit that you are using Catapres.

Things you should not do

- Do not stop taking your medicine or lower the dosage without checking with your doctor.
- Do not take Catapres to treat any other complaints unless your doctor tells you to.
- Do not give Catapres to anyone else, even if they have the same condition as you.

Driving or using machines

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

Catapres, like other medicines used to treat high blood pressure, may cause dizziness or drowsiness in some people. Make sure you know how you react to Catapres before you drive or operate machinery.

If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.

You may feel light-headed or dizzy when you begin to take Catapres or if the dose is increased. This is because your blood pressure is falling suddenly. Standing up slowly will help your body get used to the change in position and blood pressure. The problem usually goes away after the first few days.

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

- Keep your tablets in the blister strip until it is time to take them.
 - The blister strip protects the tablets. If you take the tablets out of the blister strip they may not keep well.
- Keep your tablets in a cool dry place where the temperature stays below 30°C.
- Heat and dampness can destroy some medicines.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines

Keep it where young children cannot reach it.

When to discard your medicine

Do not take Catapres after the expiry date printed on the carton or blister strips or if the packaging is torn or shows signs of tampering.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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 pharmacist if you notice anything else that may be making you feel unwell.

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 <u>www.tga.gov.au/reporting-problems</u>. 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 100 contains

Active ingredient (main ingredient)	Clonidine hydrochloride 100 micrograms.
Other ingredients (inactive ingredients)	Maize starch, colloidal anhydrous silica, povidone, stearic acid, calcium hydrogen phosphate and lactose monohydrate
Potential allergens	Lactose monohydrate

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

What Catapres looks like

Catapres is the brand name of your medicine.

Catapres 100 tablets are white, round, flat tablets with bevelled edges, one side marked with "01C / break line / 01C".

Catapres 100 tablets are available in blister packs of 10* and 100 tablets.

* not currently distributed in Australia. (AUST R 17921).

Who distributes Catapres 100 tablets

Clinect Pty Ltd

Catapres® 100

120-132 Atlantic Drive Keysborough, VIC 3173 Australia Telephone: 1800 899 005

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