

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Cinfaval 80 mg film-coated tablets VALSARTAN

#### **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, 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **What is in this leaflet:**

1. What **Cinfaval 80 mg tablets** is and what it is used for
2. What you need to know before you take **Cinfaval 80 mg tablets**
3. How to take **Cinfaval 80 mg tablets**
4. Possible side effects
5. How to store **Cinfaval 80 mg tablets**
6. Further information

#### **1. What Cinfaval 80 mg is and what it is used for**

**Cinfaval** belongs to a class of medicines known as angiotensin II receptor antagonists, which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase. **Cinfaval** works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

**Cinfaval** can be used for three different conditions:

- To treat high blood pressure. High blood pressure increases the workload on the heart and arteries. If not treated it can damage the blood vessels of the brain, heart, and kidneys, and may result in a stroke, heart failure, or kidney failure. High blood pressure increases the risk of heart attacks. Lowering your blood pressure to normal reduces the risk of developing these disorders.
- To treat people after a recent heart attack (myocardial infarction). “Recent” here means between 12 hours and 10 days.
- To treat symptomatic heart failure.

valsartan is used when a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors (a medication to treat heart failure) cannot be used or it may be used in addition to ACE inhibitors when beta blockers (another medication to treat heart failure) cannot be used. Heart failure symptoms include shortness of breath, and swelling of the feet and legs due to fluid build-up. It is caused when the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body.

#### **2. What you need to know before you take Cinfaval 80 mg film-coated tablets**

**Do not use Cinfaval**

- if you are allergic (hypersensitive) to valsartan or to any of the other ingredients of **Cinfaval**;
- if you suffer severe liver disease.
- if you are more than 3 months pregnant (it is also preferable to avoid Cinfaval in early pregnancy – see pregnancy section).

### **Take special care with Cinfaval**

Inform your doctor if you:

- If you have a liver disease;
- If you have severe kidney disease or if you are undergoing dialysis.
- If you are suffering from a narrowing of the kidney artery
- If you have recently undergone kidney transplantation (received a new kidney).
- If you are treated after a heart attack or for heart failure, your doctor may check your kidney function.
- If you have severe heart disease other than heart failure or heart attack
- if you are taking medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin. It may be necessary to check the amount of potassium in your blood at regular intervals.
- if you suffer from aldosteronism. This is a disease in which your adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of valsartan is not recommended.
- if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water pills (diuretics).
- the use of valsartan in children and adolescents is not recommended (below the age of 18 years).
- If you are pregnant, think you may be pregnant, or are planning to have a baby you must tell your doctor. Use of **Cinfaval** is not recommended at the start of pregnancy (first 3 months) and you must not take it in the last 6 months of pregnancy because it can cause serious damage to your baby, see section on Pregnancy and breast-feeding.

### **If any of these apply to you, tell your doctor before you take Cinfaval**

#### **Taking other medicines**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, including medicines obtained without a prescription.

The effect of the treatment can be influenced if valsartan is taken together with certain other medicines. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This applies to both prescription and non-prescription medicines, especially:

- Other medicines that lower blood pressure, particularly water pills (diuretics).
- Medicines that increase the amount of potassium in your blood. These include potassium-sparing medicines, potassium supplements or salt substitutes containing potassium and heparin.
- **Certain type of pain killers** called non-steroidal anti-inflammatory medicines (**NSAIDs**).
- Lithium, a medicine used to treat some types of psychiatric illness.

#### **In addition:**

- if you are being **treated after a heart attack**, a combination with **ACE inhibitors** (a medication to treat heart attack) is not recommended.
- if you are being **treated for heart failure**, a triple combination with **ACE inhibitors and beta blockers** (medications to treat heart failure) is not recommended.

### **Taking Cinfaval with food and drink**

**Cinfaval** can be administered with or without food.

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

Ask your doctor or pharmacist for advice before taking any medicine.

- **You must tell your doctor if you think that you are (or might become) pregnant.** Your doctor will normally advise you to stop taking Valsartan before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Valsartan. Valsartan 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 it is used after the third month of pregnancy.
- **Tell your doctor if you are breast-feeding or about to start breast-feeding.** Valsartan 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**

Before you drive a vehicle, use tools or operate machines, or carry out other activities that require concentration, make sure you know how Valsartan affects you. Like many other medicines used to treat high blood pressure, Valsartan may in rare cases cause dizziness and affect the ability to concentrate.

### **Important information about some of the ingredients of Cinfaval**

This medicine contains the sugars lactose and sorbitol. If your doctor has told you that you suffer intolerance to some sugars, ask him or her before taking this medicine.

