PACKAGE LEAFLET: Information for the patient

CO-ULTESAN

Film-coated tablets – (150 mg/12.5 mg), (300 mg/12.5 mg), (300 mg/25 mg)

(Irbesartan / Hydrochlorothiazide)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT CO-ULTESAN IS AND WHAT IT IS USED FOR

Co-Ultesan is a combination of two active substances, irbesartan and hydrochlorothiazide.

Irbesartan belongs to a group of medicines known as angiotensin II receptors antagonists. Angiotensin II is a substance produced in the body which 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 belongs to 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 Co-Ultesan work together to lower blood pressure further than if either was given alone.

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

2. BEFORE YOU TAKE CO-ULTESAN

Do not take Co-Ultesan:

- if you are **allergic** (hypersensitive) to irbesartan or to any of the excipients of this medicine (listed in section 6);
- if you are **allergic** (hypersensitive) to hydrochlorothiazide or to any other sulfonamide-derived medicines;
- if you are **more than 3 months pregnant.** (It is also better to avoid Co-Ultesan in early pregnancy – see pregnancy section);
- if you are breast-feeding;
- 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 levels 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.

Co-Ultesan should not be given to children and adolescents (under 18 years).

Take special care with Co-Ultesan

Talk to your doctor before taking Co-Ultesan and if any of the following applies 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 Co-Ultesan.
- 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 Co-Ultesan, 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.
See also information under the heading “Do not take Co-Ultesan”.
You must tell your doctor if you think you are (or might become) pregnant. Co-Ultesan 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 Co-Ultesan);

- 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 experience a decrease in vision or pain in one or both of your eyes while taking Co-Ultesan. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increased pressure in your eye(s) (glaucoma). 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 Co-Ultesan treatment and seek medical attention.

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

Use in children

Co-Ultesan should not be given to children and adolescents (under 18 years).

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those without prescription.

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

Co-Ultesan must not be taken concomitantly with aliskiren (contraindicated).

Taking angiotensin-II receptor antagonists with ACE-inhibitors or cyclosporin may increase the risk of hyperkalaemia.

You may need to have blood checks if you take:

- potassium supplements;
- salt substitutes containing potassium;
- potassium-sparing medicines (such as certain diuretics);
- 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).

Taking Co-Ultesan with food and drinks

Co-Ultesan can be taken with or without food.

Due to the hydrochlorothiazide contained in Co-Ultesan, 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

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Co-Ultesan before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Co-Ultesan. Co-Ultesan 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.

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breastfeeding.

Co-Ultesan is not recommended for mothers who are breastfeeding, 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

If during treatment you experience dizziness or weakness, talk to your doctor before attempting to drive or use machines.

Important information about some of the excipients of Co-Ultesan

Co-Ultesan contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE CO-ULTESAN

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

Dosage

This medicinal product is available in 3 strengths: Co-Ultesan 150 mg/12.5 mg, Co-Ultesan 300 mg/12.5 mg and Co-Ultesan 300 mg/25 mg.

The recommended dose of Co-Ultesan 150 mg/12.5 mg is one or two tablets daily.

The recommended dose of Co-Ultesan 300 mg/12.5 mg and Co-Ultesan 300 mg/25 mg is one tablet daily.

Co-Ultesan 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 Co-Ultesan.

Method of administration

Co-Ultesan is for oral use. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take Co-Ultesan 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 Co-Ultesan until your doctor tells you otherwise.

The maximal blood pressure lowering effect should be reached 6-8 weeks after starting treatment.

If you take more Co-Ultesan than you should

If you have accidentally taken more Co-Ultesan than you should, or if the children have accidentally taken this drug, please contact your doctor, hospital, or emergency to get an opinion on the risk and advice on the actions that should be taken.

If you forget to take Co-Ultesan

If you forget to take Co-Ultesan, take your dose as soon as you remember, unless it is time to take the next dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Co-Ultesan

If you feel better, do not stop treatment without consulting a doctor.

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 shortness of breath, stop taking Co-Ultesan and contact your doctor immediately.

Side effects are listed below according to their frequency:

Very common: can affect more than 1 in 10 patients.

Common: can affect 1 to 10 patients among 100.

Uncommon: can affect 1 to 10 patients among 1,000.

Rare: can affect 1 to 10 patients among 10,000.

Very rare: can affect less than 1 patient in 10,000.

