# COAPROVEL® FILM-COATED TABLET

Irbesartan/ Hydrochlorothiazide (150 mg/12.5 mg)
Irbesartan/ Hydrochlorothiazide (300 mg/12.5 mg)

**What is in this leaflet**

1. What CoAprovel is used for
2. How CoAprovel works
3. Before you use CoAprovel
4. How to use CoAprovel
5. While you are using it
6. Side effects
7. Storage and Disposal of CoAprovel
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

**What CoAprovel is used for**

**CoAprovel is used to treat high blood pressure**, when treatment with irbesartan or hydrochlorothiazide alone did not provide adequate control of your blood pressure.

**How CoAprovel works**

CoAprovel is a combination of two active substances, irbesartan and hydrochlorothiazide.

Irbesartan belongs to a group of medicines known as angiotensin-II receptor antagonists.

Angiotensin-II is a substance produced in the body that binds to receptors in blood vessels causing them to tighten. This results in an increase in blood pressure. Irbesartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower.

Hydrochlorothiazide is one of a group of medicines (called thiazide diuretics) that causes increased urine output and so causes a lowering of blood pressure.

The two active ingredients in CoAprovel work together to lower blood pressure further than if either was given alone.

**Before you use CoAprovel**

*-When you must not use it*

**Do not take CoAprovel**

- if you are **allergic** (hypersensitive) to irbesartan or any of the other ingredients of CoAprovel
- if you are **allergic** (hypersensitive) to hydrochlorothiazide or any other sulfonamide-derived medicines
- if you are **more than 3 months pregnant**. (It is also better to avoid CoAprovel in early pregnancy – see pregnancy section)
- if you have **severe liver** or **kidney problems**
- if you have **difficulty in producing urine**
- if your doctor determines that you have **persistently high calcium or low potassium levels in your blood**
- if you have **diabetes or impaired kidney function** and you are treated with a blood pressure lowering medicine containing aliskiren.

CoAprovel should not be given to children and adolescents (under 18 years).

*-Before you start to use it*

**CoAprovel contains lactose**. If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine.

**CoAprovel contains sodium.** This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

*-Taking other medicines*

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Diuretic agents such as the hydrochlorothiazide contained in CoAprovel may have an effect on other medicines. Preparations containing lithium should not be taken with CoAprovel without close supervision by your doctor.

Your doctor may need to change your dose and/or to take other precautions: If you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take CoAprovel" and "Things you must do").

**You may need to have blood checks if you take:**

- potassium supplements
- salt substitutes containing potassium
- potassium sparing medicines or other diuretics (water tablets)
- some laxatives
- medicines for the treatment of gout
- therapeutic vitamin D supplements
- medicines to control heart rhythm
- medicines for diabetes (oral agents as repaglinide or insulins)
- carbamazepine (a medicine for the treatment of epilepsy).

It is also important to tell your doctor if you are taking other medicines to reduce your blood pressure, steroids, medicines to treat cancer, pain killers, arthritis medicines, or colestyramine and colestipol resins for lowering blood cholesterol.

**Taking CoAprovel with food and drink**

CoAprovel can be taken with or without food.

Due to the hydrochlorothiazide contained in CoAprovel, if you drink alcohol while on treatment with this medicine, you may have an increased feeling of dizziness on standing up, specially when getting up from a sitting position.

**How to use CoAprovel**

Always take CoAprovel exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

*-How much to use*

The recommended dose of CoAprovel 150 mg/12.5 mg film-coated tablets is one or two tablets a day.

The usual dose of CoAprovel 300 mg/12.5mg film-coated tablets & CoAprovel 300 mg/25 mg film-coated tablets is one tablet a day.

CoAprovel will usually be prescribed by your doctor when your previous treatment did not reduce your blood pressure enough. Your doctor will instruct you how to switch from the previous treatment to CoAprovel.

*-When to use it*

CoAprovel is for oral use. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take CoAprovel with or without food. Try to take your daily dose at about the same time each day.

*-How long to use it*

It is important that you continue to take CoAprovel until your doctor tells you otherwise. The maximal blood pressure lowering effect should be reached 6-8 weeks after beginning treatment.

