

Co-Diovan®

Film Coated Tablet

Valsartan and hydrochlorothiazide

Consumer Medicine Information (CMI) summary

The [full CMI](#) 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 Co-Diovan?

Co-Diovan contains the active ingredients Valsartan and hydrochlorothiazide. Co-Diovan is used to treat high blood pressure. Symptoms include headache, fatigue, irregular heartbeat and vision problems.

For more information, see Section [1. Why am I using Co-Diovan?](#) in the full CMI.

2. What should I know before I use Co-Diovan?

Do not use if you have ever had an allergic reaction to Co-Diovan 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 [2. What should I know before I use Co-Diovan?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Co-Diovan 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 do I use Co-Diovan?

- Your doctor will advise you on the appropriate dose.
- Follow the instructions provided and use Co-Diovan until your doctor tells you to stop.

More instructions can be found in Section [4. How do I use Co-Diovan?](#) in the full CMI.

5. What should I know while using Co-Diovan?

Things you should do	• Remind any doctor, dentist, pharmacist or specialist you visit that you are using Co-Diovan. • Tell your doctor if you become pregnant or intend to become pregnant or if you are breastfeeding. • Contact your doctor immediately if you develop any signs of allergic reaction.
Things you should not do	• Do not stop using this medicine suddenly. • Do not give Co-Diovan to anyone else, even if they seem to have the same condition as you. • Do not use Co-Diovan in children.
Driving or using machines	• Co-Diovan may cause dizziness in some people. Be careful before driving or using any machines or tools.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Store below 30°C. • Protect from moisture.

For more information, see Section [5. What should I know while using Co-Diovan?](#) in the full CMI.

6. Are there any side effects?

Common side effects include dizziness, headache, muscular weakness, joint pain, blurred vision, dry mouth, feeling sick, tiredness. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Co-Diovan®

Film Coated Tablet

Active ingredients: Valsartan and hydrochlorothiazide

Consumer Medicine Information (CMI)

This leaflet provides important information about using Co-Diovan. **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 Co-Diovan.**

Where to find information in this leaflet:

1. [Why am I using Co-Diovan?](#)
2. [What should I know before I use Co-Diovan?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Co-Diovan?](#)
5. [What should I know while using Co-Diovan?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Co-Diovan?

Co-Diovan contains the active ingredients Valsartan and Hydrochlorothiazide.

Co-Diovan is used to treat high blood pressure. Symptoms include headache, fatigue, irregular heartbeat and vision problems. Co-Diovan helps to reduce blood pressure in two ways:

Valsartan helps to lower your blood pressure by blocking the effect of angiotensin II. This is a substance which makes your blood vessels tighten, which raises your blood pressure. When Valsartan blocks it, your blood vessels become relaxed, making it easier for blood to flow and thus helping to lower your blood pressure.

Hydrochlorothiazide is a diuretic (water pill) type of medicine. It helps in reducing the amount of excess fluid in the body by increasing the amount of urine produced and thereby helps in lowering your blood pressure.

2. What should I know before I use Co-Diovan?

Warnings

Do not use Co-Diovan

- If you are allergic to Valsartan, Hydrochlorothiazide or other sulfonamide-derived medicines or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Symptoms of allergic reaction may include shortness of breath, difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, hives.
- In pregnancy
- In children
- If you have severe liver diseases, symptoms such as and tiredness, itchy skin, and yellowing of the skin and

eyes or intense itching, dark urine and light-colored stools.

- If you suffer from symptoms such as tiredness, weakness, little to no urine output or severe kidney problems.
- If you have following symptoms:
 - o Muscle weakness and muscle cramps, irregular heartbeat, weakness.
 - o Feeling sick, vomiting, headache, loss of energy
 - o Tiredness, pain in bone, headache
 - o Joint pain and swelling, redness and warmth around affected joints.
- If you use a medicine called aliskiren.

Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.
- are taking any medicines similar to Hydrochlorothiazide (diuretics).
- have severe heart failure.
- suffer from problems with your kidneys.
- have headache, muscle weakness, tiredness.
- have an allergy or symptoms such as wheezing, shortness of breath, coughing.
- have heart problems
- suffer from skin rashes (butterfly-shaped), tiredness, joint and muscle pain.
- have eye problems.
- suffer from non-melanoma skin cancer.
- have any breathing problems.
- suffer from mild to moderate liver diseases or any kidney problems.
- have high levels of cholesterol, triglycerides in your blood.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not use Co-Diovan during pregnancy or if you are planning to become pregnant. It may affect your unborn baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not use Co-Diovan during breastfeeding.

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 may interfere with Co-Diovan and affect how it works.

