

PATIENT INFORMATION LEAFLET (PIL)

IRBIS-HT 300/12.5 (Irbesartan and Hydrochlorothiazide Tablets 300 mg/12.5 mg)

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

What is in this leaflet

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1. WHAT IRBESARTAN HYDROCHLOROTHIAZIDE TABLETS ARE AND WHAT THEY ARE USED FOR

Irbesartan Hydrochlorothiazide tablets 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 Irbesartan Hydrochlorothiazide tablets work together to lower blood pressure further than if either was given alone.

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Irbesartan Hydrochlorothiazide tablets 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 Irbesartan Hydrochlorothiazide tablets if you

- are **allergic** to irbesartan or hydrochlorothiazide, or any of the other ingredients of this medicine, or to medicines chemically related to sulfonamide (ask your doctor or pharmacist for further clarification).
- are **more than 3 months pregnant**. (It is also better to avoid Irbesartan Hydrochlorothiazide tablets in **early pregnancy**).
- have **severe liver or kidney problems**.
- have **difficulty in producing urine**.
- have a 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**

Warnings and precautions

Talk to your doctor before using Irbesartan Hydrochlorothiazide tablets:

- 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 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.

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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 Hydrochlorothiazide tablets”

You must tell your doctor if you think that you are (or might become) pregnant. Irbesartan Hydrochlorothiazide tablets 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.

You should also tell your doctor if you:

- are on a **low-salt diet**
- 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 Irbesartan Hydrochlorothiazide tablets)
- 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
- are going to have an **operation** (surgery) or be given **anaesthetics**
- have changes in your vision or pain in one or both of your eyes while taking Irbesartan Hydrochlorothiazide tablets. This could be a sign that you are developing **glaucoma**, increased pressure in your eye(s). You should discontinue Irbesartan Hydrochlorothiazide tablets treatment and seek medical attention.

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

Children and adolescents

Irbesartan hydrochlorothiazide should not be given to children and adolescents (under 18 years).

Other medicines and Irbesartan Hydrochlorothiazide tablets

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

You may need to have blood checks if you take:

- potassium supplements
- salt substitutes containing potassium

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- 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 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 Irbesartan Hydrochlorothiazide tablets”)

Irbesartan Hydrochlorothiazide tablets with food, drink and alcohol

Irbesartan Hydrochlorothiazide tablets can be taken with or without food.

Due to the hydrochlorothiazide contained in Irbesartan Hydrochlorothiazide tablets, 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 Irbesartan Hydrochlorothiazide tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Irbesartan Hydrochlorothiazide tablets. Irbesartan Hydrochlorothiazide tablets 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. Irbesartan Hydrochlorothiazide tablets is not recommended for mothers who are breast-feeding, and your

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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

No studies on the effects on the ability to drive and use machines have been performed. Irbesartan Hydrochlorothiazide tablets 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.

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 is one 150mg/12.5mg, 300mg/12.5mg or 300mg/25mg tablet a day or two 150mg/12.5mg tablets a day. Irbesartan Hydrochlorothiazide tablets 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 Irbesartan Hydrochlorothiazide tablets.

Method of administration

Irbesartan Hydrochlorothiazide tablets is for oral use. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take Irbesartan Hydrochlorothiazide tablets 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 Hydrochlorothiazide tablets 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

Irbesartan Hydrochlorothiazide tablets 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 Irbesartan Hydrochlorothiazide tablets than you should

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

If you forget to take Irbesartan Hydrochlorothiazide tablets

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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 Hydrochlorothiazide tablets and contact your doctor immediately.

Side effects reported in clinical studies for patients treated with Irbesartan Hydrochlorothiazide tablets were:

- **Common (may affect up to 1 in 10 people):** nausea/vomiting, abnormal urination, fatigue and dizziness (including when getting up from a lying or sitting position) and 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 and 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 and 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. In patients taking irbesartan alone, in addition to the side effects listed above, chest pain has also been reported.

Additional side effects associated with the other component of Irbesartan Hydrochlorothiazide tablets (hydrochlorothiazide) alone are: loss of appetite; stomach irritation; stomach cramps; constipation; jaundice seen as yellowing of the skin and/or whites of the eyes; inflammation of the

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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; dizziness at night; 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.

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. Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at www.mhra.gov.uk/yellowcard. Alternatively you can call Freephone 0800 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy.

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/PVC/ PVDC and Al/PVC/PE/PVDC blister packaging: Store below 30° C and 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.

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6. CONTENTS OF THE PACK AND OTHER INFORMATION

What IIRBIS-HT 300/12.5 (rbesartan and Hydrochlorothiazide Tablets 300 mg/12.5 mg) contains

The active substance is Irbesartan and Hydrochlorothiazide.

Each film coated tablet contains Irbesartan Ph.Eur 300 mg

Hydrochlorothiazide Ph.Eur 12.5 mg

- The other ingredients are:
- Cellulose, Microcrystalline (Avicel PH 101), Carmellose Calcium (Calcium CMC) (ECG-505), Povidone K-30 (Kollidon-30), Purified Water, Silica, Colloidal Anhydrous (Aerosil-200), Calcium Stearate (Synpro VG) and Opadry II Pink 32F84768.

What IRBIS-HT 150/12.5 (Irbesartan and Hydrochlorothiazide Tablets 300 mg/12.5 mg) looks like and contents of the pack

Pink coloured, capsule shaped, biconvex film coated tablets, debossed with '199' on one side and 'I' on the other side.

IRBIS-HT 150/12.5 (Irbesartan and Hydrochlorothiazide Tablets 300 mg/12.5 mg) are available in blister packs of:

10's pack – 25 microns Al.foil, 250 microns white opaque PVC/ PVdC film

10's pack – 25 microns Al.foil, 250 microns white opaque PVC/25 microns PE/40 GSM PVdC

Name and full physical address of Marketing Authorization Holder and Manufacturing site

Marketing Authorization Holder

Name: Hetero Labs Limited
Business Address: 7-2-A2, Hetero Corporate,
Industrial Estates, Sanath
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