

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cinfaval 40 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 40 mg tablets** is and what it is used for
2. What you need to know before you take **Cinfaval 40 mg tablets**
3. How to take **Cinfaval 40 mg tablets**
4. Possible side effects
5. How to store **Cinfaval 40 mg tablets**
6. Contents of the pack and other information

1. What Cinfaval 40 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 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, have recently taken or might take any other medicines, 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 indicated that you suffer intolerance to certain sugars, ask him or her before taking this medicine.

3. How to take Cinfaval 40 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.

After a heart attack, treatment is generally 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 jointly 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.

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

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 twice daily. 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.

- 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 40 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. Contents of the pack and other information

Cinfaval is supplied as film-coated tablets.

What Cinfaval contains

The active substance is valsartan. Each tablet contains 40 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) and macrogol) and yellow iron oxide (E-172).

What Cinfaval looks like and contents of the pack

Cinfaval 40 mg tablets coated, cylindrical, yellow, scored tablets.

Cinfaval 40 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.**

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cinfaival 80 mg film-coated tablets VALSARTAN

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

1. What Cinfaival 80 mg is and what it is used for

Cinfaival 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. **Cinfaival** works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

Cinfaival 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 Cinfaival 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 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:

- 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.
- 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.
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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 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 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

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 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:

- 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 160 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 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 Industrial 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.**

PACKAGE LEAFLET: INFORMATION FOR THE USER
Cinfaval 320 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 symptoms 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** 320 mg is and what it is used for
- 2 What you need to know before you take **Cinfaval** 320 mg
- 3 How to take **Cinfaval** 320 mg
- 4 Possible side effects
- 5 How to store **Cinfaval** 320 mg
- 6 Further information

1. What Cinfaval 320 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. Valsartan works by blocking the effect of the angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

Cinfaval 320 mg film-coated tablets can be used

- to treat high blood pressure. High blood pressure increases the workload on the heart and the 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.

2. What you need to know before you take Cinfaval 320 mg

Do not take Cinfaval:

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

If any of these situations affect you, do not take **Cinfaval**.

Take special care with Cinfaval:

- if you have a liver disease;
- if you have a serious 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 heart failure, your doctor may check your kidney function;

- if you have a 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 produce a high amount of the hormone aldosterone. If this applies to you, the use of **Cinfaval** is not recommended;
- if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting or high doses of water pills (diuretics).
- Valsartan is not recommended for use in children and adolescents (below 18 years of age).
- You must inform your doctor if you think you are pregnant (or that you could be pregnant). Use of valsartan is not recommended at the start of pregnancy and you must not take it if you are more than 3 months pregnant because it can cause serious damage to your baby if used at this stage (see section on pregnancy).

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

Cinfaval If any of these situations affect you, inform your doctor before taking **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.

The effect of treatment with valsartan can be altered if taken with certain medicines. In these cases, it may prove necessary to change the dose, take other precautions or, in some cases, discontinue treatment of some of the medicines. This applies both to prescription and non-prescription medicines, especially:

- other medicines that lower blood pressure, especially water pills (diuretics);
- medicines that increase the amount of potassium in blood. These include potassium-supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin;
- some medicines to treat pain called non-steroidal anti-inflammatory drugs (NSAIDs);
- lithium, a medicine used to treat certain types of psychiatric illnesses.

Taking Cinfaval with food and drink

You can take valsartan 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 you are (or might become pregnant). Your doctor will normally advise you to stop taking valsartan before getting pregnant or as soon as you know you are pregnant and you will be advised to take another medicine in place of valsartan. Use of valsartan is not recommended at the start of pregnancy and you must not take it if you are more than 3 months pregnant because it can cause serious damage to your baby if used after the third month of pregnancy.

- Tell your doctor if you are breast-feeding or about to start breast-feeding. Use of valsartan is not recommended in breast-feeding mothers and your doctor can choose another treatment for you if you want to start breast-feeding, especially if your baby is newborn or was premature.

Driving and using machines

Before driving a vehicle, using tools or operate machines, or carrying out any other activities that require concentration ensure you know how valsartan affects you. As with many medicines used to treat high blood pressure, on rare cases valsartan can 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 you doctor has indicated that you suffer intolerance to some sugars, ask him or her before taking this medicine.

3. How to take Cinfaval 320 mg

To obtain the best results and reduce the risk of side effects, always take Cinfaval exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. People with high blood pressure do not usually notice any sign of the illness; many feel normal. This makes it very important to attend appointments with your doctor, even if you feel well.

High blood pressure:

The starting dose is 80 mg daily. In some cases your doctor may prescribe higher doses (e.g. 160 mg or 320 mg). Valsartan can also be combined with another medicine (e.g. a diuretic).

You can take valsartan without food. Swallow valsartan with a glass of water. Take valsartan at approximately the same time each day.

If you take more Cinfaval that 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 to take a dose, take it as soon as you remember. However, if it is nearly 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 on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

These side effects can occur with certain frequencies, defined below:

- very common: affects more than 1 in 10 patients;
- common: affects between 1 and 10 in every 100 patients;
- uncommon: affects between 1 and 10 in every 1000 patients;
- rare: affects between 1 and 10 in every 10,000 patients;
- very rare: affects less than 1 in every 10,000 patients;
- not known frequency: the frequency cannot be estimated from the available data.

Some symptoms require immediate medical attention:

You may experience symptoms of angioedema such as

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

If you experience any of these symptoms, consult a doctor immediately.

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 reactions including rash, itching, dizziness, swelling of the 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, muscular pain, swollen lymph nodes and/or flu-like symptoms (signs of serum sickness);
- purplish-red spots, fever, itching (signs of inflammation of the blood vessels, also called vasculitis);
- unusual bleeding or bruising (signs of thrombocytopenia);
- muscle pain (myalgia);
- fever, sore throat or mouth ulcers from infections (symptoms of a low level of white blood cells, also called neutropenia);
- decrease of level of haemoglobin and decrease of the percentage of red blood cells in blood (which can in severe cases, lead to anaemia),
- increase of the level of potassium in the blood (which can, in severe cases trigger muscle spasms and an 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).

The frequency of some side effects can vary depending on your condition. For example, some side effects such as dizziness and decrease 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 320 mg

Do not store at a temperature above 30°C. Store in the original packaging.

Keep out of the sight and reach of children.

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

Do not use **Cinfaval** if you notice that the package is damaged or there are signs of deterioration.

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. Other information

What Cinfaval 320 mg contains

The active substance is valsartan. Each tablet contains 320 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) and macrogol), red/brown iron oxide (E-172) and indigo carmine blue lacquer.

What the product looks like and contents of the pack

Cinfaval 320 mg are scored, greyish-purple, oblong coated tablets.

Cinfaval 320 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 Industrial Areta
31620 Huarte-Pamplona (Navarra)

This package leaflet was approved on 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

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