

Package leaflet: Information for the user

Co-Cinfaval 80 mg/12.5 mg film-coated tablets VALSARTAN HYDROCHLOROTHIAZIDE

Read 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 symptoms are the same as yours.
- If any of the side effects gets serious talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. What Co-Cinfaval is and what it is used for

valsartan/hydrochlorothiazide film-coated tablets contain two active substances known as valsartan and hydrochlorothiazide. These components help to control high blood pressure (hypertension).

- **Valsartan** belongs to a class of medicines known as “angiotensin II receptor antagonists” that help to control high blood pressure. Angiotensin II is a bodily substance that causes vessels to tighten, causing an increase in blood pressure. Valsartan works by blocking the effect of angiotensin II. This makes the blood vessels relax and blood pressure decrease.
- **Hydrochlorothiazide** belongs to a class of medicines known as thiazide diuretics (also known as “water tablets”). Hydrochlorothiazide increases urine output, which also helps reduce blood pressure.

valsartan/hydrochlorothiazide is used to treat high blood pressure when it cannot be properly controlled through the use of a single substance.

Hypertension (high blood pressure) increases the workload on the heart and the arteries. If it is not treated, it can damage the blood vessels to the brain, heart and kidneys and can cause a stroke, heart failure or kidney failure. High blood pressure increases the risk of heart attacks. Reducing blood pressure to normal values reduces the risk of developing these disorders.

2. What you need to know before you take Co-Cinfaval

Do not take Co-Cinfaval:

- if you are allergic (hypersensitive) to valsartan, hydrochlorothiazide, sulphonamide derivatives (substances chemically related to hydrochlorothiazide) or any of the other ingredients in **valsartan/hydrochlorothiazide**.
- if you are **more than 3 months pregnant**. (In any case, it is also preferable to avoid taking this medicine at the start of pregnancy; see the section on Pregnancy).
- if you have a **serious** liver disease.
- if you suffer from a **severe** renal disease.
- If you have **severe** kidney disease

- if you have difficulties urinating.
- if you are treated with an artificial kidney.
- if you have potassium or sodium blood levels that are lower than normal, or if the level of calcium in your blood is higher than normal, despite treatment.
- if you have gout.

If any of these situations affects you, do not take this medicine and consult your doctor.

Warnings and precautions

- if you are taking potassium-sparing medicines, potassium supplements, salt substitutes that contain potassium or other medicines that may increase potassium blood levels, such as heparin. Your doctor may need to monitor potassium levels regularly.
- if you have low potassium blood levels.
- if you experience severe vomiting or diarrhoea.
- if you are taking high doses of a diuretic.
- if you suffer from serious heart disease.
- if you have a narrowing (stenosis) of the kidney artery.
- if you have recently received a kidney transplant.
- if you suffer from hyperaldosteronism, a disease where the adrenal glands produce a high amount of the hormone aldosterone. In this case, taking **valsartan/hydrochlorothiazide** is not recommended.
- if you suffer from a kidney or liver disease.
- if you have fever, skin rash and joint pain, which could be signs of systemic lupus erythematosus (a so-called autoimmune disease).
- if you have diabetes, gout, high cholesterol or fats in your blood.
- if you have experienced an allergic reaction in the past to the use of another medicine of this class used to reduce blood pressure (angiotensin II receptor antagonists), or if you have any other allergies or asthma.
- it may cause increased skin sensitivity when exposed to sunlight.

Co-Cinfaval is not recommended for use in children and adolescents (under 18 years of age).

If you are pregnant, think you may be pregnant, or are planning to have a baby you must tell your doctor. Use of **Co-Cinfaval** is not recommended at the start of pregnancy (first 3 months) and you must not take it after the third month of pregnancy because it can cause serious damage to your baby, see section on Pregnancy.

