

## Irbesartan Hydrochlorothiazide 150mg/12.5mg, 300mg/12.5mg and 300mg/25mg Film-coated Tablets

**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.
- The full name of this product is Irbesartan Hydrochlorothiazide 150mg/12.5mg, 300mg/12.5mg and 300mg/25mg Film-coated Tablets, but within the leaflet it will be referred to as Irbesartan Hydrochlorothiazide tablets.

**What is in this leaflet:**

- 1 What Irbesartan Hydrochlorothiazide tablets are and what they are used for**
- 2 What you need to know before you take Irbesartan Hydrochlorothiazide tablets**
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### **1 What Irbesartan Hydrochlorothiazide tablets are and what they are used for**

Irbesartan Hydrochlorothiazide tablets are 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.

Irbesartan Hydrochlorothiazide tablets are 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 Irbesartan Hydrochlorothiazide tablets** **Do not take Irbesartan Hydrochlorothiazide tablets if you:**

- are **allergic** to irbesartan or hydrochlorothiazide, or 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).
- are **more than 3 months pregnant**. It is also better to avoid Irbesartan Hydrochlorothiazide tablets in **early pregnancy** – see “Warnings and precautions” and Pregnancy section.
- 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 or pharmacist before taking Irbesartan Hydrochlorothiazide tablets if you:

- get excessive **vomiting** or **diarrhoea**
- suffer from **kidney problems**, or have had a kidney transplant
- suffer from **heart problems**
- suffer from **liver problems**
- suffer from **diabetes**
- suffer from **lupus erythematosus** (also known as lupus or SLE)
- 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)
- 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.
- 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 cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Irbesartan Hydrochlorothiazide tablets

- 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 a week of taking Irbesartan Hydrochlorothiazide tablets. 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.

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 are 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**
- have signs such as abnormal **thirst, dry mouth, general weakness, drowsiness, muscle pain or cramps, nausea, vomiting**, or an abnormally **fast heartbeat** 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**.

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

#### **Children and adolescents**

Irbesartan Hydrochlorothiazide tablets 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
- 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, non-depolarising skeletal muscle relaxants (e.g. tubocurarine), anticholinergic agents (e.g. atropine, biperiden) 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” and “Warnings and precautions”).

#### **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 are 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 are 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

No studies on the effects on the ability to drive and use machines have been performed. Irbesartan Hydrochlorothiazide tablets are unlikely to affect your ability to drive or use machines. However, occasionally dizziness or weariness may occur during treatment for high blood pressure. If you experience these, talk to your doctor before attempting to drive or use machines.

### Information on sodium content

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

## 3 How to take Irbesartan Hydrochlorothiazide tablets

Always take this medicine exactly as your doctor or pharmacist 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 on how to switch from the previous treatment to Irbesartan Hydrochlorothiazide tablets.

### Method of administration

Irbesartan Hydrochlorothiazide tablets are 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

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 (creatinine 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, 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 the following have also been reported:

- **Uncommon** (may affect up to 1 in 100 people): chest pain.
- **Not known** (frequency cannot be estimated from the available data): severe allergic reactions (anaphylactic shock), decrease in the number of platelets (a blood cell essential for the clotting of the blood).

Additional **side effects associated with** the other component of Irbesartan Hydrochlorothiazide tablets (**hydrochlorothiazide**) alone are:

- **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 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 height; numbness, tingling or pins and needles; light-headedness; restlessness; electrolyte imbalance (including hypokalaemia and hyponatraemia); 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 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Irbesartan Hydrochlorothiazide tablets

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

Do not take 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 Irbesartan Hydrochlorothiazide tablets contain

- The active substances are irbesartan and hydrochlorothiazide.

Each Irbesartan Hydrochlorothiazide 150mg/12.5mg film-coated tablet contains 150mg of irbesartan and 12.5mg hydrochlorothiazide.

Each Irbesartan Hydrochlorothiazide 300mg/12.5mg film-coated tablet contains 300mg of irbesartan and 12.5mg of hydrochlorothiazide. Each Irbesartan Hydrochlorothiazide 300mg/25mg film-coated tablet contains 300mg of irbesartan and 25mg of hydrochlorothiazide.

The other ingredients are:

- Tablet core: mannitol (E421), povidone (K29-32 or equivalent), microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.
- Film-coat: polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc, iron oxide yellow (E172), iron oxide red (E172). Irbesartan Hydrochlorothiazide 300mg/12.5mg and 300mg/25mg film-coated tablets also contain iron oxide black (E172).

### What Irbesartan Hydrochlorothiazide tablets look like and contents of the pack

Irbesartan Hydrochlorothiazide 150mg/12.5mg film-coated tablets are pink, biconvex, oval-shaped, 6.5 x 12.7mm film-coated tablet with an H engraved on one side and I on the other side.

Irbesartan Hydrochlorothiazide 300mg/12.5mg film-coated tablets are pink, biconvex, oval-shaped, 8.2 x 16.0mm film-coated tablet with an H engraved on one side and I on the other side.

Irbesartan Hydrochlorothiazide 300mg/25mg film-coated tablets are dark pink, biconvex, oval-shaped, 8.2 x 16.0mm film-coated tablet with an H engraved on one side and I on the other side.

Pack sizes: 28 film-coated tablets.

### Marketing Authorisation Holder

Accord, Barnstaple, EX32 8NS, UK

### Manufacturer

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