Tell your doctor if you take any of the following medicines:

- Medicines used to relieve pain, swelling e.g. non-steroidal anti-inflammatory drugs (NSAIDs), salicylic acid derivatives indomethacin including Selective Cyclooxygenase-2 Inhibitors (COX-2 Inhibitors)
- Medicines used to treat high blood pressure and some other heart problems such as diuretic medicines, ACE-inhibitors, aliskiren and beta blockers
- Potassium supplements, potassium-sparing diuretics, or other drugs that may alter potassium levels e.g. heparin, trimethoprim containing medicines
- Antiretrovirals (ritonavir), antibiotics (rifamycins)
- Other antihypertensive drugs e.g. guanethidine, methyl dopa, beta-blockers, vasodilators, calcium channel blockers, methyl dopa.
- Diazoxide, drug used to treat low blood sugar level.
- Non-depolarising muscle relaxants (e.g. curare derivatives).
- Insulin and antidiabetic medicines
- Medicines used for treatment of heart problems and high blood pressure e.g. kaliuretic diuretics
- Carbenoxolone, medicine used for treatment of various stomach problems.
- Penicillin G, antibiotic used in treatment of bacterial infections
- Medicines used to treat irregular heart beats e.g. antiarrhythmics and digitalis glycosides
- Antidepressants, antipsychotics e.g. Lithium
- Antiepileptics e.g. carbamazepine
- Anticholinergic agents (e.g. atropine, biperiden, which are used to treat Parkinson's disease, relieve stomach cramps, spasms
- Pressor amines (e.g. noradrenaline)
- Medicines used to lower cholesterol e.g. cholestyramine or colestipol resins
- Tetracycline, a drug used to treat some infections
- Alcohol, anaesthetics and sedatives (sleeping tablets)
- Radioactive iodine, used as a medical tracer or diagnosis
- Cyclophosphamide, methotrexate, a drug used to treat arthritis and some cancers
- Medicines or supplements containing calcium
- Vitamin D
- Medicines used in organ transplants e.g. cyclosporin
- Steroid medicines such as cortisone, prednisone and ACTH
- Amphotericin, a drug used to treat fungal infections
- Medicines used to treat gout e.g. Allopurinol, probenacid or sulfinpyrazone

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

4. How do I use Co-Diovan?

How much to take

- Your doctor will advise you on the appropriate dose.
- Follow the instructions provided and use Co-Diovan until your doctor tells you to stop.
- The usual dose is one tablet per day as advised by your doctor.

When to take Co-Diovan

- Co-Diovan should be taken at the same time each day.
- 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).

How to take Co-Diovan

- Swallow the tablet with a full glass of water.
- Take Co-Diovan consistently with or without food
- If you feel that your stomach gets upset after taking Co-Diovan, always take it after a meal.

If you forget to use Co-Diovan

Co-Diovan should be used regularly at the same time each day. If you miss your dose at the usual time, take the dose as soon as you remember and then go back to taking it as you would normally.

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 use too much Co-Diovan

If you think that you have used too much Co-Diovan, you may need urgent medical attention.

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 Co-Diovan?

Things you should do

- Check your skin for any new lesions and report any suspicious skin lesions to your doctor immediately.
- There may be a risk of developing non-melanoma skin cancer while on treatment with Co-Diovan.

- Avoid direct exposure to sunlight and UV rays, in case of exposure, use adequate protection to avoid the risk of skin cancer.

Call your doctor straight away if you:

- develop any signs of allergic reaction.
- become pregnant or intend to become pregnant or if you are breastfeeding.
- are going to have surgery, tell your doctor that you are taking Co-Diovan.
- notice symptoms such as increased sensitivity of the skin to sun. Symptoms of sunburn such as redness, itching, swelling, blistering which may occur more quickly than normal.
- have muscle weakness or cramps, tiredness.
- Remind any doctor, dentist, pharmacist or specialist you visit that you are using Co-Diovan.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not give Co-Diovan to anyone else, even if they seem to have the same condition as you.
- Do not use Co-Diovan to treat any other complaints unless your doctor tells you to.

Lab tests:

- Your doctor may do a routine blood checkup, ECG during treatment with Co-Diovan.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Co-Diovan affects you.

Co-Diovan may cause dizziness in some people. Precaution should be taken before driving or using any machines or tools.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store below 30°C.
- Keep in the original package.
- Protect from moisture.

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.

Keep it where young children cannot reach it.

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.