Other medicines and Co-Cinfaval

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 treatment with **Co-Cinfaval** 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 is particularly applicable to the following medicines:

- lithium, a medicine used to treat certain types of psychiatric illnesses
- medicines that may affect or be affected by potassium blood levels, such as digoxin, a medicine used to control heart rhythm, certain antipsychotic medicines
- medicines that may increase potassium blood levels, such as potassium supplements, salt substitutes that contain potassium, potassium-sparing medicines, heparin
- medicines that may decrease potassium blood levels, such as corticosteroids, certain laxatives

- diuretics (water tablets), medicines for treating gout, such as allopurinol, therapeutic vitamin D and calcium supplements, medicines for treating diabetes (oral antidiabetics or insulin).
- other medicines for reducing blood pressure, such as beta-blockers or methyldopa, or medicines that tighten your blood vessels or stimulate the heart, such as noradrenaline and adrenaline
- medicines to increase blood sugar levels, such as diazoxide
- medicines used to treat cancer, such as methotrexate and cyclophosphamide
- medicines used to treat pain
- arthritis medicines
- muscle relaxants such as the tubocurarine
- anticholinergic drugs, such as atropine or biperiden
- amantadine (a medicine used to prevent influenza)
- cholestyramine and colestipol (medicines used to treat high levels of fats in blood)
- cyclosporine, a medicine used to prevent organ transplant rejection
- certain antibiotics (tetracyclines), anaesthetics and sedatives
- carbamazepine, a medicine used to treat seizures conditions.

Co-Cinfaval with food and drink

Co-Cinfaval can be taken with or without food.

Avoid drinking alcohol until you have checked with your doctor. Alcohol can reduce your blood pressure even more and/or increase the possibility of dizziness and feeling of weakness.

Pregnancy and breast-feeding

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

- **If you are pregnant, think you may be pregnant, or are planning to have a baby you must tell your doctor.** In general, your doctor will advise you to stop taking **Co-Cinfaval** before getting pregnant or as soon as you are pregnant and you will be advised to take another antihypertensive medicine instead. Use of **Co-Cinfaval** is not recommended at the start of pregnancy and under no circumstances must be administered from the third month of pregnancy because it can cause serious damage to your baby when given after this time.

- **Tell your doctor if you are going to start or are already breast-feeding,** as administration of **Co-Cinfaval** is not recommended for women at this time. Your doctor may decide to give you another treatment that is more suitable if you wish to breast-feed, especially for new-borns or premature babies.

Driving and using machines

Before driving a vehicle, using tools or handling machines, or carrying out any other activities that require concentration ensure you know how you react to the effects of **Co-Cinfaval**. As with many medicines used to treat high blood pressure, on rare occasions, **Co-Cinfaval** can cause dizziness and affect the ability to concentrate.

Important information about some of the ingredients of Co-Cinfaval:

This medicine contains hydrochlorothiazide which may give a positive result in blood tests for performance drugs.

This medication contains sorbitol and lactose. If your doctor has indicated that you suffer from intolerance to some sugars, ask him or her before taking this medicinal product.

3. How to take Co-Cinfaval

Always take this medicine exactly as your doctor has told you. This will help to obtain the best results and reduce the risk of side effects. 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.

Your doctor will prescribe the exact number of tablets of **Co-Cinfaval** you must take. Depending on how you respond to the treatment, your doctor may suggest increasing or decreasing the dose.

- The standard dose of **Co-Cinfaval** is one tablet a day.
- Do not change the dose or stop taking the treatment without asking your doctor.
- This medicine must be taken at the same time every day, usually in the morning.
- **Co-Cinfaval** can be taken with or without food.
- Swallow the tablet with a glass of water.

If you take more Co-Cinfaval than you should

If you experience severe dizziness and/or faint, lie down and contact your doctor immediately. In case of overdose or accidental intake, notify your doctor or pharmacist immediately.

If you forget to take Co-Cinfaval

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, do not take the forgotten dose.

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

If you stop taking Co-Cinfaval

If you stop taking **Co-Cinfaval** your high blood pressure may become worse. Do not stop taking the medicine unless your doctor tells you to.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, though 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 1,000 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 side effects may be severe and require immediate medical attention:

You should immediately inform your doctor if you notice symptoms of angioedema such as:

- swelling in your face, tongue or pharynx
- difficulty in swallowing
- hives and breathing difficulties.

