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Package Leaflet: Information for the patient

SANOFI

COAPROVEL® 300 mg/12,5 mg

film-coated tablets
irbesartan/hydrochlorothiazide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. WHAT COAPROVEL IS AND WHAT IT IS USED FOR

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.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE COAPROVEL

Do not take CoAprovel
- if you are **allergic** to irbesartan or any of the other ingredients of this medicine (listed in section 6)
- if you are **allergic** 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.

Warnings and precautions
Talk to your doctor before taking CoAprovel and **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 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.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.
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.

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

Other medicines and CoAprovel
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
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 "Warnings and precautions").

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 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.

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.

Pregnancy, breast-feeding and fertility
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.

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.

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 medicinal product.

3. HOW TO TAKE COAPROVEL

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage
The recommended dose of CoAprovel 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.

Method of administration
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. 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 take more CoAprovel than you should
If you accidentally take too many tablets, contact your doctor immediately.

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.

If you forget to take CoAprovel
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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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.

The frequency of the side effects listed below is defined using the following convention:
Common: may affect up to 1 in 10 people
Uncommon: may affect up to 1 in 100 people

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 substances 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), and decrease in the number of platelets (a blood cell essential for the clotting of the blood) have also been reported.

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.
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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

United Kingdom
You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland
You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE COAPROVEL

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and on the blister after EXP. The expiry date refers to the last day of that month.
Do not store above 30°C.
Store in the original package in order to protect from moisture.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What CoAprovel contains
- The active substances are irbesartan and hydrochlorothiazide. Each film-coated tablet of CoAprovel 300 mg/12.5 mg contains 300 mg irbesartan and 12.5 mg hydrochlorothiazide.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hypromellose, silicon dioxide, magnesium stearate, titanium dioxide, macrogol 3000, red and yellow ferric oxides, carnauba wax. Please see section 2 «CoAprovel contains lactose».

What CoAprovel looks like and contents of the pack
CoAprovel 300 mg/12.5 mg film-coated tablets are peach, biconvex, oval-shaped, with a heart debossed on one side and the number 2876 engraved on the other side.

CoAprovel 300 mg/12.5 mg film-coated tablets are supplied in blister packs of 14, 28, 30, 56, 84, 90 or 98 film-coated tablets. Unit dose blister packs of 56 x 1 film-coated tablet for delivery in hospitals are also available.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
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F-75008 Paris - France

Manufacturer
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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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