

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Co-Diovan.

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

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What Co-Diovan is used for

Co-Diovan is used to control high blood pressure, also called hypertension.

Everybody has blood pressure. This pressure helps get your blood all around your body.

Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

High blood pressure increases the workload of the heart and blood vessels. If it continues for a long time, it can damage the blood vessels in the brain, heart and kidneys. This can lead to stroke, heart failure or kidney failure. High blood pressure increases the risk of heart attacks. Lowering your blood pressure reduces the chance of these disorders happening.

Co-Diovan contains valsartan and hydrochlorothiazide. These medicines reduce blood pressure in two different ways.

1. Valsartan blocks the effect of angiotensin II, which is a substance in the body that tightens blood vessels and makes your blood pressure rise. When the effect of angiotensin II is blocked, your blood vessels relax and your blood pressure goes down.
2. Hydrochlorothiazide helps reduce the amount of excess fluid in the body by increasing the amount of urine produced. This helps lower your blood pressure.

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

Your doctor may have prescribed it for another purpose.

There is not enough information to recommend the use of Co-Diovan in children.

This medicine is only available with a doctor's prescription. It is not addictive.

Before you take Co-Diovan

When you must not take it

Do not take Co-Diovan if you have ever had an allergic reaction after taking:

- valsartan or hydrochlorothiazide (the active ingredients in Co-Diovan) or sulfonamide-derived medicines (such as some antibiotics eg. Bactrim® trimethoprim and sulfamethoxazole)
- any of the other ingredients listed at the end of this leaflet

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 Co-Diovan if you are pregnant or intend to become pregnant.

Co-Diovan is not recommended for use in pregnancy. Like other similar medicines, it could affect your unborn baby.

Do not take Co-Diovan if you have:

- severe kidney or liver disease including biliary cirrhosis
- cholestasis, which is reduced or stopped bile flow
- anuria, which is a condition where you are unable to urinate
- high uric acid levels in the blood, which may cause gout
- low level of potassium or sodium, or high level of calcium in your blood

Check with your doctor if you are unsure if you have any of the above conditions.

Do not take Co-Diovan if you are also taking other blood pressure lowering medicines containing aliskiren and have type 2 diabetes.

Do not take Co-Diovan after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take it

Tell your doctor if you have/have had any of the following health problems/medical conditions:

- kidney problems
- liver problems
- systemic lupus erythematosus, a disease affecting the skin, joints and kidneys
- heart problems, including obstructed blood flow from narrowing of valves (stenosis) or enlarged septum (HOCM)
- high cholesterol levels
- diabetes
- swelling, mainly of the face and throat, while taking other medicines (including an ACE inhibitor or aliskiren)
- primary hyperaldosteronism (Conn's syndrome), a hormone disorder causing fluid retention
- passing less urine than is normal for you or difficulty passing urine
- recent excessive vomiting or diarrhoea
- salt restricted diet

Your doctor may want to take special precautions if you have any of the above conditions.

Tell your doctor if you are breast-feeding a baby. Ask your doctor about the risks and benefits of taking Co-Diovan in this case.

Hydrochlorothiazide is known to pass into the breast milk, however it is not known if valsartan passes into the breast milk. Therefore Co-Diovan is not recommended if you are breast-feeding.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives. Your doctor will want to know if you are prone to allergies.

If you have not told your doctor about any of these things, tell them before you take Co-Diovan.

Taking other medicines

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

Some medicines and Co-Diovan may interfere with each other. These include:

- medicines used to treat high blood pressure and some other heart conditions including fluid tablets or diuretic medicines, ACE-inhibitors, aliskiren and beta blockers
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- tablets, preparations or supplements which contain potassium
- some antibiotics (rifamycins), anti-rejection drugs (cyclosporin), antiretrovirals (ritonavir) which may increase the effect of valsartan
- medicines or supplements containing calcium
- vitamin D
- other medicines that raise blood pressure
- medicines used to relax muscles before or during surgery
- steroid medicines such as cortisone, prednisone and ACTH
- lithium, antidepressants, antipsychotics, medicines used to treat mood swings and some types of depression
- medicines used to treat heart problems
- cyclophosphamide or methotrexate
- penicillin
- amphotericin, a medicine used to treat fungal infections
- insulin and tablets used to treat diabetes
- medicines used to treat gout
- cyclosporin
- carbamazepine (a drug used to treat epilepsy, bipolar disorders, neuralgia and other conditions)
- medicines used to lower cholesterol (e.g. cholestyramine)
- amantadine, a medicine used to treat Parkinson's disease or to prevent influenza
- anticholinergic medicines, which are used to treat Parkinson's disease, relieve stomach cramps, spasms and prevent travel sickness
- carbenoxolone, a medicine used to treat stomach ulcers
- antiarrhythmics and digitalis glycosides, medicines used to treat irregular heart beats