## **3. How to take Cinfaval 80 mg tablets**

Always take **Cinfaval** exactly as your doctor has told you in order to get the best results and reduce the risk of side effects.

People with high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with the doctor even if you are feeling well.

#### **High blood pressure**

The usual dose of **Cinfaval** is 80 mg once daily. In some cases, the doctor may prescribe higher doses (e.g., 160 mg) or adding another drug (e.g., a diuretic).

#### After a recent heart attack:

After a heart attack, treatment is usually started at 12 hours, usually at a low dose of 20 mg twice daily. Your doctor will increase the dose gradually over several weeks to a maximum of 160 mg twice daily. **Cinfaval** can be administered together with other treatments for heart attacks. Your doctor will decide what treatment is the most suitable for you. The final dose will depend on your particular tolerance. The 20 mg dose can be obtained by dividing the 40 mg tablet.

### Heart failure

The standard starting dose is 40 mg twice daily. Your doctor will then progressively increase the dose over several weeks to a maximum of 160 mg. The final dose depends on what you as an individual patient can tolerate.

valsartan can be given together with other treatment for heart failure, and your doctor will decide which treatment is suitable for you.

You can take **Cinfaval** with or without food. Swallow **Cinfaval** with a glass of water. Take **Cinfaval** at about the same time each day.

### **If you take more Cinfaval than you should**

If you think you or anyone else has taken more **Cinfaval** than they should, ask your doctor or pharmacist immediately or go to the nearest hospital.

A dose that is too high can cause severe dizziness or fainting.

### **If you forget to take Cinfaval**

Do not take a double dose to make up a forgotten dose.

If you forget taking one dose, take it as soon as you remember. However, if it almost time for the next dose, wait for the next dose and take it at the usual time.

### **If you stop taking Cinfaval**

Stopping your treatment with Valsartan may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

If you have any further questions about the use of this product, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, **Cinfaval** can cause side effects, although not everybody gets them.

These side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data.

### **Some symptoms require immediate medical attention:**

You might experience symptoms of angioedema such as:

- swollen face, tongue or throat;
- difficulty in swallowing;
- hives and breathing difficulties.

**If you get any of these, see a doctor immediately**

**Other side effects include:**

**Common:**

- dizziness, postural dizziness
- low blood pressure with symptoms such as dizziness
- decreased kidney function (signs of renal impairment)

**Uncommon:**

- allergic reaction with symptoms such as rash, itching, dizziness, swelling of face or lips or tongue or throat, difficulty breathing or swallowing (signs of angioedema)
- sudden loss of consciousness
- spinning sensation
- severely decreased kidney function (signs of acute renal failure)
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- headache
- cough
- abdominal pain
- nausea
- diarrhoea
- tiredness
- weakness

**Not known:**

- rash, itching, together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms (signs of serum sickness)
- purplish-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis)
- unusual bleeding or bruising (signs of thrombocytopenia)
- muscle pain (myalgia)
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia)
- decrease of level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can, in severe cases, lead to anaemia)
- increase of level of potassium in the blood (which can, in severe cases, trigger muscle spasms, abnormal heart rhythm)
- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can, in severe cases, trigger yellow skin and eyes)
- increase of level of blood urea nitrogen and increase of level of serum creatinine (which can indicate abnormal kidney function)

The frequency of some side effects may vary depending on your condition. For example, side effects such as dizziness, and decreased kidney function, were seen less frequently in patients treated with high blood pressure than in patients treated for heart failure or after a recent heart attack.

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

**5. How to store Cinfaval 80 mg tablets**

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

Store below 30°C.

Do not use **Cinfaval** after the expiry date which is stated on the container after “EXP”. The expiry date refers to the last day of that month.

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 to protect the environment.

## **6. Other information**

**Cinfaval** is supplied as film-coated tablets.

### **What Cinfaval contains**

The active substance is valsartan. Each tablet contains 80 mg of valsartan.

The other ingredients are:

Tablet core: microcrystalline cellulose (E-460), colloidal anhydrous silica, sorbitol (E-420), magnesium carbonate (E-504), pregelatinised starch, povidone (E-1201), sodium stearyl fumarate, sodium lauryl sulphate and crospovidone.

Coating: Opadry OY-L-28900 (lactose monohydrate, hypromellose (E-464), titanium dioxide (E-171), macrogol).

