Package leaflet: Information for the user

Irbesartan/Hydrochloorthiazide STADA 150/12,5 mg, filmomhulde tabletten
Irbesartan/Hydrochloorthiazide STADA 300/12,5 mg, filmomhulde tabletten
Irbesartan/Hydrochloorthiazide STADA 300/25 mg, filmomhulde tabletten

irbesartan/hydrochlorothiazide

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 <PRODUCTNAME> is and what it is used for

<productname> is a combination of two active substances, irbesartan and hydrochlorothiazide. Irbesartan belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body that 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 is one of 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 <productname> work together to lower blood pressure further than if either was given alone.

<productname> is used to treat high blood pressure, when treatment with irbesartan or hydrochlorothiazide alone did not provide adequate control of your blood pressure.

2. What you need to know before you take <productname>

DO NOT take <productname>
- if you are **allergic** to irbesartan or any of the other ingredients of this medicine (listed in section 6)
- if you are **allergic** to hydrochlorothiazide or any other sulfonamide-derived medicines
- if you are **more than 3 months pregnant**. (It is also better to avoid <productname> in early pregnancy – see pregnancy section)
- 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 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.

Warnings and precautions
Talk to your doctor before taking <productname> **if any of the following apply 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 <productname>.
- 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 <productname>, 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 <productname>”

You must tell your doctor if you think you are (or might become) pregnant. <productname> 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 <productname>)
- 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 have **decrease in your vision or pain in one or both of your eyes** while taking <productname>. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye (glaucoma) and can happen within hours to weeks of taking <productname>. 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 <productname> treatment and seek prompt medical attention

< to be included according the national requirement:>
<Anti-doping test: The hydrochlorothiazide contained in this medicine could produce a positive result in an anti-doping test.>

Children and adolescents
<productname> should not be given to children and adolescents (under 18 years).

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

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

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 <productname>” and “Warnings and precautions”).

You may need to have blood checks if you take:
- potassium supplements
- salt substitutes containing potassium
- potassium sparing medicines or other diuretics (water tablets)
- some laxatives
- medicines for the treatment of gout
- therapeutic vitamin D supplements
- medicines to control heart rhythm
- medicines for diabetes (oral agents as repaglinide 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.

<productname> with food and drink
<productname> can be taken with or without food.

Due to the hydrochlorothiazide contained in <productname>, if you drink alcohol while on treatment with this medicine, you may have an increased feeling of dizziness on standing up, especially when getting up from a sitting position.

Pregnancy, breast-feeding and fertility
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking <productname> before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of <productname>. <productname> 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. <productname> 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

<productname> 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.

<productname> 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 <productname>

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

Dosage
<productname> 150 mg/12.5 mg film-coated tablets
The recommended dose of <productname> is one or two tablets a day. <productname> 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 <productname>.

<productname> 300 mg/12.5 mg film-coated tablets and <productname> 300 mg/ 25 mg film-coated tablets
The recommended dose of <productname> is one tablet a day. <productname> 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 <productname>.

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

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

If you take more <productname> than you should
If you accidentally take too many tablets, contact your doctor immediately.

Children should not take <productname>
<productname> should not be given to children under 18 years of age. If a child swallows some tablets, contact your doctor immediately.

If you forget to take <productname>
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.

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.
Very rare (may affect up to 1 in 10,000 people): Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).
If you get any of the above symptoms or get short of breath, stop taking <productname> and contact your doctor immediately.

Side effects reported in clinical studies for patients treated with the combination of irbesartan and hydrochlorothiazide were:

Common side effects *(may affect up to 1 in 10 people):*
- 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).

If any of these side effects causes you problems, talk to your doctor.

Uncommon side effects *(may affect up to 1 in 100 people):*
- 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.

If any of these side effects causes you problems, talk to your doctor.

Side effects reported since the launch of the combination of irbesartan and hydrochlorothiazide
Some undesirable effects have been reported since marketing of irbesartan / hydrochlorothiazide. Undesirable effects where the frequency is not known are: headache, ringing in the ears, cough, taste disturbance, indigestion, pain in joints and muscles, liver function abnormal and impaired kidney function, increased level of potassium in your blood and allergic reactions such as rash, hives, swelling of the face, lips, mouth, tongue or throat. Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.

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

Side effects associated with irbesartan alone
In addition to the side effects listed above, chest pain, severe allergic reactions (anaphylactic shock), decreased number of red blood cells (anaemia – symptoms may include tiredness, headaches, being short of breath when exercising, dizziness and looking pale) and decrease in the number of platelets (a blood cell essential for the clotting of the blood) and low blood sugar levels have also been reported.

