Package leaflet: Information for the patient

Ifirmasta 150 mg film-coated tablets
Irbesartan

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 Ifirmasta is and what it is used for

Ifirmasta belongs to a group of medicines known as angiotensin-II receptor 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. Ifirmasta prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower. Ifirmasta slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Ifirmasta 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.

2. What you need to know before you take Ifirmasta

Do not take Ifirmasta
- if you are **allergic** to irbesartan or any of the other ingredients of this medicine (listed in section 6),
- if you are **more than 3 months pregnant**. (It is also better to avoid Ifirmasta in early pregnancy – see pregnancy section),
- 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 or pharmacist before taking Ifirmasta and **if any of the following apply to you**:
- if you get **excessive vomiting or diarrhoea**,
- if you suffer from **kidney problems,**
- if you suffer from **heart problems**,
- if you receive Ifirmasta 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 (for example 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 Ifirmasta".

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

Children and adolescents
This medicine should not be used in children and adolescents (< 18 years) because the safety and efficacy have not yet been fully established.

Other medicines and Ifirmasta
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 Ifirmasta" and "Warnings and precautions").

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.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

3. How to take Ifirmasta

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

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

- **Patients with high blood pressure**
  The usual dose is 150 mg once a day. The dose may later be increased to 300 mg (two tablets a day) 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, 300 mg (two tablets a day) once daily is 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 maximal blood pressure lowering effect should be reached 4-6 weeks after beginning treatment.

Use in children and adolescents
Ifirmasta 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 Ifirmasta than you should
If you accidentally take too many tablets, contact your doctor immediately.

If you forget to take Ifirmasta
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.

As with similar medicines, 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 these symptoms or get short of breath **stop taking irbesartan and contact your doctor immediately.**

The frequency of the side effects listed below is defined using the following convention:
Very common: may affect more than 1 in 10 people
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 irbesartan were:

- 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, and 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 renal 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 decreased levels of a protein in the red blood cells (haemoglobin) were also reported.

- Uncommon (may affect up to 1 in 100 people): heart rate increased, flushing, cough, diarrhoea, indigestion/heartburn, sexual dysfunction (problems with sexual performance), chest pain.

Some undesirable effects have been reported since marketing of irbesartan. Undesirable effects where the frequency is not known are: 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 renal 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.

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. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ifirmasta

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 Ifirmasta contains
- The active substance is irbesartan. Each film-coated tablet contains 150 mg irbesartan (as hydrochloride).
- The other ingredients are mannitol, hydroxypropylcellulose, low-substituted hydroxypropyl cellulose (LH-21), low-substituted hydroxypropyl cellulose (LH-11), talc, macrogol 6000, castor oil, hydrogenated in the core of tablet and polyvinyl alcohol, titanium dioxide (E171), macrogol 3000 and talc in film-coating.

What Ifirmasta looks like and contents of the pack
Ifirmasta 150 mg film-coated tablets are: white, oval film-coated tablets.

Ifirmasta 150 mg film-coated tablets are available in boxes of 14, 28, 30, 56, 84, 90 and 98 film-coated tablets in blisters and in boxes of 56 x 1 film-coated tablets in perforated unit dose blisters.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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

België/Belgique/Belgien
KRKA Belgium, SA.
Tél/Tel: + 32 (0) 487 50 73 62

България
КРКА България ЕООД
Тел.: + 359 (02) 962 34 50

Česká republika
KRKA ČR, s.r.o.
Tel: + 420 (0) 221 115 150

Danmark
KRKA Sverige AB
Tlf: + 46 (0)8 643 67 66 (SE)

Deutschland
TAD Pharma GmbH
Tel: + 49 (0) 4721 606-0

Eesti
KRKA, d.d., Novo mesto Eesti filiaal
Tel: + 372 (0) 6 671 658

Ελλάδα
ELOGIS PHARMA
Τηλ: + 30 210 4101670

España
KRKA Farmacéutica, S.L.
Tel: + 34 911 61 03 81

France
KRKA France Eurl
Tél: + 33 (0)1 57 40 82 25

Hrvatska
KRKA - FARMA d.o.o.
Tel: + 385 1 6312 100

Ireland
KRKA Pharma Dublin, Ltd.
Tel: + 353 1 293 91 80

Ísland
LYFIS ehf.
Sími: + 354 534 3500

Lietuva
UAB KRKA Lietuva
Tel: + 370 5 236 27 40

Luxembourg/Luxemburg
KRKA Belgium, SA.
Tél/Tel: + 32 (0) 487 50 73 62 (BE)

Magyarország
KRKA Magyarország Kereskedelmi Kft.
Tel.: + 36 (1) 355 8490

Malta
E. J. Busuttil Ltd.
Tel: + 356 21 445 885

Nederland
KRKA Belgium, SA.
Tel: + 32 (0) 487 50 73 62 (BE)

Norge
KRKA Sverige AB
Tlf: + 46 (0)8 643 67 66 (SE)

Österreich
KRKA Pharma GmbH, Wien
Tel: + 43 (0)1 66 24 300

Polska
KRKA-POLSKA Sp. z o.o.
Tel.: + 48 (0)22 573 7500

Portugal
KRKA Farmacêutica, Sociedade Unipessoal Lda.
Tel: + 351 (0)21 46 43 650

România
KRKA Romania S.R.L., Bucharest
Tel: + 4 021 310 66 05

Slovenija
KRKA, d.d., Novo mesto
Tel: + 386 (0) 1 47 51 100

Slovenská republika
KRKA Slovensko, s.r.o.
Tel: + 421 (0) 2 571 04 501

Italia
KRKA Farmaceutici Milano S.r.l.
Tel: + 39 02 3300 8841

Κύπρος
Kipa Pharmacal Ltd.
Τηλ: + 357 24 651 882

Latvija
KRKA Latvija SIA
Tel: + 371 6 733 86 10

Suomi/Finland
KRKA Finland Oy
Puh/Tel: + 358 20 754 5330

Sverige
KRKA Sverige AB
Tel: + 46 (0)8 643 67 66 (SE)

United Kingdom
Consilient Health (UK) Ltd.
Tel: + 44(0)203 751 1888

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