Other side effects include:

Uncommon

- cough
- low blood pressure
- light-headedness
- dehydration (with symptoms such as thirst, dry mouth and tongue, reduced rate of urination, dark-coloured urine, dry skin)
- muscle pain
- tiredness
- tingling or numbness
- blurred vision
- noises (i.e. hissing or buzzing) in the ears

Very rare

- dizziness
- diarrhoea
- joint pain

Not known

- breathing difficulties
- severely decreased urine output
- low blood sodium level (sometimes accompanied by nausea, tiredness, confusion, malaise, convulsions)
- low blood potassium level (sometimes with muscular weakness, muscle spasms, abnormal heart rhythm)
- low level of white blood cells (with symptoms such as fever, skin infections, sore throat or mouth ulcers from infections, weakness)
- increase in the blood bilirubin level (which in serious cases can cause the skin and eyes to turn yellow)
- increase in blood urea nitrogen level and increase in creatinine in the blood (which can indicate kidney function abnormalities)
- increase in uric acid level in blood (which can, in serious cases, trigger gout)
- syncope (fainting)

Adverse effects seen with valsartan or hydrochlorothiazide taken separately, but not observed in Co-Cinfaval:

Valsartan

Uncommon

- spinning sensation
- abdominal pain

Not known frequency

- rash, with or without itching, together with any of the following signs or symptoms: fever, joint pain, muscular pain, swelling of the lymph nodes and/or flu-like symptoms
- rash, purplish-red spots, fever, itching (signs of inflammation of the blood vessels)
- low platelet levels (sometimes with more frequent bleeding or bruising than usual)
- high blood potassium level (sometimes with muscle spasms, abnormal heart rhythm)
- allergic reactions (with symptoms such as rash, itching, hives, difficulty in breathing or swallowing, dizziness)
- swelling, mainly of the face and throat, rash, itching
- increased liver function values
- reduction of the level of haemoglobin and reduction of the percentage of red blood cells in blood (that, in severe cases, may cause anaemia),

- kidney failure

Hydrochlorothiazide

Common

- skin rash with itching and other types of rash
- loss of appetite
- vomiting and slight nausea
- faintness, fainting on standing up
- impotence

Rare

- swelling and blisters (due to increased sensitivity to the sun)
- constipation, stomach or intestinal discomfort, liver disorders (yellow skin or eyes)
- irregular heartbeat
- headache
- sleep disorders
- sad mood (depression)
- low platelet levels (sometimes with bleeding or bruising underneath the skin)

Very rare

- inflammation of the blood vessels with symptoms such as rash, purplish-red spots, fever
- itching or skin reddening
- blisters on the lips, eyes or mouth
- skin peeling
- fever
- face rash associated with joint pain
- muscle disorders
- fever (cutaneous lupus erythematosus)
- severe pain in the upper stomach; absence or low level of different types of blood cells
- serious allergic reactions
- breathing difficulties
- lung infection, shortness of breath

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Co-Cinfaval

- 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 container. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not use this medicine if you notice visible 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. Contents of the pack and other information

What Co-Cinfaval 80 mg/12.5 mg contains

- The active substances are valsartan and hydrochlorothiazide. Each tablet contains 80 mg of valsartan and 12.5 mg of hydrochlorothiazide.
- The other ingredients are: Microcrystalline cellulose (E-460) + colloidal anhydrous silica, sorbitol (E-420i), magnesium carbonate (E-504) + pregelatinised corn starch, pregelatinised corn starch, povidone (E-1201), stearyl and sodium fumarate, sodium lauryl sulphate, crospovidone, colloidal anhydrous silica.
- The film coating contains: Lactose monohydrate, hypromellose (E-464), titanium dioxide (E-171), macrogol 4000, red iron oxide (E-172).

What Co-Cinfaval 80 mg/12.5 mg looks like and contents of the pack

- The coated tablets of **Co-Cinfaval 80 mg/12.5 mg** are cylindrical, biconvex pink-coloured tablets.
- The tablets come in packages of 28 tablets (in 7-tablet blister packs). .

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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

Bulk Manufacturer and Packaging:

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

Additional packaging site:

LABORATORIOS CINFA, S.A.
Avda. Roncesvalles s/n
31699 Olloki (Navarra)
SPAIN

Batch releaser:

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

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

Co-Cinfaval 160 mg/12.5 mg film-coated tablets VALSARTAN HYDROCHLOROTHIAZIDE

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1. What Co-Cinfaval is and what it is used for

valsartan/hydrochlorothiazide film-coated tablets contain two active substances known as valsartan and hydrochlorothiazide. These components help to control high blood pressure (hypertension).

