



Leaflet folded on middle with visibly first side (title);  
PhC that comes out of the middle of leaflet must be visible!/  
 - Black U

Article No.: xxxxxx
Article name.: xx PL Irbesartan 75 mg XU
Dimension: 148 ± 0,5 mm x 420 ± 0,8 mm
Material: Woodfree paper 50 g/m <sup>2</sup>
PhC No.: /
Measure: 1:1
Date: 20.06.2022
Prepared by:
Checked by:
Packaging Design

130 mm ± 0,5 mm

direction of reading PhC



**If you take more Irbesartan than you should**

If you accidentally take too many tablets, contact your doctor immediately.

**If you forget to take Irbesartan**

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, decreased number of red blood cells (anaemia – symptoms may include tiredness, headaches, being short of breath when exercising, dizziness and looking pale), 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) severe allergic reactions (anaphylactic shock) and low blood sugar levels. 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 Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Irbesartan**

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 Irbesartan contains**

- The active substance is irbesartan. Each film-coated tablet contains 75 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 Irbesartan looks like and contents of the pack**

Irbesartan 75 mg film-coated tablets are: white, oval film-coated tablets.

Irbesartan 75 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

TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

**This leaflet was last revised in May 2022.**



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direction on fibre

420 mm ± 0,8 mm

130 mm ± 0,5 mm

direction of reading PhC