APO-CLONIDINE

Contains the active ingredient clonidine hydrochloride

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about APO-CLONIDINE

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking APO-CLONIDINE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

Keep this leaflet with your medicine.

You may need to read it again.

pressure may be different at different times of the day. You have hypertension when your blood pressure stays higher than normal, even when you are calm or relaxed.

There are usually no signs of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. You may feel fine and have no symptoms, but if high blood pressure is not treated, it can lead to serious health problems (such as heart disease).

APO-CLONIDINE works by relaxing and widening blood vessels and so helps to lower your blood pressure.

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

Ask your doctor if you have any questions about why APO-CLONIDINE has been prescribed for you.

Your doctor may have prescribed APO-CLONIDINE for another reason.

What this medicine is used for

APO-CLONIDINE lowers high blood pressure, also called hypertension.

Everyone has blood pressure. This pressure helps your blood move around your body. Your blood

Before you take this medicine

When you must not take it

Do not take APO-CLONIDINE if you have an allergy to:

• any medicine containing clonidine

 any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take APO-CLONIDINE if

- you have the rare hereditary condition of galactose intolerance.
- you have certain heart problems, such as irregular/ slow heart beat.
- 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 APO-CLONIDINE passes into breast milk and there is a possibility that your baby may be affected.

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 APO-CLONIDINE, is used with methylphenidate in children with ADHD. Therefore, APO-CLONIDINE in this combination is not recommended.

Do not take APO-CLONIDINE after the expiry date printed on the

APO-CLONIDINE TABLETS

carton or blister strips or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell 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.

If you have not told your doctor about any of the above, tell him/her before you start taking APO-CLONIDINE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy,

supermarket or health food shop.

Some medicines and APO-CLONIDINE 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 be affected by APO-CLONIDINE, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given this medicine.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

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.

How to take it

Swallow the tablets with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it for

Continue taking APO-CLONIDINE for as long as your doctor tells you.

APO-CLONIDINE 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 APO-CLONIDINE, 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.

Ask your doctor or pharmacist if you have any concerns.

If you forget to take it

It is important to take APO-CLONIDINE as directed.

If you miss a dose, take it as soon as you remember. However, if you remember when it is almost time for your next dose, take only your usual dose at that time.

Do not take a double dose to make up for the dose that 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 take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Emergency at your nearest hospital, if you have taken more than the recommended or prescribed dose of APO-CLONIDINE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking this medicine

Things you must do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking APO-CLONIDINE.

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

It may affect other medicines used during surgery.

If you become pregnant while taking APO-CLONIDINE, tell your doctor immediately.

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

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

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

Things you must not do

Do not take APO-CLONIDINE to treat any other complaints unless your doctor tells you to. Do not give APO-CLONIDINE to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how APO-CLONIDINE affects you.

APO-CLONIDINE, 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 APO-CLONIDINE 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 APO-CLONIDINE 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.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APO-CLONIDINE.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

The more frequently reported side effects of APO-CLONIDINE are lightheadedness when you stand up suddenly, drowsiness, dryness of the mouth, nausea and vomiting.

Less frequently reported side effects of APO-CLONIDINE include the following:

- 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 heart beat
- blood glucose increased.

Occasional reports of abnormal liver function tests and cases of hepatitis have also been reported.

Tell your doctor or pharmacist as soon as possible if you experience any side effects during or after taking APO-CLONIDINE, so that these may be properly treated.

Other side effects not listed above may also occur in some people.

Tell your doctor or pharmacist if you notice anything unusual, during or after taking APO-CLONIDINE.

Storage and disposal

Storage

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.

APO-CLONIDINE TABLETS

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store APO-CLONIDINE or any other medicine in the bathroom or near a sink. Do not leave it in the car or on the window sill.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What APO-Clonidine tablet looks like

100mcg Apo- Clonidine tablets are scored, pink tablets, marked with YS 01 on one side and a score line on the reverse side.

APO-CLONIDINE tablets are available in bottles of 100 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each APO-CLONIDINE tablet contains 100 micrograms clonidine hydrochloride.

The other ingredients are;

- Allura Red AC hydroxypropylcellulose
- microcrystalline cellulose
- magnesium stearate
- maize starch
- lactose

• calcium hydrogen phosphate colloidal anhydrous silica

Australian Registration Numbers

APO-Clonidine 100mcg tablets (bottle pack): AUST R 265776.

Sponsor

Southern Cross Pharma Pty Ltd 56 Illabunda Drive Malua Bay NSW 2536 Australia

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Distributor

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