- **Valsartan** belongs to a class of medicines known as “angiotensin II receptor antagonists” that help to control high blood pressure. Angiotensin II is a bodily substance that causes vessels to tighten, causing an increase in blood pressure. Valsartan works by blocking the effect of angiotensin II. This makes the blood vessels relax and blood pressure decrease.
- **Hydrochlorothiazide** belongs to a class of medicines known as thiazide diuretics (also known as “water tablets”). Hydrochlorothiazide increases urine output, which also helps reduce blood pressure.

valsartan/hydrochlorothiazide is used to treat high blood pressure when it cannot be properly controlled through the use of a single substance.

Hypertension (high blood pressure) increases the workload on the heart and the arteries. If it is not treated, it can damage the blood vessels to the brain, heart and kidneys and can cause a stroke, heart failure or kidney failure. High blood pressure increases the risk of heart attacks. Reducing blood pressure to normal values reduces the risk of developing these disorders.

2. What you need to know before you take Co-Cinfaval

Do not take Co-Cinfaval:

- if you are allergic (hypersensitive) to valsartan, hydrochlorothiazide, sulphonamide derivatives (substances chemically related to hydrochlorothiazide) or any of the other ingredients in **valsartan/hydrochlorothiazide**.
- if you are **more than 3 months pregnant**. (In any case, it is also preferable to avoid taking this medicine at the start of pregnancy; see the section on Pregnancy).
- if you have a **severe** liver disease.
- if you suffer from a **serious** renal disease.
- If you have **severe** kidney disease
- if you have difficulties urinating.
- if you are treated with an artificial kidney.

- if you have potassium or sodium blood levels that are lower than normal, or if the level of calcium in your blood is higher than normal, despite treatment.
- if you have gout.

If any of these situations affects you, do not take this medicine and consult your doctor.

Warnings and precautions

- if you are taking potassium-sparing medicines, potassium supplements, salt substitutes that contain potassium or other medicines that may increase potassium blood levels, such as heparin. Your doctor may need to monitor potassium levels regularly.
- if you have low potassium blood levels.
- if you experience severe vomiting or diarrhoea.
- if you are taking high doses of a diuretic.
- if you suffer from serious heart disease.
- if you have a narrowing (stenosis) of the kidney artery.
- if you have recently received a kidney transplant.
- if you suffer from hyperaldosteronism, a disease where the adrenal glands produce a high amount of the hormone aldosterone. In this case, taking **valsartan/hydrochlorothiazide** is not recommended.
- if you suffer from a kidney or liver disease.
- if you have fever, skin rash and joint pain, which could be signs of systemic lupus erythematosus (a so-called autoimmune disease).
- if you have diabetes, gout, high cholesterol or fats in your blood.
- if you have experienced an allergic reaction in the past to the use of another medicine of this class used to reduce blood pressure (angiotensin II receptor antagonists), or if you have any other allergies or asthma.
- it may cause increased skin sensitivity when exposed to sunlight.

Co-Cinfaval is not recommended for use in children and adolescents (under 18 years of age).

If you are pregnant, think you may be pregnant, or are planning to have a baby you must tell your doctor. Use of **Co-Cinfaval** is not recommended at the start of pregnancy (first 3 months) and you must not take it after the third month of pregnancy because it can cause serious damage to your baby, see section on Pregnancy.

Other medicines and Co-Cinfaval

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 treatment with **Co-Cinfaval** 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 is particularly applicable to the following medicines:

- lithium, a medicine used to treat certain types of psychiatric illnesses
- medicines that may affect or be affected by potassium blood levels, such as digoxin, a medicine used to control heart rhythm, certain antipsychotic medicines
- medicines that may increase potassium blood levels, such as potassium supplements, salt substitutes that contain potassium, potassium-sparing medicines, heparin
- medicines that may decrease potassium blood levels, such as corticosteroids, certain laxatives
- diuretics (water tablets), medicines for treating gout, such as allopurinol, therapeutic vitamin D and calcium supplements, medicines for treating diabetes (oral antidiabetics or insulin).
- other medicines for reducing blood pressure, such as beta-blockers or methyldopa, or medicines that tighten your blood vessels or stimulate the heart, such as noradrenaline and adrenaline
- medicines to increase blood sugar levels, such as diazoxide
- medicines used to treat cancer, such as methotrexate and cyclophosphamide

- medicines used to treat pain
- arthritis medicines
- muscle relaxants such as the tubocurarine
- anticholinergic drugs, such as atropine or biperiden
- amantadine (a medicine used to prevent influenza)
- cholestyramine and colestipol (medicines used to treat high levels of fats in blood)
- cyclosporine, a medicine used to prevent organ transplant rejection
- certain antibiotics (tetracyclines), anaesthetics and sedatives
- carbamazepine, a medicine used to treat seizures conditions.

