Package leaflet: Information for the patient

Irbesartan comp HEXAL® 300/12,5 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 [Nationally completed name] is and what it is used for

[Nationally completed name] is a combination of two active substances, irbesartan and hydrochlorothiazide.

Irbesartan belongs to a group of medicines called angiotensin-II receptor antagonists. These work by widening the blood vessels which in turn lowers the blood pressure.
Hydrochlorothiazide belongs to a group of medicines called diuretics (water tablets).
The two active substances in [Nationally completed name] work together to lower blood pressure further than if either was given alone.

[Nationally completed name] is used in the treatment of high blood pressure (hypertension), 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 [Nationally completed name]
Do NOT take [Nationally completed name] if you:
- are **allergic to irbesartan, hydrochlorothiazide or any of the other ingredients** of this medicine (listed in section 6)
- are **allergic to sulphonamide-derived substances** (e.g. other thiazides, some antibacterial medicines such as co-trimoxazole, ask your doctor if you are not sure)

- are **more than 3 months pregnant**. (It is also better to avoid [Nationally completed name] in early pregnancy – see pregnancy section)
- have severely **impaired liver** function
- have severely **impaired kidney** function or your kidneys are not producing any urine
- have condition which is associated with **persistently high calcium** or **low potassium** levels in your blood
- have **diabetes or impaired kidney function** and you are treated with a blood pressure lowering medicine containing aliskiren.

Children and adolescents
[Nationally completed name] should not be given to children and adolescents under 18 years.

Warnings and precautions
These tablets are not generally recommended in the following cases if you:
- have **primary aldosteronism** (Conn's syndrome), **a tumour of the adrenal gland** associated with muscle weakness, excessive thirst and frequent urination
- have **liver or kidney problems**
- are also taking **lithium** for mental health problems (see also 'Other medicines and [Nationally completed name]' below)
- are taking **aliskiren**, a medicine to treat high blood pressure.

You must tell your doctor if you think that you are (<u>or might become</u>) pregnant. [Nationally completed name] 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).

Talk to your doctor or pharmacist 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**
- take diuretics **(water pills)**
- are on a **salt-restricted diet**
- have or have had **severe vomiting** and/or **diarrhoea**
- have **heart failure**
- have **narrow arteries to your kidneys** (renal artery stenosis)
- have recently had a **kidney transplant**
- have 'aortic or mitral valve stenosis' **(narrowing of the valves of the heart)** or 'hypertrophic cardiomyopathy' (a disease causing **thickening of heart muscle)**
- are **diabetic**
- have a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus also known as **lupus** or **SLE**)
- get **photosensitivity reaction** (sensitivity of the skin to the sun) while on treatment
- have **high calcium** or **potassium levels** or you are on a **low potassium diet**
- need **an anaesthetic** (even at the dentist) or before surgery

- 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 [Nationally completed name])
- experience a **decrease in vision or eye pain**. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking [Nationally completed name]. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulphonamide allergy, you can be at higher risk of developing this. You should discontinue [Nationally completed name] treatment and seek medical attention.
- 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 [Nationally completed name].
- 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 [Nationally completed name], 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 [Nationally completed name]".

Talk to your doctor if you are an **athlete taking a doping test**, as [Nationally completed name] contain an active substance that can cause positive results in a doping test.

Other medicines and [Nationally completed name]
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:
- **lithium** (a medicine for **treatment of mania** or **depression**)
- **ACE-inhibitor** or **aliskiren** (see also information under the headings "Do not take [Nationally completed name]" and "Warnings and precautions")
- **potassium supplements**
- **potassium-containing salt** substitutes
- **potassium-sparing medicines**
- 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 or insulins)
- **steroids**
- medicines to **treat cancer**
- **pain killers** or **arthritis medicines**
- **colestyramine and colestipol resins** for lowering blood cholesterol
- **carbamazepine** (a medicine for **the treatment of epilepsy**).

[Nationally completed name] with food and drink

Do not drink alcohol whilst taking these tablets because alcohol and [Nationally completed name] may increase each other's effects. 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.

Dietary salt in excessive quantities may counteract the effect of these tablets.

[Nationally completed name] may 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.

Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking [Nationally completed name] before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of [Nationally completed name]. [Nationally completed name] is not recommended during 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. [Nationally completed name] 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
[Nationally completed name] 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.

[Nationally completed name] 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.

[Nationally completed name] contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take [Nationally completed name]

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

[Nationally completed name] will be prescribed by your doctor when your previous treatment for high blood pressure did not reduce your blood pressure sufficiently.
Your doctor will instruct you how to switch from the previous treatment to these tablets.

Use in adults and elderly
The usual dose is one tablet once daily.

Use in children and adolescents (under 18 years)
[Nationally completed name] is not recommended for use in children and adolescents under 18 years of age.

Take your tablet with a glass of water, preferably at the same time each day, with or without a meal.

If you take more [Nationally completed name] than you should
If you take too many tablets, contact your nearest hospital casualty department or tell your doctor immediately. If this happens you may experience symptoms of low blood pressure such as dizziness or faintness, and lying down with the legs raised can help.