Not known: frequency cannot be estimated from the available data.

Side effects reported in clinical trials for patients treated with Co-Ultesan

Common:

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).

Uncommon:

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.

Uncommon cases of jaundice (jellowing of the skin and/or whites of the eyes) have also been reported.

Not known:

Headache, ringing in the ears, cough, taste disturbance, indigestion, pain in joints and muscles, liver function abnormal and impaired kidney function, increased levels of potassium in your blood and allergic reactions such as rash, hives, swelling of the face, lips, mouth, tongue or throat.

As for any combination of two active substances, side effects associated with each individual component cannot be excluded.

Side effects related to irbesartan alone

Side-effects are usually mild.

Common:

Symptomatic hypotension including dizziness may occur, particularly in patients with intravascular volume depletion (e.g. those taking high-dose diuretics), nausea, vomiting, fatigue, musculoskeletal pain, orthostatic hypotension.

Uncommon:

Chest pain, flushing, tachycardia, cough, diarrhea, dyspepsia, sexual dysfunction.

Rare:

Rash, urticaria, angioedema has also been reported with some angiotensin-II receptor antagonists.

Not known:

Anemia, headache, taste disturbance, hepatitis, tinnitus, myalgia, arthralgia, renal dysfunction, cutaneous vasculitis, hyperkalaemia, anaphylactic reaction including anaphylactic shock, hypoglycaemia, thrombocytopenia.

Side effects associated with hydrochlorothiazide alone

Not known:

Anorexia (loss of appetite), gastric irritation, nausea, vomiting, constipation, diarrhoea, sialadenitis (infection of salivary glands), headache, dizziness, photosensitivity reactions, orthostatic hypotension, paraesthesia, impotence, yellow vision, hypersensitivity reactions including: skin rashes, fever, pulmonary oedema, pneumonitis, anaphylaxis, toxic epidermal necrolysis; lupus erythematosus and cholestatic jaundice, pancreatitis, blood dyscrasias including thrombocytopenia, granulocytopenia, leucopenia, and aplastic and haemolytic anaemia; hyperglycaemia, glucosuria, hyperuricaemia which may precipitate attacks of gout, electrolyte imbalances including: hypochloraemic alkalosis, hyponatraemia, hypokalaemia, hypomagnesaemia, changes in plasma lipids, 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 (chroroidal effusion) or acute angle-closure glaucoma), renal dysfunction, muscle spasms, depression.

Very rare:

Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).

It is known that side effects associated with hydrochlorothiazide may increase with higher doses of hydrochlorothiazide.

If you get any of these side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CO-ULTESAN

Keep out of the reach and sight of children.
Do not use Co-Ultesan after the expiry date which is stated on the package.
Store below 25°C!
Store in the original package in order to protect from light and humidity.

6. FURTHER INFORMATION

What Co-Ultesan contains

The active substances are irbesartan and hydrochlorothiazide.
Each film-coated tablet of Co-Ultesan 150 mg/12.5 mg contains 150 mg irbesartan and 12.5 mg hydrochlorothiazide.
The **excipients** are: cellactose 80, microcrystalline cellulose, partially pregelatinised starch, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, Opadry® II white (consisting of polyvinyl alcohol, titanium dioxide, polyethylene glycol and talc).
Each film-coated tablet of Co-Ultesan 300 mg/12.5 mg contains 300 mg irbesartan and 12.5 mg hydrochlorothiazide.
The **excipients** are: cellactose 80, microcrystalline cellulose, partially pregelatinised starch, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, Opadry® II pink (polyvinyl alcohol, titanium dioxide, polyethylene glycol/macrogol, talc, red iron oxide non-irradiated, yellow iron oxide non-irradiated).

Each film-coated tablet of Co-Ultesan 300 mg/25 mg contains 300 mg irbesartan and 25 mg hydrochlorothiazide.
The **excipients** are: cellactose 80, microcrystalline cellulose, partially pregelatinised starch, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, Opadry® II red

(polyvinyl alcohol, polyethylene glycol/macrogol, titanium dioxide, talc, red iron oxide non-irradiated, yellow iron oxide non-irradiated).

Content of the pack

Co-Ultesan 150 mg/12.5 mg: box with 30 film-coated tablets.

Co-Ultesan 300 mg/12.5 mg: box with 30 film-coated tablets.

Co-Ultesan 300 mg/25 mg: box with 30 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

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