PACKAGE LEAFLET

Package leaflet: Information for the user

Irbesartan/Hydroklortiazid Actavis 150 mg/12.5 mg film-coated tablets.
Irbesartan/Hydroklortiazid Actavis 300 mg/12.5 mg film-coated tablets.
Irbesartan/Hydroklortiazid Actavis 300 mg/25 mg film-coated tablets.
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 /…/ is and what it is used for

/.../ 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 /.../ work together to lower blood pressure further than if either was given alone.

/.../ is used in the treatment of high blood pressure (essential 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 /…/

Do not take /.../
- if you are **allergic** to irbesartan, hydrochlorothiazide, any of the other ingredients of this medicine (listed in section 6) or to medicines chemically related to sulfonamide (ask your doctor or pharmacist for further clarification)
- if you are **more than** 3 months **pregnant**. (It is also better to avoid /…/ in early pregnancy – see Warnings and precautions and Pregnancy section)
- if you have **severe liver** or **kidney problems**
- if you have **difficulty in producing urine**
- if you have a condition which is associated with **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 using /…/
- 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 /.../.
- 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 /.../, 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 /…/”

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking /…/. Your doctor will decide on further treatment. Do not stop taking /…/ on your own.

You must tell your doctor if you think that you are (or might become) pregnant. /.../ 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 /.../)
- 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 **changes in your vision or pain in one or both of your eyes** while taking /…/. This could be a sign of fluid accumulation in the vascular layer of the eye (choroidal effusion) or that you are developing glaucoma, increased pressure in your eye(s). You should discontinue /…/ treatment and seek medical attention.

Hydrochlorothiazide contained in this medicine could produce a positive result in an anti-doping test.

Children and adolescents
/.../ should not be given to children and adolescents (under 18 years).

Other medicines and /…/

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 /.../ may have an effect on other medicines. Preparations containing lithium should not be taken with /.../ without close supervision by your doctor.

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, colestyramine and colestipol resins to reduce cholesterol in your blood, nondepolarizing skeletal muscle relaxants (e.g. tubocurarine), anticholinergic agents (e.g. atropine, beperiden) or amantadine.

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 /…/” and “Warnings and precautions”)

/.../ with food, drink and alcohol
/.../ can be taken with or without food.

Due to the hydrochlorothiazide contained in /.../, 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 and breast-feeding
Pregnancy
You must tell your doctor if you think that you are (or might become) pregnant. Your doctor will normally advise you to stop taking /…/ before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of /.../. /.../ 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. /…/ 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.

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.

Driving and using machines
/.../ 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.

/…/ **contains sodium**

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

3. How to take /…/

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

Dosage
The recommended dose of /.../ is one tablet or two tablets [*only for 150/12.5 mg tablets*] a day. /.../ will usually be prescribed by your doctor when your previous treatment for high blood pressure did not provide appropriate blood pressure reduction. Your doctor will instruct you how to switch from the previous treatment to /.../.

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

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

Use in children and adolescents
/.../ should not be given to children and adolescents under 18 years of age. If a child swallows some tablets, contact your doctor immediately.

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

If you forget to take /.../
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 these symptoms or get short of breath, stop taking /.../ and contact your doctor immediately.

Side effects reported in clinical studies for patients treated with /.../ were:

Common (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).

Uncommon (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.
- yellowing of the skin and/or whites of the eyes (jaundice).

Not known (frequency cannot be estimated from the available data):
- headache,
- ringing in the ears,
- cough,
- taste disturbance,
- indigestion,
- pain in joints and muscles,
- liver function abnormal,
- inflammation of the liver causing yellowing of the skin or eyes,
- impaired kidney function,
- kidney failure,
- increased level of potassium in your blood,
- allergic reactions such as rash, hives, swelling of the face, lips, mouth, tongue or throat.

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, the following has also been reported:
- **Uncommon** (may affect up to 1 in 100 people): Chest pain.
- **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.
- **Not known** (frequency cannot be estimated from the available data): Decreased number of red blood cells (anaemia – symptoms may include tiredness, headaches, being short of breath when exercising, dizziness and looking pale), decrease in the number of platelets (a blood cell essential for the clotting of the blood), severe allergic reactions (anaphylactic shock), low blood sugar levels.

Side effects associated with hydrochlorothiazide alone
Not known (frequency cannot be estimated from the available data):
Loss of appetite; stomach irritation; diarrhoea; constipation; jaundice seen as 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; yellow 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; dizziness at height; numbness, tingling or pins and needles; light-headedness; restlessness; electrolyte imbalance (including hypokalaemia and hyponatraemia); changes in vision or pain in one or both eyes (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 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 /…/

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 tablet container, carton and on the blister after EXP. The expiry date refers to the last day of that month.

Al/PVDC/PVC blister packaging: Do not store above 25°C
HDPE tablet containers with desiccant: This medicinal product does not require any special 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 /…/ contains
- The active substances are irbesartan and hydrochlorothiazide. Each film-coated tablet contains 150 mg of irbesartan and 12.5 mg of hydrochlorothiazide.Each film-coated tablet contains 300 mg of irbesartan and 12.5 mg of hydrochlorothiazide. Each film-coated tablet contains 300 mg of irbesartan and 25 mg of hydrochlorothiazide.
- The other ingredients are:
  Tablet core: mannitol (E-421), povidone (K29-32 or equivalent), microcrystalline cellulose, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate*;*
  Film-coat: polyvinyl alcohol, titanium dioxide (E-171), macrogol 3350, talc, iron oxide yellow (E-172), iron oxide red (E-172), iron oxide black (E-172) {only for /…/ 300 mg/12.5 mg and /…/ 300/25 mg film-coated tablets}.

What /…/ looks like and contents of the pack
/.../ 150 mg/12.5 mg film-coated tablets.
Pink, biconvex, oval-shaped, 6.5 x 12.7 mm film-coated tablet with a H engraved on one side and I on the other side.
/.../ 300 mg/12.5 mg film-coated tablets.
Pink, biconvex, oval-shaped, 8.2 x 16.0 mm film-coated tablet with a H engraved on one side and I on the other side.
/.../ 300 mg/25 mg film-coated tablets.
Dark pink, biconvex, oval-shaped, 8.2 x 16.0 mm film-coated tablet with a H engraved on one side and I on the other side.

Al/PVDC/PVC blister packaging: 14, 28, 30, 56, 60, 98 and 100 film-coated tablets

HDPE tablet container: 100, 250 and 500 film-coated tablets
The tablet container contains a desiccant, do not swallow the desiccant.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

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

<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in 2026-01-15.