If you forget to take [Nationally completed name]
It is important to take your medicine every day. However, if you forget to take one or more doses, take it as soon as you remember and then continue with your normal schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking [Nationally completed name]
Always consult your doctor, if you wish to stop taking this medicine. Even if you feel well, it may be necessary to continue taking this medicine.

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.

If you notice any of the following side effects, contact your doctor immediately:
- swelling of the face, lips, mouth, tongue eyes or throat (angioedema)
- difficulty breathing, dizziness (severe hypersensitivity)

These are symptoms of serious allergic reaction they must be treated **immediately**, usually in a hospital.
- acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion), this is a very rare side effect (may affect up to 1 in 10,000 people)

Contact your doctor immediately also in case of:
- jaundice (yellow skin and/or eyes)

Other side effects

Common (may affect up to 1 in 10 people):
- dizziness
- nausea/vomiting
- abnormal urination
- fatigue
- increases in blood urea nitrogen, creatinine and creatine kinase

Uncommon (may affect up to 1 in 100 people):
- diarrhoea
- dizziness when standing up
- fainting low blood pressure
- elevated heart rate
- swelling
- flushing
- sexual problems, libido changes
- low blood levels of potassium and sodium

Not known (frequency cannot be estimated from the available data):
- skin rash, hives, itching
- high potassium blood levels
- headache
- ringing, buzzing, roaring or clicking in the ears
- cough
- indigestion (dyspepsia)
- loss of appetite
- changed liver function or hepatitis (inflammation of liver)
- pain in joints and muscles
- impaired kidney function

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 glucose 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 characterized 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; short sightedness, 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); skin and lip cancer (non-melanoma skin cancer).

It is also 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.

[*For the printed material, please refer to the guidance of the annotated QRD template.]

5. How to store [Nationally completed name]

Keep out this medicine of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister, carton and bottle after "EXP". The expiry date refers to the last day of that month.

PVC/PVDC/ALU blisters:
Do not store above 25 °C.
Store in the original package in order to protect from moisture.

ALU/ALU blisters:
Store in the original package in order to protect from moisture.

NL/H/1579/002 only
HDPE bottles:
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 [Nationally completed name] contains

The active substances are irbesartan and hydrochlorothiazide.
Each film-coated tablet contains 300 mg of irbesartan and 12.5 mg of hydrochlorothiazide.

The other ingredients are:
Tablet core: Microcrystalline cellulose, lactose monohydrate (see end of the section 2 for further information), croscarmellose sodium, colloidal anhydrous silica, hypromellose 3 mPas, silicified microcrystalline cellulose and magnesium stearate.
Film-coating: Hypromellose 6 mPas, hydroxypropylcellulose, macrogol 6000, lactose monohydrate (see end of the section 2 for further information), titanium dioxide (E 171), iron oxide (yellow and red) (E 172) and talc.

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] is an apricot, oval biconvex film-coated tablet, debossed with 300H on one side.

NL/H/1579/002

The film-coated tablets are packed in PVC/PDVC/ALU blisters or ALU/ALU blisters and inserted in a carton or are packed in a HDPE bottle with a PP screw cap and silica gel desiccant.

Pack sizes:
PVC/PVDC/ALU blister:
7, 10, 14, 20, 28, 30, 49, 50, 56, 60, 84, 90, 98, 100 film-coated tablets.

ALU/ALU blister:
7, 10, 14, 20, 28, 30, 49, 50, 56, 60, 84, 90, 98, 100 film-coated tablets.

HDPE bottle:
100 film-coated tablets.

NL/H/1581/002

The film-coated tablets are packed in PVC/PDVC/ALU blisters or ALU/ALU blisters and inserted in a carton.

PVC/PVDC/ALU blister:
7, 10, 14, 20, 28, 30, 49, 50, 56, 60, 90, 98, 100 film-coated tablets.

ALU/ALU blister:
7, 10, 14, 20, 28, 30, 49, 50, 56, 60, 90, 98, 100 film-coated tablets.

NL/H/1582/002

The film-coated tablets are packed in PVC/PDVC/ALU blisters or ALU/ALU blisters and inserted in a carton.

PVC/PVDC/ALU blister:
7, 10, 14, 20, 28, 30, 49, 50, 56, 60, 90, 98, 100 film-coated tablets.

ALU/ALU blister:
7, 10, 14, 20, 28, 30, 49, 50, 56, 60, 90, 98, 100 film-coated tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Hexal AG
Industriestrasse 25
83607 Holzkirchen
Duitsland

Fabrikanten
Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

Salutas Pharma GmbH
Otto-von Guericke Allee 1
39179 Barleben
Duitsland

Lek Pharmaceuticals d.d.
Trimlini 2D
9220 Lendava
Slovenië

LEK S.A.
ul. Domaniewska 50 C
02-672 Warschau
Polen

In het register ingeschreven onder:
RVG 107107.

Dit geneesmiddel is geregistreerd in de lidstaten van de EEA onder de volgende namen:
Duitsland: Irbesartan comp HEXAL 300 mg/12,5 mg Filmtabletten
Nederland: Irbesartan comp HEXAL 300/12,5 mg, filmomhulde tabletten
Luxemburg: Irbesartan comp HEXAL 300 mg/12,5 mg Filmtabletten

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024