

Coras

contains the active ingredient *diltiazem hydrochloride*

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Please read this leaflet carefully.

This leaflet answers some common questions about Coras.

It is not to be used in relation to any other product, which may also contain the same active ingredient.

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 Coras against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Coras is used for

Coras is used to prevent angina.

Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. This may be caused by too little blood and oxygen getting to the heart. The pain of angina is usually brought on by exercise or stress.

Ask your doctor if you have any questions about why Coras has been prescribed for you.

Your doctor may have prescribed Coras for another reason.

Coras contains the active ingredient diltiazem hydrochloride. It belongs to a group of medicines called calcium channel blockers.

These medicines work by widening blood vessels, letting more blood and oxygen reach the heart. They do not change the amount of calcium in your blood or bones.

Coras is not recommended for use in children, as its safety and effectiveness have not been established in children.

Coras is available only with a doctor's prescription.

Before you take Coras

When you must not take it

Do not take Coras if you are allergic to medicines containing diltiazem hydrochloride or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Coras if you have:

- * had a heart attack
- * sick sinus syndrome (unless you have a working pacemaker fitted)
- * second or third degree AV block (unless you have a working pacemaker fitted)

- * severe congestive heart failure
- * low blood pressure, also called hypotension.

Do not take Coras if you are pregnant.

There is very little information on the use of this medicine in pregnant women. However, Coras like other medicines in its group, may cause unwanted effects in the unborn baby. Therefore, the use of Coras is not recommended in pregnant women.

Do not take Coras if you are breastfeeding.

Coras passes into breast milk, however it is not known whether this has harmful effects on the breastfed baby. Therefore, Coras is not recommended in breastfeeding. Your doctor will tell you what to do.

Do not take Coras if the expiry date (EXP) printed on the bottle has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Coras if the packaging shows signs of tampering or the tablets do not look quite right.

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

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you plan to become pregnant or breastfeed.

Coras is not recommended in pregnancy or breastfeeding.

Tell your doctor if you have any medical conditions, especially the following:

- * other heart problems
- * diabetes
- * liver disease
- * kidney disease.

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you plan to have surgery (that requires a general anaesthetic), including dental surgery.

If you have not told your doctor about any of the above, tell them before you start taking Coras.

Taking other medicines

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

Some medicines may be affected by Coras, or may affect how well it works. These include:

- * beta-blockers, medicines used to treat high blood pressure or other heart conditions such as propranolol
- * digoxin, a medicine used to treat heart failure or to control a fast irregular heart beat
- * cimetidine, a medicine used to treat reflux and ulcers
- * diazepam, a medicine used to treat anxiety and some other conditions
- * amiodarone, a medicine used to control irregular heart beats
- * other medicines used to prevent angina
- * cyclosporin, a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system
- * statins, medicines used to lower high blood cholesterol and triglyceride levels such as simvastatin.

Your doctor can tell you what to do if you are taking any of these

medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Coras.

How to take Coras

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 on the bottle, ask your doctor or pharmacist for help.

How much to take

The dose varies from person to person.

The usual starting dose is 30 mg four times a day. Your doctor may increase this dose depending on how you respond to this medicine. The maximum recommended dose is 360 mg per day.

People over 65 years of age may require smaller doses.

How to take Coras

Swallow the tablets with a glass of water.

Coras tablets can be divided in half along the breakline, if your doctor has prescribed half a tablet.

When to take Coras

Take Coras at about the same time each day.

This will allow Coras to have its best effect and help you remember when to take it.

Coras can be taken with or without food.

How long to take Coras for

Keep taking Coras for as long as your doctor recommends.

This medicine helps to control your angina, but does not cure it. It is important to keep taking your medicine every day even if you feel well.

If you forget to take Coras

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

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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 take too much Coras (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (Australia telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Coras.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Coras, you may feel faint, dizzy or lightheaded, have a very slow heart beat, have difficulty breathing or feel pain, which could be severe, in your left arm or chest.

While you are taking Coras

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Coras.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Coras.

If you plan to have surgery, including dental surgery, tell your surgeon or anaesthetist that you are taking Coras.

If you become pregnant while taking Coras, tell your doctor immediately.

Tell your doctor if you continue to have angina attacks or if they become more frequent.

Your doctor may need to adjust the dose of Coras you are taking.

Visit your doctor regularly so they can check on your progress.

Your doctor may want you to have some tests from time to time.

Things you must not do

Do not stop taking Coras, or change the dose, without checking with your doctor.

Stopping Coras suddenly may cause severe angina. Your doctor may want you to gradually reduce the amount of Coras you are taking before stopping completely.

Do not use Coras to treat any other conditions unless your doctor tells you to.

Do not give Coras to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Coras affects you.

It is unlikely that Coras will affect your ability to drive or operate machinery. However, Coras may

cause dizziness, lightheadedness or fainting in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Your doctor may advise you to keep a supply of angina tablets or spray for use under the tongue.

These medicines for angina are used to treat an acute attack of angina pain.

Be careful getting up from a sitting or lying position.

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

Side effects

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

Coras helps most people with angina, but it may have unwanted side effects in some people.

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

If you are over 65 years of age, you may have an increased chance of getting side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

Tell your doctor if you notice any of the following and they worry you:

- * dizziness, lightheadedness
- * headache
- * nausea
- * unusual tiredness, weakness
- * hot flushes.

The above list includes the common and mild side effects of your medicine.

Tell your doctor immediately if you notice any of the following:

- * swelling of the ankles, feet or lower legs
- * skin rash or increased sensitivity to the sun (such as symptoms of sunburn occurring more quickly than normal)
- * personality changes, depression, hallucinations, nervousness
- * unusual movements, such as trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs.

The above list includes serious side effects which may require medical attention. Serious side effects are not common.

See your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- * chest pain
- * fast, slow or irregular heart beats
- * fainting
- * serious skin rash, peeling of the skin, blistering, itching or hives
- * swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
- * bruising or bleeding more easily than usual
- * signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- * tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- * shortness of breath (sometimes with tiredness, weakness and reduced ability to exercise).

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

Tell your doctor if you notice anything that is making you feel unwell.

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

Some of these side effects (for example, changes in liver function) can only be found when your doctor does tests from time to time to check your progress.

After taking Coras

Storage

Keep Coras where children cannot reach it.

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

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they will not keep well.

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

Do not store Coras or any other medicine in the bathroom or near a sink.

Do not leave Coras in the car or on window sills.

Heat, light and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Coras, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Coras is a round, off-white, scored tablet, marked "DI" breakline "60" on one side and a Greek alpha symbol on the other side.

Each bottle contains 90 tablets.

Ingredients

The active ingredient in Coras is diltiazem hydrochloride.

Each Coras tablet contains 60 mg of diltiazem hydrochloride.

The tablets also contain the following inactive ingredients:

- * lactose
- * hypromellose
- * povidone
- * ethylcellulose
- * macrogol 8000
- * hydrogenated vegetable oil
- * magnesium stearate
- * purified talc.

The tablets are gluten free.

Manufacturer

Coras is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

www.alphapharm.com.au

Australian registration number:

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