

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Irbea 75 mg film-coated tablets

Irbesartan

**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 Irbea is and what it is used for
- 2- What you need to know before you take Irbea
- 3- How to take Irbea
- 4- Possible side effects
- 5- How to store Irbea
- 6- Contents of the pack and other information

#### **1. What Irbea is and what it is used for**

Irbea belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels causing them to tighten. This results in an increase in blood pressure. Irbea prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower. Irbea slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Irbea is used in adult patients

- To treat high blood pressure (essential hypertension).
- To protect the kidney in patients with high blood pressure, type 2 diabetes and laboratory evidence of impaired kidney function.

#### **2. What you need to know before you take Irbea**

Do not take Irbea

- If you are **allergic** to irbesartan or any other ingredients of this medicine (listed in section 6).
- If you are **more than 3 months pregnant**. (It is also better to avoid Irbea in early pregnancy - see pregnancy section).
- **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 Irbea and **if any of the following apply to you:**

- If you get **excessive vomiting or diarrhoea**.

- If you suffer from **kidney problems**.
- If you suffer from **heart problems**.
- If you receive irbea for **diabetic kidney disease**. In this case your doctor may perform regular blood tests, especially for measuring blood potassium levels in case of poor kidney function.
- If you are **going to have an operation** (surgery) or **be given anaesthetics**.
- 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.

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 Irbea".

You must tell your doctor if you think you are (or might become) pregnant. Irbea 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).

### **Children and adolescents**

This medicinal product should not be used in children and adolescents because the safety and efficacy have not yet been fully established.

### **Other medicines and Irbea**

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 an ACE-inhibitor or aliskiren (see also information under the headings "Do not take Irbea" and "Warnings and precautions").

### **You may need to have blood checks if you take:**

- Potassium supplements.
- Salt substitutes containing potassium.
- Potassium-sparing medicines (such as certain diuretics).
- Medicines containing lithium.

If you take certain painkillers, called non-steroidal anti-inflammatory drugs, the effect of irbesartan may be reduced.

### **Irbea with food and drink**

Irbea can be taken with or without food.

### **Pregnancy and breast-feeding**

#### **Pregnancy**

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Irbea before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Irbea. Irbea 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 breastfeeding. Irbea is not recommended for mothers who are breastfeeding, 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**

No studies on the effects on the ability to drive and use machines have been performed. Irbea 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.

**Irbea contains lactose.** 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 may produce stomach problems and diarrhoea as it contains hydrogenated castor oil.

This medicine does not contain gluten.

### **3. How to take Irbea**

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

#### **Method of administration**

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

#### **- Patients with high blood pressure**

The usual dose is 150 mg once a day. The dose may later be increased to 300 mg once daily depending on blood pressure response.

#### **- Patients with high blood pressure and type 2 diabetes with kidney disease**

In patients with high blood pressure and type 2 diabetes, 300 mg once daily is the preferred maintenance dose for treatment of associated kidney disease.

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those on haemodialysis, or those over the age of 75 years.

The maximal blood pressure lowering effect should be reached 4-6 weeks after beginning treatment.

#### **Use in children and adolescents**

Irbea should not be given to children under 18 years of age. If a child swallows some tablets, contact your doctor immediately.

**If you take more Irbea than you should:**

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

**If you forget to take Irbea:**

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 Irbea and contact your doctor immediately**.

The frequency of the side effects listed below is defined using the following convention:

Very common: may affect more than 1 in 10 people.

Common: may affect up to 1 in 10 people.

Uncommon: may affect up to 1 in 100 people.

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

- Very common (may affect more than 1 in 10 people): if you suffer from high blood pressure and type 2 diabetes with kidney disease, blood tests may show an increased level of potassium.
- Common (may affect up to 1 in 10 people): dizziness, feeling sick/ vomiting, fatigue and blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatinine kinase enzyme). In patients with high blood pressure and type 2 diabetes with kidney disease, dizziness when getting up from a lying or sitting position, low blood pressure when getting up from a lying or sitting position, pain in joints or muscles and decreased levels of a protein in the red blood cells (haemoglobin) were also reported.
- Uncommon (may affect up to 1 in 100 people): heart rate increased, flushing, cough, diarrhoea, indigestion/heartburn, sexual dysfunction (problems with sexual performance), chest pain.