Co-Cinfaval with food, drink and alcohol

Co-Cinfaval can be taken with or without food.

Avoid drinking alcohol until you have checked with your doctor. Alcohol can reduce your blood pressure even more and/or increase the possibility of dizziness and feeling of weakness.

Fertility, pregnancy and lactation

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

- **If you are pregnant, think you may be pregnant, or are planning to have a baby you must tell your doctor.** In general, your doctor will advise you to stop taking **Co-Cinfaval** before getting pregnant or as soon as you are pregnant and you will be advised to take another antihypertensive medicine instead. Use of **Co-Cinfaval** is not recommended at the start of pregnancy and under no circumstances must be administered from the third month of pregnancy because it can cause serious damage to your baby when given after this time.

- **Tell your doctor if you are going to start or are already breast-feeding,** as administration of **Co-Cinfaval** is not recommended for women at this time. Your doctor may decide to give you another treatment that is more suitable if you wish to breast-feed, especially for new-borns or premature babies.

Driving and using machines

Before driving a vehicle, using tools or handling machines, or carrying out any other activities that require concentration ensure you know how you react to the effects of **Co-Cinfaval**. As with many medicines used to treat high blood pressure, on rare occasions, **Co-Cinfaval** can cause dizziness and affect the ability to concentrate.

Important information about some of the ingredients of Co-Cinfaval:

This medicine contains hydrochlorothiazide which may give a positive result in blood tests for performance drugs.

This medication contains sorbitol and lactose. If you doctor has indicated that you suffer from intolerance to some sugars, ask him or her before taking this medicinal product.

3. How to take Co-Cinfaval

Always take this medicine exactly as your doctor has told you. This will help to obtain the best results and reduce the risk of side effects. 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.

Your doctor will prescribe the exact number of tablets of **Co-Cinfaval** you must take. Depending on how you respond to the treatment, your doctor may suggest increasing or decreasing the dose.

- The standard dose of **Co-Cinfaval** is one tablet a day.

- Do not change the dose or stop taking the treatment without asking your doctor.
- This medicine must be taken at the same time every day, usually in the morning.
- **Co-Cinfaval** can be taken with or without food.
- Swallow the tablet with a glass of water.

If you take more Co-Cinfaval than you should

If you experience severe dizziness and/or faint, lie down and contact your doctor immediately. In case of overdose or accidental intake, notify your doctor or pharmacist immediately.

If you forget to take Co-Cinfaval

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, do not take the forgotten dose.

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

If you stop taking Co-Cinfaval

If you stop taking **Co-Cinfaval** your high blood pressure may become worse. Do not stop taking the medicine unless your doctor tells you to.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, though 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 1,000 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: the frequency cannot be estimated from the available data

Some side effects may be severe and require immediate medical attention:

You should immediately inform your doctor if you notice symptoms of angioedema such as:

- swelling in your face, tongue or pharynx
- difficulty in swallowing
- hives and breathing difficulties.

Other side effects include:

Uncommon

- cough
- low blood pressure
- light-headedness
- dehydration (with symptoms such as thirst, dry mouth and tongue, reduced rate of urination, dark-coloured urine, dry skin)
- muscle pain
- tiredness
- tingling or numbness
- blurred vision
- noises (i.e. hissing or buzzing) in the ears