- tetracycline, a medicine used to treat some infections
- alcohol
- sleeping tablets
- radioactive iodine, used as a medical tracer or diagnosis

Your doctor and pharmacist have a more complete list of medicines to be careful of while taking Co-Diovan.

How to take Co-Diovan

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

These instructions may differ from the information contained in this leaflet.

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

How much to take

The usual dose is 80/12.5 mg, 160/12.5 mg or 320/12.5 mg once a day. If your blood pressure is still too high after 4 weeks, your doctor may increase the dose to 160/25 mg or 320/25 mg once a day.

When to take it

When you take the first dose from the pack of Co-Diovan, take the one marked with the correct day of the week (e.g. if it is Wednesday, take the dose from the section of the foil marked Wednesday).

Co-Diovan comes in a calendar pack with the days of the week marked on it to help you remember to take your medicine each day.

Take your Co-Diovan dose at the same time each day.

This also helps you remember to take it, especially if you take it as part of your usual routine (e.g. at breakfast time). This medicine will keep working for the whole 24 hours until the next dose is due.

How to take it

Swallow the tablet with a full glass of water. Always take Co-Diovan the same way in relation to food.

It does not matter if you take Co-Diovan after food or on an empty stomach, as long as you take it the same way each day.

If your stomach is upset after taking Co-Diovan, always take it after a meal (e.g. breakfast).

How long to take it

Take this medicine until your doctor tells you to stop even if you feel quite well.

People who have high blood pressure often feel well and do not notice any signs of this problem.

It will take at least 4 weeks for this medicine to have its full effect. After that, it can be continued for as long as needed to control your blood pressure.

If you forget to take it

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

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

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

This may increase the chance of side effects.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone number: 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Co-Diovan. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

Too much Co-Diovan may make you feel dizzy, light headed or faint. You may experience rapid, shallow breathing or cold, clammy skin. Your heartbeat may be faster than usual. This is because your blood pressure is too low.

While you are taking Co-Diovan

Things you must do

If you become pregnant while taking Co-Diovan, tell your doctor immediately. You should not take this medicine while you are pregnant.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Be sure to keep all of your doctor's appointments so that your progress can be checked. Do this even if you feel well.

People with high blood pressure often do not notice any signs of this problem. But it is important to keep track of your progress. Your doctor will want to check your blood pressure regularly to make sure the medicine is working. Your doctor will also check your kidney and liver function from time to time to prevent unwanted side effects.

If you are going to have surgery, tell your doctor and anaesthetist that you are taking Co-Diovan.

Co-Diovan may affect some medicines you receive during surgery.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Co-Diovan.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Co-Diovan.

Things you must not do

Do not use Co-Diovan to treat any other complaints unless your doctor says you can.

Do not give this medicine to anyone else, even if their condition seems to be similar to yours.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Co-Diovan until you know how it affects you.

This medicine can cause tiredness, sleepiness or dizziness in some people. If you have these symptoms, do not drive or do anything else that could be dangerous.

If this medicine makes you feel dizzy or light-headed, be careful when getting up from a sitting or lying position.

Dizziness can usually be prevented by getting up slowly and flexing leg muscles and toes to get the blood flowing. When getting out of bed, dangle your legs over the side for a minute or two before standing up.

When you are outdoors, wear protective clothing and use at least a 15+ sunscreen. Do not use a sunlamp.

This medicine may cause your skin to be much more sensitive to sunlight than it normally is.

Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn. If your skin does appear to be burning, tell your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Co-Diovan, even if you do not think it is connected with the medicine.