Some undesirable effects have been reported since marketing of Irbea. Undesirable effects where the frequency is not known are: feeling of spinning, headache, taste disturbance, ringing in the ears, muscle cramps, pain in joints and muscles, abnormal liver function, increased blood potassium levels, impaired kidney function, and inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis). Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.

#### 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.

By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Irbea**

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. Content of the pack and other information**

##### **What Irbea contains**

- The active substance is irbesartan. Each tablet of Irbea 75 mg contains 75 mg irbesartan.
- The other ingredients are: povidone (E-1201), magnesium stearate (E-470b), microcrystalline cellulose (E-460), lactose monohydrate, croscarmellose sodium, colloidal anhydrous silica, hydrogenated castor oil and maize starch.

##### **What Irbea looks like and contents of the pack**

Irbea 75 mg white film-coated tablets

Each package contains 28 tablets, in 7-tablets blister packs.

##### **Marketing Authorisation Holder:**

Laboratorios Cinfa, S.A.

Olaz-Chipi, 10 - Poligono Industrial Areta

31620 Huarte-Pamplona (Navarra) - Spain

##### **Manufacturer:**

Laboratorios Cinfa, S.A.

Olaz-Chipi, 10 - Poligono Industrial Areta

31620 Huarte-Pamplona (Navarra) - Spain

**This leaflet was last revised in 09/2014.**

#### **This is a Medicament**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

– Keep all medicaments out of reach of children.

**Council of Arab Health Ministers**  
**Union of Arab Pharmacists**

**Package leaflet: Information for the user**  
**Irbea 150 mg film-coated tablets**  
Irbesartan

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**1. What Irbea is and what it is used for**

Irbea belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels causing them to tighten. This results in an increase in blood pressure. Irbea prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower. Irbea slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Irbea is used in adult patients

- to treat high blood pressure (essential hypertension)
- to protect the kidney in patients with high blood pressure, type 2 diabetes and laboratory evidence of impaired kidney function.

**2. What you need to know before you take Irbea**

Do not take Irbea

- if you are **allergic** to irbesartan or any other ingredients of this medicine (listed in section 6)
- if you are **more than 3 months pregnant**. (It is also better to avoid Irbea in early pregnancy – see pregnancy section)
- **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 Irbea and **if any of the following apply to you:**

- if you get **excessive vomiting or diarrhoea**
- if you suffer from **kidney problems**
- if you suffer from **heart problems**
- if you receive Irbea for **diabetic kidney disease**. In this case your doctor may perform regular

blood tests, especially for measuring blood potassium levels in case of poor kidney function

- if you are **going to have an operation** (surgery) or **be given anaesthetics**
- 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

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 Irbea”.

You must tell your doctor if you think you are (or might become) pregnant. Irbea 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).

### **Children and adolescents**

This medicinal product should not be used in children and adolescents because the safety and efficacy have not yet been fully established.

### **Other medicines and Irbea**

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 an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Irbea” and “Warnings and precautions”).

### **You may need to have blood checks if you take:**

- potassium supplements
- salt substitutes containing potassium
- potassium-sparing medicines (such as certain diuretics)
- medicines containing lithium

If you take certain painkillers, called non-steroidal anti-inflammatory drugs, the effect of irbesartan may be reduced.

### **Irbea with food and drink**

Irbea can be taken with or without food.

### **Pregnancy and breast-feeding**

#### **Pregnancy**

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Irbea before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Irbea. Irbea 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. Irbea 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**

No studies on the effects on the ability to drive and use machines have been performed. Irbea 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.

**Irbea contains lactose.** 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 may produce stomach problems and diarrhoea as it contains hydrogenated castor oil.

This medicine does not contain gluten.