Less serious side effects

Less serious side effects	What to do
General problems: • Headache • Dizziness • Back pain • Joint pain • Tiredness • Unusual hair loss or thinning • Anxiety • Unusual weakness • Dry mouth and skin, dark colour urine, tiredness, dizziness • Excessive sweating • Inability to sleep • Muscle spasms • Muscle strain • Muscular weakness • Fever • Sleepiness • Vision blurred • Vision problems	Speak to your doctor if you have any of these less serious side effects and they worry you.
Respiratory problems: • Sore throat, stuffy nose, cough, mild body pain • Sore throat and discomfort when swallowing • Runny or blocked nose, sneezing, facial pressure or pain • Cough • Sore throat, dry cough, fever, muscle pain.	
Stomach problems: • Diarrhoea • Pain in stomach • Indigestion • Dry mouth • Feeling sick	

Serious side effects

Serious side effects	What to do
Respiratory problems: - Shortness of breath, wheezing, feeling of chest tightness or pain, cough - Shortness of breath, fever, fast breathing, extreme tiredness Abnormal blood tests: - Muscle weakness or cramps, tiredness, muscle spasms may indicate decrease in potassium level in your blood. - Swelling in your legs or around your eyes, shortness of breath may indicate increase in creatinine level. - Swelling in your arms, legs, or feet, muscle cramps, tiredness may indicate increased blood urea nitrogen level in your blood. - Fever, tiredness, sore throat, mouth ulcers may indicate low level of Neutrophils in your blood. - Feeling sick, vomiting, headache, loss of energy may indicate low level of sodium in your blood. - Tiredness, pain in bone, headache may indicate high level of calcium in your blood. - Tremors or shaking, muscle spasms, cramps may indicate low level of magnesium your blood. Eye problems: - Decreased vision, eye pain, vision distortion, blind spots, and other changes in vision, - Headache, blurred vision, eye pain - Severe eye pain, redness of eye, feeling sick Other problems: - Decreased urine output, dark colour urine. - Tiredness, vomiting, shortness of breath.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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 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 Co-Diovan contains

Active ingredient (main ingredient)	Valsartan and hydrochlorothiazide.
Other ingredients (inactive ingredients)	Co-Diovan 80/12.5: silica-colloidal anhydrous; crospovidone; hypromellose; magnesium stearate; cellulose-microcrystalline; macrogol 8000; talc-purified; titanium dioxide; iron oxide red; iron oxide yellow. Co-Diovan 160/12.5: silica-colloidal anhydrous; crospovidone; hypromellose; magnesium stearate; cellulose-microcrystalline; macrogol 8000; talc-purified; titanium dioxide; iron oxide red. Co-Diovan 160/25: silica-colloidal anhydrous; crospovidone; hypromellose; magnesium stearate; cellulose-microcrystalline; macrogol 4000; talc-purified; titanium dioxide, iron oxide red, iron oxide yellow, iron oxide black. Co-Diovan 320/12.5: silica-colloidal anhydrous; crospovidone; hypromellose; magnesium stearate; cellulose-microcrystalline; macrogol 4000; talc-purified; titanium dioxide, iron oxide red, iron oxide black. Co-Diovan 320/25: silica-colloidal anhydrous; crospovidone; hypromellose; magnesium stearate; cellulose-microcrystalline; macrogol 4000; talc-purified; titanium dioxide, iron oxide yellow.
Potential allergens	NA

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

What Co-Diovan looks like

Co-Diovan 80/12.5: Ovaloid, non-divisible, film-coated tablets coloured light orange and imprinted with HGH on one side and CG on the other side. It is available in PA/Al/PVC/Al blister packs of 7, 14, 28, 30 and 56.

Co-Diovan 160/12.5: Ovaloid, non-divisible, film-coated tablets coloured dark red and imprinted with HHH on one side and CG on the other side. It is available in PA/Al/PVC/Al blister packs of 7, 14, 28, 30 and 56.

Co-Diovan 160/25: Ovaloid, non-divisible, film-coated tablets coloured brown-orange and imprinted with HXH on one side and NVR on the other side. It is available in PA/Al/PVC/Al blister packs of 7, 14, 28, 30 and 56.

Co-Diovan 320/12.5: Ovaloid, non-divisible, film-coated tablets coloured pink and imprinted with HIL on one side and NVR on the other side. It is available in PA/Al/PVC/Al blister packs of 7, 14, 28, 30 and 56.

Co-Diovan 320/25: Ovaloid, non-divisible, film-coated tablets coloured yellow and imprinted with CTI on one side and NVR on the other side. It is available in PA/Al/PVC/Al blister packs of 7, 14, 28, 30 and 56.

Not all strengths and pack sizes may be marketed.

Australian Registration Numbers

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

Who distributes Co-Diovan

Co-Diovan is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

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Telephone: 1 800 671 203

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