Very rare

- dizziness

- diarrhoea
- joint pain

Not known

- breathing difficulties
- severely decreased urine output
- low blood sodium level (sometimes accompanied by nausea, tiredness, confusion, malaise, convulsions)
- low blood potassium level (sometimes with muscular weakness, muscle spasms, abnormal heart rhythm)
- low level of white blood cells (with symptoms such as fever, skin infections, sore throat or mouth ulcers from infections, weakness)
- increase in the blood bilirubin level (which in serious cases can cause the skin and eyes to turn yellow)
- increase in blood urea nitrogen level and increase in creatinine in the blood (which can indicate kidney function abnormalities)
- increase in uric acid level in blood (which can, in serious cases, trigger gout)
- syncope (fainting)

Adverse effects seen with valsartan or hydrochlorothiazide taken separately, but not observed in Co-Cinfaval:

Valsartan

Uncommon

- spinning sensation
- abdominal pain

Not known frequency

- rash, with or without itching, together with any of the following signs or symptoms: fever, joint pain, muscular pain, swelling of the lymph nodes and/or flu-like symptoms
- rash, purplish-red spots, fever, itching (signs of inflammation of the blood vessels)
- low platelet levels (sometimes with more frequent bleeding or bruising than usual)
- high blood potassium level (sometimes with muscle spasms, abnormal heart rhythm)
- allergic reactions (with symptoms such as rash, itching, hives, difficulty in breathing or swallowing, dizziness)
- swelling, mainly of the face and throat, rash, itching
- increased liver function values
- reduction of the level of haemoglobin and reduction of the percentage of red blood cells in blood (that, in severe cases, may cause anaemia),
- kidney failure

Hydrochlorothiazide

Common

- skin rash with itching and other types of rash
- loss of appetite
- vomiting and slight nausea
- faintness, fainting on standing up
- impotence

Rare

- swelling and blisters (due to increased sensitivity to the sun)
- constipation, stomach or intestinal discomfort, liver disorders (yellow skin or eyes)
- irregular heartbeat

- headache
- sleep disorders
- sad mood (depression)
- low platelet levels (sometimes with bleeding or bruising underneath the skin)

Very rare

- inflammation of the blood vessels with symptoms such as rash, purplish-red spots, fever
- itching or skin reddening
- blisters on the lips, eyes or mouth
- skin peeling
- fever
- face rash associated with joint pain
- muscle disorders
- fever (cutaneous lupus erythematosus)
- severe pain in the upper stomach; absence or low level of different types of blood cells
- serious allergic reactions
- breathing difficulties
- lung infection, shortness of breath

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Co-Cinfaval

- 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 container. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not use this medicine if you notice visible 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. Contents of the pack and other information

What Co-Cinfaval 160 mg/12.5 mg contains

- The active substances are valsartan and hydrochlorothiazide. Each tablet contains 160 mg of valsartan and 12.5 mg of hydrochlorothiazide.
- The other ingredients are: Microcrystalline cellulose (E-460) + colloidal anhydrous silica, sorbitol (E-420i), magnesium carbonate (E-504) + pregelatinised corn starch, pregelatinised corn starch, povidone (E-1201), stearyl and sodium fumarate, sodium lauryl sulphate, crospovidone, colloidal anhydrous silica.
- The film coating contains: Lactose monohydrate, hypromellose (E-464), titanium dioxide (E-171), macrogol 4000, red iron oxide (E-172), brown iron oxide (E-172).

What valsartan/hydrochlorothiazide 160 mg/12.5 mg looks like and contents of the pack

- The coated tablets of **Co-Cinfaval 160 mg/12.5 mg** are cylindrical, biconvex reddish-coloured tablets.
 - The tablets come in packages of 28 tablets (in 7-tablet blister packs).
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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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

Co-Cinfaval 160 mg/25 mg film-coated tablets VALSARTAN HYDROCHLOROTHIAZIDE

Read 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 symptoms are the same as yours.
- If any of the side effects gets serious talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. What Co-Cinfaval is and what it is used for

valsartan/hydrochlorothiazide film-coated tablets contain two active substances known as valsartan and hydrochlorothiazide. These components help to control high blood pressure (hypertension).

- **Valsartan** belongs to a class of medicines known as “angiotensin II receptor antagonists” that help to control high blood pressure. Angiotensin II is a bodily substance that causes vessels to tighten, causing an increase in blood pressure. Valsartan works by blocking the effect of angiotensin II. This makes the blood vessels relax and blood pressure decrease.
- **Hydrochlorothiazide** belongs to a class of medicines known as thiazide diuretics (also known as “water tablets”). Hydrochlorothiazide increases urine output, which also helps reduce blood pressure.

valsartan/hydrochlorothiazide is used to treat high blood pressure when it cannot be properly controlled through the use of a single substance.