**Cinfaval 80 mg** contains red iron oxide (E-172).

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

**Cinfaval 80 mg** are scored, pink, cylindrical, coated tablets.

**Cinfaval 80 mg** is supplied in packages containing 28 tablets (in 7 tablets blister-packs)

### **Marketing Authorisation Holder and Manufacturer:**

LABORATORIOS CINFA, S.A.  
Olaz-Chipi, 10 – Polígono Areta  
31620 Huarte-Pamplona (Navarra)

**This leaflet was approved in December 2012**

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Cinfaval 160 mg film-coated tablets VALSARTAN

#### **Read all of this leaflet carefully before you start taking this medicine**

- Keep this leaflet. You may need to read it again.
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- 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.
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#### **What is in this leaflet:**

1. What **Cinfaval 160 mg tablets** is and what it is used for
2. What you need to know before you take **Cinfaval 160 mg tablets**
3. How to take **Cinfaval 160 mg tablets**
4. Possible side effects
5. How to store **Cinfaval 160 mg tablets**
6. Further information

#### **1. What Cinfaval 160 mg is and what it is used for**

**Cinfaval** belongs to a class of medicines known as angiotensin II receptor antagonists, which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase. **Cinfaval** works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

**Cinfaval** can be used for three different conditions:

- To treat high blood pressure. High blood pressure increases the workload on the heart and arteries. If not treated it can damage the blood vessels of the brain, heart, and kidneys, and may result in a stroke, heart failure, or kidney failure. High blood pressure increases the risk of heart attacks. Lowering your blood pressure to normal reduces the risk of developing these disorders.
- To treat people after a recent heart attack (myocardial infarction). “Recent” here means between 12 hours and 10 days.
- To treat symptomatic heart failure. **valsartan** is used when a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors (a medication to treat heart failure) cannot be used or it may be used in addition to ACE inhibitors when beta blockers (another medication to treat heart failure) cannot be used.  
Heart failure symptoms include shortness of breath, and swelling of the feet and legs due to fluid build-up. It is caused when the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body.

#### **2. What you need to know before you take Cinfaval 160 mg film-coated tablets**

**Do not use Cinfaval**

- if you are allergic (hypersensitive) to valsartan or to any of the other ingredients of **Cinfaval**;
- if you suffer severe liver disease.
- if you are more than 3 months pregnant (it is also preferable to avoid Cinfaval in early pregnancy – see pregnancy section).

### **Take special care with Cinfaval**

Inform your doctor if you:

- if you have a liver disease;
- If you have severe kidney disease or if you are undergoing dialysis.
- If you are suffering from a narrowing of the kidney artery
- If you have recently undergone kidney transplantation (received a new kidney).
- If you are treated after a heart attack or for heart failure, your doctor may check your kidney function.
- If you have severe heart disease other than heart failure or heart attack
- if you are taking medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin. It may be necessary to check the amount of potassium in your blood at regular intervals.
- 
- if you suffer from aldosteronism. This is a disease in which your adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of valsartan is not recommended.
- if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water pills (diuretics).
- the use of valsartan in children and adolescents is not recommended (below the age of 18 years).
- If you are pregnant, think you may be pregnant, or are planning to have a baby you must tell your doctor. Use of **Cinfaval** is not recommended at the start of pregnancy (first 3 months) and you must not take it in the last 6 months of pregnancy because it can cause serious damage to your baby, see section on Pregnancy and breast-feeding.

**If any of these apply to you, tell your doctor before you take**

### **Taking other medicines**

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The effect of the treatment can be influenced if Valsartan is taken together with certain other medicines. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This applies to both prescription and non-prescription medicines, especially:

- Other medicines that lower blood pressure, particularly water pills (diuretics).
- Medicines that increase the amount of potassium in your blood. These include potassium-sparing medicines, potassium supplements or salt substitutes containing potassium and heparin.
- **certain type of pain killers** called non-steroidal anti-inflammatory medicines (**NSAIDs**).
- Lithium, a medicine used to treat some types of psychiatric illness.

### **In addition:**

- if you are being **treated after a heart attack**, a combination with **ACE inhibitors** (a medication to treat heart attack) is not recommended.

- if you are being **treated for heart failure**, a triple combination with **ACE inhibitors and beta blockers** (medications to treat heart failure) is not recommended.

#### **Taking Cinfaval with food and drink**

**Cinfaval** can be administered with or without food.

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

Ask your doctor or pharmacist for advice before taking any medicine.

- **You must tell your doctor if you think that you are (or might become) pregnant.** Your doctor will normally advise you to stop taking Valsartan before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Valsartan. Valsartan 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 it is used after the third month of pregnancy.
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#### **Driving and using machines**

Before you drive a vehicle, use tools or operate machines, or carry out other activities that require concentration, make sure you know how Valsartan affects you. Like many other medicines used to treat high blood pressure, Valsartan may in rare cases cause dizziness and affect the ability to concentrate.

#### **Important information about some of the ingredients of Cinfaval**

This medicine contains the sugars lactose and sorbitol. If your doctor has told you that you suffer intolerance to some sugars, ask him or her before taking this medicine.

