Package leaflet: Information for the user

Irbesartan STADA 75 mg, filmomhulde tabletten.
Irbesartan STADA 150 mg, filmomhulde tabletten.
Irbesartan STADA 300 mg, filmomhulde tabletten.

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 Irbesartan STADA is and what it is used for

Irbesartan STADA 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. Irbesartan STADA prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower. Irbesartan STADA slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Irbesartan STADA is used in adult patients to:
- treat high blood pressure (essential hypertension)
- 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 Irbesartan STADA

DO NOT take Irbesartan STADA
- if you are allergic to irbesartan or any other ingredients of this medicine (listed in section 6)
- if you are **more than 3 months pregnant.** (It is also better to avoid Irbesartan STADA 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 Irbesartan STADA or 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 Irbesartan STADA 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 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 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 Irbesartan STADA”

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Irbesartan STADA. Your doctor will decide on further treatment. Do not stop taking Irbesartan STADA on your own.
You must tell your doctor if you think you are (or might become) pregnant. Irbesartan STADA 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 medicinal product should not be used in children and adolescents because the safety and efficacy have not yet been fully established.

Other medicines and Irbesartan STADA
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 Irbesartan STADA” 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
- repaglinide (medication used for lowering blood sugar levels)

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

Irbesartan STADA with food and drink
Irbesartan STADA can be taken with or without food.

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.

<u>Pregnancy</u>
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Irbesartan STADA before you become pregnant or as soon

as you know you are pregnant and will advise you to take another medicine instead of Irbesartan STADA. Irbesartan STADA 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.
Irbesartan STADA 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
Irbesartan STADA 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.

Irbesartan STADA contains lactose and sodium
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 medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Irbesartan STADA

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

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

- **Patients with high blood pressure**

Irbesartan STADA 75 mg
The recommended dose is 150 mg once a day (two tablets a day). The dose may later be increased to 300 mg (four tablets a day) once daily depending on blood pressure response.

Irbesartan STADA 150 mg
The recommended dose is 150 mg once a day (one tablet a day). The dose may later be increased to 300 mg (two tablets a day) once daily depending on blood pressure response.

Irbesartan STADA 300 mg
The recommended dose is 150 mg once a day (for this dose other strengths of Irbesartan STADA are available). The dose may later be increased to 300 mg (one tablet a day) once daily depending on blood pressure response.

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

Irbesartan STADA 75 mg
In patients with high blood pressure and type 2 diabetes, 300 mg (four tablets a day) once daily is the recommended maintenance dose for the treatment of associated kidney disease.

Irbesartan STADA 150 mg
In patients with high blood pressure and type 2 diabetes, 300 mg (two tablets a day) once daily is the recommended maintenance dose for the treatment of associated kidney disease.

Irbesartan STADA 300 mg
In patients with high blood pressure and type 2 diabetes, 300 mg (one tablet a day) once daily is the recommended 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
Irbesartan STADA 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 Irbesartan STADA than you should
If you accidentally take too many tablets, contact your doctor immediately.

STADASTADA**If you forget to take Irbesartan STADA**
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 STADA and contact your doctor immediately.**

Side effects reported in clinical studies for patients treated with irbesartan were:STADA
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 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.
Rare (may affect up to 1 in 1 000 people):
intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.

Undesirable effects where the frequency is not known (frequency cannot be estimated from the available data) 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 kidney 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 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 Irbesartan STADA

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.

This medicinal product does not require any special temperature storage conditions.

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 STADA contains

The active substance is irbesartan.

One Irbesartan STADA 75 mg film-coated tablet contains 75 mg irbesartan.
One Irbesartan STADA 150 mg film-coated tablet contains 150 mg irbesartan.
One Irbesartan STADA 300 mg film-coated tablet contains 300 mg irbesartan.

The other ingredients in the tablet core are:

- Lactose monohydrate
- Pregelatinised maize starch
- Copovidone
- Croscarmellose (E468)
- Anhydrous colloidal silica (E551)
- Magnesium stearate (E470b)

The other ingredients in the film coating are:

- Hypromellose (E464)
- Macrogol 400
- Titanium dioxide (E171)

What Irbesartan STADA 75 mg, 150 mg and 300 mg film-coated tablets look like and contents of the pack

Irbesartan STADA 75 mg film-coated tablets are white, biconvex, oval-shaped and approximately 10 mm long.

Irbesartan STADA 150 mg film-coated tablets are white, biconvex, oval-shaped and approximately 13 mm long.

Irbesartan STADA 300 mg film-coated tablets are white, biconvex, oval-shaped and approximately 16 mm long.

Irbesartan STADA 75 mg film coated tablets
Pack sizes of 14, 28, 30, 50, 56 or 98 tablets in PVC/PVDC/aluminium blisters.
Pack sizes of 14 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1 or 98 x 1 tablets in PVC/PVDC/Aluminium perforated unit dose blisters.

Irbesartan STADA 150 mg film coated tablets
Pack sizes of 14, 28, 30, 50, 56 or 98 tablets in PVC/PVDC/aluminium blisters.
Pack sizes of 14 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1 or 98 x 1 film-coated tablets in PVC/PVDC/Aluminium perforated unit dose blisters.

Irbesartan STADA 300 mg film coated tablets
Pack sizes of 14, 28, 30, 50, 56 or 98 tablets in PVC/PVDC/aluminium blisters.
Pack sizes of 14 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1 or 98 x 1 film-coated tablets in PVC/PVDC/Aluminium perforated unit dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

STADA Arzneimittel AG
Stadastrasse 2 – 18
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Duitsland

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and /or

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Roemenië

This medicinal product is authorised in the Member States of the EEA under the following names:

DE: Irbesartan AL 75 mg/150 mg/300 mg Filmtabletten
IT: Irbesartan EG 75 mg/ 150 mg/ 300 mg compresse rivestite con film
NL: Irbesartan STADA 75 mg/ 150 mg/ 300 mg filmomhulde tabletten

Deze bijsluiter is voor de laatste keer goedgekeurd in april 2025.