*-If you forget to use it*
If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

*-If you use too much (overdose)*
If you accidentally take too many tablets, contact your doctor immediately.

**While you are using it**
*-Things you must do*
**Tell your doctor** if any of the following apply to you:
- if you get **excessive vomiting or diarrhoea**
- if you suffer from **kidney problems** or have a **kidney transplant**
- if you suffer from **heart problems**
- if you suffer from **liver problems**
- if you suffer from **diabetes**
- if you develop **low blood sugar levels** (symptoms may include sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heart beat), particularly if you are being treated for diabetes
- if you suffer from **lupus erythematosus** (also known as lupus or SLE)
- if you suffer from **primary aldosteronism** (a condition related to high production of the hormone aldosterone, which causes sodium retention and, in turn, an increase in blood pressure).
- if you are taking any of the following medicines used to treat high blood pressure:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril) in particular if you have diabetes-related kidney problems.
  - aliskiren.
- if you have had **skin cancer or if you develop an unexpected skin lesion** during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking CoAprovel.
- if you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking CoAprovel, seek medical attention immediately.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.
Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking CoAprovel. Your doctor will decide on further treatment. Do not stop taking CoAprovel on your own.
See also information under the heading "Do not take CoAprovel".
You must tell your doctor if you think you are (or might become) pregnant. CoAprovel is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

**You should also tell your doctor:**
- if you are on a **low-salt diet**
- if you have signs such as **abnormal thirst**, **dry mouth**, **general weakness**, **drowsiness**, **muscle pain or cramps**, **nausea**, **vomiting**, or an **abnormally fast heart beat** which may indicate an excessive effect of hydrochlorothiazide (contained in CoAprovel)
- if you experience an increased **sensitivity of the skin to the sun** with symptoms of sunburn (such as redness, itching, swelling, blistering) occurring more quickly than normal
- if you are **going to have an operation** (surgery) or **be given anaesthetics**
- if you have **decrease in your vision or pain in one or both of your eyes** while taking CoAprovel. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye (glaucoma) and can happen within hours to a week of taking CoAprovel. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this. You should discontinue CoAprovel treatment and seek prompt medical attention.

The hydrochlorothiazide contained in this medicine could produce a positive result in an anti-doping test.

**Pregnancy**
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking CoAprovel before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of CoAprovel. CoAprovel is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

**Breast-feeding**
Tell your doctor if you are breast-feeding or about to start breast-feeding. CoAprovel is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

*-Things you must not do*
**Children should not take CoAprovel**
CoAprovel should not be given to children under 18 years of age. If a child swallows some tablets, contact your doctor immediately.

*-Things to be careful of*
**Driving and using machines**
CoAprovel is unlikely to affect your ability to drive or use machines. However, occasionally dizziness or weariness may occur during treatment of high blood pressure. If you experience these, talk to your doctor before attempting to drive or use machines.

**Side Effects**
Like all medicines, CoAprovel can cause side effects, although not everybody gets them.
Some of these effects may be serious and may require medical attention.
Rare cases of allergic skin reactions (rash, urticaria), as well as localised swelling of the face, lips and/or tongue have been reported in patients taking irbesartan.

**If you get any of the above symptoms or get short of breath,** stop taking CoAprovel and contact your doctor immediately.
Side effects reported in clinical studies for patients treated with CoAprovel were:
**Common side effects** *(may affect up to 1 in 10 people)*
- nausea/vomiting
- abnormal urination
- fatigue

- dizziness (including when getting up from a lying or sitting position)
- blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatine kinase) or raised levels of substance that measure kidney function (blood urea nitrogen, creatinine).

**If any of these side effects causes you problems**, talk to your doctor.
**Uncommon side effects** *(may affect up to 1 in 100 people)*
- diarrhoea
- low blood pressure
- fainting
- heart rate increased
- flushing
- swelling
- sexual dysfunction (problems with sexual performance)
- blood tests may show lowered levels of potassium and sodium in your blood.