### **3. How to take Cinfaval 160 mg tablets**

Always take **Cinfaval** exactly as your doctor has told you in order to get the best results and reduce the risk of side effects.

People with high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with the doctor even if you are feeling well.

High blood pressure The usual dose of **Cinfaval** is 80 mg once daily. In some cases, the doctor may prescribe higher doses (e.g., 160 mg) or adding another drug (e.g., a diuretic).

After a recent heart attack: After a heart attack, treatment is usually started at 12 hours, usually at a low dose of 20 mg twice daily. Your doctor will increase the dose gradually over several weeks to a maximum of 160 mg twice daily. **Cinfaval** can be administered together with other treatments for heart attacks. Your doctor will decide what treatment is the most suitable for you. The final dose will depend on your particular tolerance. The 20 mg dose can be obtained by dividing the 40 mg tablet.

### Heart failure

The standard starting dose is 40 mg twice daily. Your doctor will then progressively increase the dose over several weeks to a maximum of 160 mg. The final dose depends on what you as an individual patient can tolerate.

Valsartan can be given together with other treatment for heart failure, and your doctor will decide which treatment is suitable for you.

You can take **Cinfaval** with or without food. Swallow **Cinfaval** with a glass of water. Take **Cinfaval** at about the same time each day.

### **If you take more Cinfaval than you should**

If you think you or anyone else has taken more **Cinfaval** than they should, ask your doctor or pharmacist immediately or go to the nearest hospital.

### **If you forget to take Cinfaval**

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If you forget taking one dose, take it as soon as you remember. However, if it is almost time for the next dose, wait for the next dose and take it at the usual time.

### **If you stop taking Cinfaval**

Stopping your treatment with Valsartan may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

If you have any further questions about the use of this product, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, **Cinfaval** can cause side effects, although not everybody gets them.

These side effects may occur with certain frequencies, which are defined as follows:

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### **Some symptoms require immediate medical attention:**

You might experience symptoms of angioedema such as:

- swollen face, tongue or throat;
- difficulty in swallowing;
- hives and breathing difficulties.

**If you get any of these, see a doctor immediately**

### **Other side effects include:**

#### **Common:**

- dizziness, postural dizziness

- low blood pressure with symptoms such as dizziness
- decreased kidney function (signs of renal impairment)

**Uncommon:**

- allergic reaction with symptoms such as rash, itching, dizziness, swelling of face or lips or tongue or throat, difficulty breathing or swallowing (signs of angioedema)
- sudden loss of consciousness
- spinning sensation
- severely decreased kidney function (signs of acute renal failure)
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- headache
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- abdominal pain
- nausea
- diarrhoea
- tiredness
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**Not known**

- rash, itching, together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms (signs of serum sickness)
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- unusual bleeding or bruising (signs of thrombocytopenia)
- muscle pain (myalgia)
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia)
- decrease of level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can, in severe cases, lead to anaemia)
- increase of level of potassium in the blood (which can, in severe cases, trigger muscle spasms, abnormal heart rhythm)
- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can, in severe cases, trigger yellow skin and eyes)
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**5. How to store Cinfaval 160 mg tablets**

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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 to protect the environment.

## **6. Other information**

**Cinfaval** is supplied as film-coated tablets.

### **What Cinfaval contains**

The active substance is valsartan. Each tablet contains 160 mg of valsartan.

The other ingredients are:

Tablet core: microcrystalline cellulose (E-460), colloidal anhydrous silica, sorbitol (E-420), magnesium carbonate (E-504), pregelatinised starch, povidone (E-1201), sodium stearyl fumarate, sodium lauryl sulphate and crospovidone.

Coating: Opadry OY-L-28900 (lactose monohydrate, hypromellose (E-464), titanium dioxide (E-171), macrogol).

**Cinfaval 160 mg** contains yellow/brown iron oxide (E-172).

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

**Cinfaval 160 mg** are scored, ochre coloured, cylindrical, coated tablets.

**Cinfaval 160 mg** is supplied in packages containing 28 tablets (in 7 tablets blister-packs).

### **Marketing Authorisation Holder and Manufacturer:**

LABORATORIOS CINFA, S.A.  
Olaz-Chipi, 10 – Polígono Areta  
31620 Huarte-Pamplona (Navarra)

**This leaflet was approved in December 2012**

**This is medicament**

- A medicament is a product which affects your health, and its consumption contrary to instruction is dangerous for you.
- Strictly follow the doctor's prescription, the method of use, and the instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt the treatment period without consulting your physician.
- Do not repeat the same prescription without consulting your doctor.
- Keep medication out of reach & sight of children

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