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

- headache
- dizziness, spinning sensation, blurred vision
- sleepiness, tiredness or weakness
- pain in the back or joints
- runny or bleeding nose or congested sinuses
- dry cough, sore throat or hoarse voice
- dry mouth
- diarrhoea, constipation or wind
- nausea (feeling sick), vomiting, loss of appetite, stomach upset or indigestion
- back pain, muscle pain, muscle tenderness or weakness, cramps or joint pain
- tingling or numbness in hands or feet
- blistering skin
- symptoms of sunburn which happens more quickly than normal
- difficulty sleeping
- feeling anxious or sad
- dizziness on standing up, especially when getting up from a sitting or lying position
- problems with sexual function
- pain when passing urine, frequent urge to urinate
- hair loss
- facial pain

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

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing
- feeling of fast or irregular heart beat (pounding, racing, skipping beats)
- chest pain
- tiredness or lack of energy, being short of breath when exercising, dizziness and looking pale
- constant "flu-like" symptoms such as chills, fever, sore throat, aching joints, sores in mouth, swollen glands
- pain in the stomach, often accompanied by nausea and vomiting

- signs of a serious skin reaction such as painful red areas, large blisters, peeling of layers of skin, bleeding in the lips, eyes, mouth, nose or genitals. These signs may be accompanied by fever and chills, aching muscles and feeling generally unwell
- unusual bleeding or bruising under the skin
- severe dizziness or fainting
- passing less urine than normal
- liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine
- decrease in vision or pain in your eyes

The above side effects are rare, but may be serious. You may need urgent medical attention.

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

Some people may get other side effects of Co-Diovan.

After using Co-Diovan

Storage

- Keep your tablets in the original container until it is time to take them.
- Store them in a cool dry place below 30°C (room temperature).
- Do not store Co-Diovan or any other medicine in the bathroom or near a sink.
- Do not leave Co-Diovan in the car or on window sills.

Heat and dampness can destroy some medicines. Co-Diovan will keep well if it is cool and dry.

Keep medicines where children cannot reach them.

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

Disposal

If your doctor tells you to stop taking Co-Diovan, or it has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

Co-Diovan tablets are supplied in blister packs of 28.

- Co-Diovan 80/12.5 tablets are light orange and imprinted with "HGH" on one side and "CG" on the other.
- Co-Diovan 160/12.5 tablets are oval and dark red with a "HHH" marked on one side of the tablet and "CG" on the other.
- Co-Diovan 160/25 tablets are oval shaped, and brown-orange in colour. They have the letters "HXH" marked on one side of the tablet and "NVR" on the other.
- Co-Diovan 320/12.5 tablets are oval shaped, and pink in colour. They have the letters "HIL" marked on one side of the tablet and "NVR" on the other.
- Co-Diovan 320/25 tablets are oval shaped, and yellow in colour. They have the letters "CTI" marked on one side of the tablet and "NVR" on the other.

Ingredients

Co-Diovan tablets contain 80 mg, 160 mg or 320 mg of valsartan and 12.5 mg or 25 mg of hydrochlorothiazide as the active ingredient.

The tablets contain the following non active ingredients:

- cellulose - microcrystalline
- crospovidone
- silica - colloidal anhydrous
- magnesium stearate
- hypromellose
- titanium dioxide
- iron oxide red
- talc

Co-Diovan 80/12.5 tablets also contain:

- macrogol 8000
- iron oxide yellow

Co-Diovan 160/12.5 tablets also contain:

- macrogol 8000

Co-Diovan 160/25 tablets also contain:

- macrogol 4000
- iron oxide yellow
- iron oxide black

Co-Diovan 320/12.5 tablets also contain:

- macrogol 4000
- iron oxide black

Co-Diovan 320/25 tablets also contain:

- macrogol 4000
- iron oxide yellow

Sponsor

Co-Diovan is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160
54 Waterloo Road
North Ryde NSW 2113
Telephone: 1 800 671 203

®= Registered Trademark

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Co-Diovan 80/12.5 mg tablets AUST R 96740
Co-Diovan 160/12.5 mg tablets AUST R 96741
Co-Diovan 160/25 mg tablets AUST R 96742
Co-Diovan 320/12.5 mg tablets AUST R 135782
Co-Diovan 320/25 mg tablets AUST R 135812

Internal use only:

(cod281113c.doc) based on PI (cod281113i.doc)