PACKAGE LEAFLET: Information for the patient

ULTESAN

Film-coated tablets – 150 mg, 300 mg

(Irbesartan)

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 ULTESAN IS AND WHAT IT IS USED FOR

Ultesan contains the active substance irbesartan which 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. Ultesan prevents the binding of angiotensin II to these receptors, causing the blood vessels to relax and the blood pressure to lower. Ultesan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Ultesan is used in adult patients:

- to treat high blood pressure (essential hypertension);
- to protect the kidney in patients with high blood pressure, type 2 diabetes and laboratory evidence of impaired kidney function.

Your doctor may have suggested Ultesan for another reason. Ask your doctor if you want to know why you were given Ultesan.

2. BEFORE YOU TAKE ULTESAN

Do not take Ultesan:

- if you are allergic (hypersensitive) to irbesartan or to any of the excipients of Ultesan (listed in section 6);
- if you are more than 3 months pregnant (it is recommended to be avoided even in the first trimester); see the heading "Pregnancy";
- if you are breastfeeding;
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

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

Take special care with Ultesan

Ask your doctor before taking Ultesan:

- if you have excessive vomiting or diarrhea;
- if you suffer from kidney problems;
- if you suffer from heart problems;
- if you receive Ultesan for diabetic kidney disease; in this case your doctor may perform regular blood tests, especially for measuring blood potassium levels in case of poor kidney function;
- if you are going to have an operation (surgery) or be given anaesthetics;
- if you are taking any of the following medicines used to treat high blood pressure:

- an ACE-inhibitor (e.g. enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
- aliskiren.

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 Ultesan").

You must tell your doctor if you think you are (or might become) pregnant.

Use in children

This medicinal product should not be used in children and adolescents because the safety and efficacy have not yet been fully established.

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.

Your doctor may need to change your dose and / or take other precautions if you are taking an ACE inhibitor or aliskiren (see also information under the headings "Do not take Ultesan" and "Take special care with Ultesan").

You may need to have blood checks if you take:

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

If you take certain painkillers, called non-steroidal anti-inflammatory drugs, the effect of irbesartan may be reduced.

Irbesartan must not be taken concomitantly with aliskiren (contraindicated).

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

Taking Ultesan with food and drinks

Ultesan can be taken with or without food.

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Ultesan before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Ultesan. 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 breastfeeding or about to start breastfeeding.
Ultesan is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

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

Important information about some of the excipients of Ultesan

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 ULTESAN

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

Method of administration

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

- *Patients with high blood pressure*

The usual dose is 150 mg once daily. The dose may later be increased to 300 mg once daily depending on blood pressure response.

- *Patients with high blood pressure and type 2 diabetes with kidney disease*

In patients with high blood pressure and type 2 diabetes, the initial dose is 150 mg once daily which can be increased to 300 mg once daily as the preferred maintenance dose for the treatment of associated kidney disease.

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those on haemodialysis, or those over the age of 75 years.

The maximum blood pressure lowering effect may be reached 4-6 weeks after starting treatment.

Use in children and adolescents

Ultesan should not be given to children under 18 years of age. If a child swallows some tablets, contact your doctor immediately.

If you take more Ultesan than you should

If you have accidentally taken more 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 Ultesan

If you forget to take 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 Ultesan

If you feel better, do not stop the 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, irbesartan can cause side effects, although not everybody gets them. Side-effects are usually mild. Some of these effects may be serious and may require medical attention. As with similar medicines, rare cases of allergic skin reactions (rash, urticaria), as well as localized swelling of the face, lips and/or tongue have been reported in patients taking irbesartan. If you get any of these symptoms or get shortness of breath, stop taking Ultesan and contact your doctor immediately.

Very common (may affect more than 1 in 10 people): if you suffer from high blood pressure and type 2 diabetes with kidney disease, blood tests may show an increased level of potassium.

Common (may affect up to 1 in 10 people): dizziness, feeling sick/vomiting, fatigue and blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatine kinase enzyme). In patients with high blood pressure and type 2 diabetes with kidney disease, dizziness when getting up from a lying or sitting position, low blood pressure when getting up from a lying or sitting position, pain in joints or muscles and anemia were also reported.

Uncommon (may affect up to 1 in 100 people): diarrhoea, dyspepsia, flushing, tachycardia, chest pain, cough, and sexual dysfunction.

Side effects with unknown frequency: feeling of spinning, headache, taste disturbance, ringing in the ears, muscle cramps, pain in joints and muscles, reduced number of platelets, abnormal liver function, increased blood potassium levels, impaired kidney function, inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis), and severe allergic reactions (anaphylactic shock). Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.

Tell your doctor or pharmacist if you get these side effects, or any other side effects not listed in this leaflet.

5. HOW TO STORE ULTESAN

Keep out of the reach and sight of children.

Do not use 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 Ultesan contains

The active substance is irbesartan.

Each film-coated tablet contains 150 mg or 300 mg irbesartan.

The excipients are:

*tablet core***:** cellactose 80, microcrystalline cellulose, partially pregelatinised starch, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.

*film-coating***:** polyvinyl alcohol, titanium dioxide, macrogol, talc.

Contents of the pack

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

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

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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This leaflet was last revised in October 2023.