**If any of these side effects causes you problems**, talk to your doctor.
**Side effects reported since the launch of CoAprovel**
Some undesirable effects have been reported since marketing of CoAprovel. Undesirable effects where the frequency is not known are: headache, ringing in the ears, cough, taste disturbance, indigestion, pain in joints and muscles, liver function abnormal and impaired kidney function, increased level of potassium in your blood and allergic reactions such as rash, hives, swelling of the face, lips, mouth, tongue or throat. Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.
As for any combination of two active substances, side effects associated with each individual component cannot be excluded.
**Side effects associated with irbesartan alone**
In addition to the side effects listed above, chest pain, severe allergic reactions (anaphylactic shock), decreased number of red blood cells (anaemia – symptoms may include tiredness, headaches, being short of breath when exercising, dizziness and looking pale) and decrease in the number of platelets (a blood cell essential for the clotting of the blood) and low blood sugar levels have also been reported.
Rare (may affect up to 1 in 1,000 people): intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.
**Side effects associated with hydrochlorothiazide alone**
Loss of appetite; stomach irritation; stomach cramps; constipation; jaundice (yellowing of the skin and/or whites of the eyes); inflammation of the pancreas characterised by severe upper stomach pain, often with nausea and vomiting; sleep disorders; depression; blurred vision; lack of white blood cells, which can result in frequent infections, fever; decrease in the number of platelets (a blood cell essential for the clotting of the blood), decreased number of red blood cells (anaemia) characterised by tiredness, headaches, being short of breath when exercising, dizziness and looking pale; kidney disease; lung problems including pneumonia or build-up of fluid in the lungs; increased sensitivity of the skin to the sun; inflammation of blood vessels; a skin disease characterized by the peeling of the skin all over the body; cutaneous lupus erythematosus, which is identified by a rash that may appear on the face, neck, and scalp; allergic reactions; weakness and muscle spasm; altered heart rate; reduced blood pressure after a change in body position; swelling of the salivary glands; high sugar levels in the blood; sugar in the urine; increases in some kinds of blood fat; high uric acid levels in the blood, which may cause gout.
**Very rare side effects** (may affect up to 1 in 10,000 people): Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).
**Not known** (frequency cannot be estimated from the available data): skin and lip cancer (non-melanoma skin cancer), decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma).
It is known that side effects associated with hydrochlorothiazide may increase with higher doses of hydrochlorothiazide.
**If any of the side effects gets serious**, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my *[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]*.

**Storage and Disposal of CoAprovel**
*-Storage*
Keep out of the reach and sight of children.
Do not store above 30°C.
Store in the original package in order to protect from moisture.
Do not use CoAprovel after the expiry date which is stated on the carton and on the blister after EXP.

*-Disposal*
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**
*-What it looks like?*
**CoAprovel 150mg/12.5mg film-coated tablets**
Peach, biconvex, oval-shaped, with a heart debossed on one side and the number 2875 engraved on the other side.
**CoAprovel 300mg/12.5mg film-coated tablets**
Peach, biconvex, oval-shaped, with a heart debossed on one side and the number 2876 engraved on the other side.

*-Ingredients*
-Active ingredients:
**CoAprovel 150mg/12.5mg film-coated tablets**
Each film-coated tablet contains 150 mg of irbesartan and 12.5 mg of hydrochlorothiazide.
**CoAprovel 300mg/12.5mg film-coated tablets**
Each film-coated tablet contains 300 mg of irbesartan and 12.5 mg of hydrochlorothiazide.

-Inactive ingredients:
Tablet core: Lactose monohydrate, Microcrystalline cellulose, Croscarmellose sodium, Hypromellose, Silicon dioxide, Magnesium stearate.
Film-coating: Lactose monohydrate, Hypromellose, Titanium dioxide, Macrogol 3000, Red and yellow ferric oxides, Carnauba wax.

*-MAL Numbers:*

CoAprovel 150 mg/12.5 mg
film-coated tablets: MAL20014479AZ
CoAprovel 300 mg/12.5 mg
film-coated tablets: MAL20014478AZ

**Manufacturer**
SANOFI WINTHROP INDUSTRIE
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Ambarès & Lagrave
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**Product Registration Holder**
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**Date of revision**
18/06/2025

**Serial Number**
NPRA (R1/4) 15122022/335