### **3. How to take Irbea**

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

#### **Method of administration**

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

- **Patients with high blood pressure**

The usual dose is 150 mg once a day. The dose may later be increased to 300 mg (two tablets a day) once daily depending on blood pressure response.

- **Patients with high blood pressure and type 2 diabetes with kidney disease**

In patients with high blood pressure and type 2 diabetes, 300 mg (two tablets a day) once daily is the preferred maintenance dose for the treatment of associated kidney disease.

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those on haemodialysis, or those over the age of 75 years.

The maximal blood pressure lowering effect should be reached 4-6 weeks after beginning treatment.

#### **Use in children and adolescents**

Irbea should not be given to children under 18 years of age. If a child swallows some tablets, contact your doctor immediately.

#### **If you take more Irbea than you should:**

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

#### **If you forget to take Irbea:**

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 Irbea and contact your doctor immediately.**

The frequency of the side effects listed below is defined using the following convention:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

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

- Very common (may affect more than 1 in 10 people): if you suffer from high blood pressure and type 2 diabetes with kidney disease, blood tests may show an increased level of potassium.
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Some undesirable effects have been reported since marketing of Irbea. Undesirable effects where the frequency is not known are: feeling of spinning, headache, taste disturbance, ringing in the ears, muscle cramps, pain in joints and muscles, abnormal liver function, increased blood potassium levels, impaired kidney function, and inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclastic vasculitis). Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.

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

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Irbea**

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. Content of the pack and other information**

### **What Irbea contains**

- The active substance is irbesartan. Each tablet of Irbea 150 mg contains 150 mg irbesartan.
- The other ingredients are: povidone (E-1201), magnesium stearate (E-470b), microcrystalline cellulose (E-460), lactose monohydrate, croscarmellose sodium, colloidal anhydrous silica, hydrogenated castor oil and maize starch.

**What Irbea looks like and contents of the pack**

Irbea 150 mg film-coated tablets are white scored tablets.  
Each package contains 28 tablets, in 7-tablets blister packs.

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31620 Huarte – Pamplona (Navarra) – Spain

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- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

**Council of Arab Health Ministers  
Union of Arab Pharmacists**

**Package leaflet: Information for the user**  
**Irbea 300 mg film-coated tablets**  
Irbesartan

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Irbea is used in adult patients

- to treat high blood pressure (essential hypertension)
- to protect the kidney in patients with high blood pressure, type 2 diabetes and laboratory evidence of impaired kidney function.

**2. What you need to know before you take Irbea**

**Do not take Irbea**

- if you are **allergic** to irbesartan or any other ingredients of this medicine (listed in section 6)
- if you are **more than 3 months pregnant**. (It is also better to avoid Irbea in early pregnancy – see pregnancy section)
- **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 Irbea and **if any of the following apply to you:**

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- if you suffer from **kidney problems**
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### **5. How to store Irbea**

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. Content of the pack and other information**

#### **What Irbea contains**

- The active substance is irbesartan. Each tablet of Irbea 300 mg contains 300 mg irbesartan.
- The other ingredients are: povidone (E-1201), magnesium stearate (E-470b), microcrystalline cellulose (E-460), lactose monohydrate, croscarmellose sodium, colloidal anhydrous silica, hydrogenated castor oil and maize starch.

#### **What Irbea looks like and contents of the pack**

Irbea 300 mg film-coated tablets are white scored tablets. Each package contains 28 tablets, in 7-tablets blister packs.

#### **Marketing Authorisation Holder:**

Laboratorios Cinfa, S.A.  
Olaz-Chipi, 10 – Polígono Industrial Areta  
31620 Huarte – Pamplona (Navarra) – Spain

**Manufacturer:**

Laboratorios Cinfa, S.A.  
Olaz-Chipi, 10 – Polígono Industrial Areta  
31620 Huarte – Pamplona (Navarra) – Spain

This leaflet was last revised in 09/2014.

**This is a Medicament**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

**Council of Arab Health Ministers  
Union of Arab Pharmacists**