Side effects associated with hydrochlorothiazide alone
Loss of appetite; stomach irritation; stomach cramps; constipation; jaundice (yellowing of the skin and/or whites of the eyes); inflammation of the pancreas characterised by severe upper

stomach pain, often with nausea and vomiting; sleep disorders; depression; blurred vision; lack of white blood cells, which can result in frequent infections, fever; decrease in the number of platelets (a blood cell essential for the clotting of the blood), decreased number of red blood cells (anaemia) characterised by tiredness, headaches, being short of breath when exercising, dizziness and looking pale; kidney disease; lung problems including pneumonia or build-up of fluid in the lungs; increased sensitivity of the skin to the sun; inflammation of blood vessels; a skin disease characterised by the peeling of the skin all over the body; cutaneous lupus erythematosus, which is identified by a rash that may appear on the face, neck, and scalp; allergic reactions; weakness and muscle spasm; altered heart rate; reduced blood pressure after a change in body position; swelling of the salivary glands; high sugar levels in the blood; sugar in the urine; increases in some kinds of blood fat; high uric acid levels in the blood, which may cause gout
Not known (frequency cannot be estimated from the available data): 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 (choroidal effusion) or acute angle-closure glaucoma).

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

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 <PRODUCTNAME>

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.

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 <productname> contains
The active substances are irbesartan and hydrochlorothiazide.

<productname> 150 mg/12.5 mg film-coated tablets
Each film-coated tablet of <productname> 150 mg/12.5 mg contains 150 mg irbesartan and 12.5 mg hydrochlorothiazide.

<productname> 300 mg/12.5 mg film-coated tablets
Each film-coated tablet of <productname> 300 mg/12.5 mg contains 300 mg irbesartan and 12.5 mg hydrochlorothiazide.

<productname> 300 mg/25 mg film-coated tablets
Each film-coated tablet of <productname> 300 mg/25 mg contains 300 mg irbesartan and 25 mg hydrochlorothiazide.

The other ingredients are lactose monohydrate, pregelatinised maize starch, copovidone, croscarmellose sodium (E468), colloidal anhydrous silica (E551), magnesium stearate (E470b), hypromellose (E464), titanium dioxide (E171), talc, macrogol 8000, iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172)

What <productname> looks like and contents of the pack
<productname> 150 mg/12.5 mg film-coated tablets
<productname> 150 mg/12.5 mg film-coated tablets are pink, oblong, biconvex film-coated tablets.

<productname> 300 mg/12.5 mg film-coated tablets
<productname> 300 mg/12.5 mg film-coated tablets are pink, oblong, biconvex film-coated tablets.

<productname> 300 mg/25 mg film-coated tablets
<productname> 300 mg/25 mg film-coated tablets are red oblong, biconvex film-coated tablets.

<productname>150 mg/ 12.5 mg film-coated tablets
Pack sizes of 7, 10, 14, 28, 30, 50, 56, 90, 98, and 100 film-coated tablets.

<productname> 300 mg/ 12.5 mg film-coated tablets
Pack sizes of 7, 10, 14, 28, 30, 50, 56, 90, 98, 100, 126, and 154 film-coated tablets.

<productname> 300 mg/ 25 mg film-coated tablets
Pack sizes of 7, 10, 14, 28, 30, 50, 56, 90, 98, 100, 126, and 154 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

STADA Arzneimittel AG
Stadastrasse 2 – 18
61118 Bad Vilbel
Duitsland

Manufacturer

STADA Arzneimittel AG, Stadastr. 2-18, D-61118 Bad Vilbel, Duitsland

In het register ingeschreven onder: RVG 106611, 106612 en 106615

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

Belgium	Irbesartan/HCT EG 150/12.5 mg; 300/12.5 mg; 300/25 mg filmomhulde tabletten
Germany	Irbesartan/HCT STADA 150/12.5 mg; 300/12.5 mg; 300/25 mg Filmtabletten
Denmark	Irbesartan/Hydrochlorthiazid STADA 150/12.5 mg; 300/12.5 mg; 300/25 mg filmovertrukne tabletter
Spain	Irbesartán/Hidroclorotiazida STADA 150/12.5 mg; 300/12.5 mg; 300/25 mg Comprimidos recubiertos con pelicula EFG

France	Irbesartan/Hydrochlorothiazide EG 150/12.5 mg; 300/12.5 mg; 300/25 mg comprimés pelliculés
Luxembourg	Irbesartan/HCT EG 150/12.5 mg; 300/12.5 mg; 300/25 mg comprimés pelliculés
The Netherlands	Irbesartan/Hydrochlorothiazide STADA 150/12.5 mg; 300/12.5 mg; 300/25 mg filmomhulde tabletten
Portugal	Irbesartan + Hidroclorotiazida STADA
Sweden	Irbesartan/Hydrochlorthiazid STADA 150/12.5 mg; 300/12.5 mg; 300/25 mg filmdragerade tabletter

Deze bijsluiter is voor de laatste keer goedgekeurd in april 2022.