Hypertension (high blood pressure) increases the workload on the heart and the arteries. If it is not treated, it can damage the blood vessels to the brain, heart and kidneys and can cause a stroke, heart failure or kidney failure. High blood pressure increases the risk of heart attacks. Reducing blood pressure to normal values reduces the risk of developing these disorders.

2. What you need to know before you take Co-Cinfaval

Do not take Co-Cinfaval:

- if you are allergic (hypersensitive) to valsartan, hydrochlorothiazide, sulphonamide derivatives (substances chemically related to hydrochlorothiazide) or any of the other ingredients in **valsartan/hydrochlorothiazide**.
- if you are **more than 3 months pregnant**. (In any case, it is also preferable to avoid taking this medicine at the start of pregnancy; see the section on Pregnancy).
- if you have a **serious** liver disease.
- if you suffer from a **severe** renal disease.
- If you have **severe** kidney disease
- if you have difficulties urinating.
- if you are treated with an artificial kidney.

- if you have potassium or sodium blood levels that are lower than normal, or if the level of calcium in your blood is higher than normal, despite treatment.
- if you have gout.

If any of these situations affects you, do not take this medicine and consult your doctor.

Warnings and precautions

- if you are taking potassium-sparing medicines, potassium supplements, salt substitutes that contain potassium or other medicines that may increase potassium blood levels, such as heparin. Your doctor may need to monitor potassium levels regularly.
- if you have low potassium blood levels.
- if you experience severe vomiting or diarrhoea.
- if you are taking high doses of a diuretic.
- if you suffer from serious heart disease.
- if you have a narrowing (stenosis) of the kidney artery.
- if you have recently received a kidney transplant.
- if you suffer from hyperaldosteronism, a disease where the adrenal glands produce a high amount of the hormone aldosterone. In this case, taking **valsartan/hydrochlorothiazide** is not recommended.
- if you suffer from a kidney or liver disease.
- if you have fever, skin rash and joint pain, which could be signs of systemic lupus erythematosus (a so-called autoimmune disease).
- if you have diabetes, gout, high cholesterol or fats in your blood.
- if you have experienced an allergic reaction in the past to the use of another medicine of this class used to reduce blood pressure (angiotensin II receptor antagonists), or if you have any other allergies or asthma.
- it may cause increased skin sensitivity when exposed to sunlight.

Co-Cinfaval is not recommended for use in children and adolescents (under 18 years of age).

If you are pregnant, think you may be pregnant, or are planning to have a baby you must tell your doctor. Use of **Co-Cinfaval** is not recommended at the start of pregnancy (first 3 months) and you must not take it after the third month of pregnancy because it can cause serious damage to your baby, see section on Pregnancy.

Other medicines and Co-Cinfaval

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 treatment with **Co-Cinfaval** 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 is particularly applicable to the following medicines:

- lithium, a medicine used to treat certain types of psychiatric illnesses
- medicines that may affect or be affected by potassium blood levels, such as digoxin, a medicine used to control heart rhythm, certain antipsychotic medicines
- medicines that may increase potassium blood levels, such as potassium supplements, salt substitutes that contain potassium, potassium-sparing medicines, heparin
- medicines that may decrease potassium blood levels, such as corticosteroids, certain laxatives
- diuretics (water tablets), medicines for treating gout, such as allopurinol, therapeutic vitamin D and calcium supplements, medicines for treating diabetes (oral antidiabetics or insulin).
- other medicines for reducing blood pressure, such as beta-blockers or methyldopa, or medicines that tighten your blood vessels or stimulate the heart, such as noradrenaline and adrenaline
- medicines to increase blood sugar levels, such as diazoxide
- medicines used to treat cancer, such as methotrexate and cyclophosphamide

- medicines used to treat pain
- arthritis medicines
- muscle relaxants such as the tubocurarine
- anticholinergic drugs, such as atropine or biperiden
- amantadine (a medicine used to prevent influenza)
- cholestyramine and colestipol (medicines used to treat high levels of fats in blood)
- cyclosporine, a medicine used to prevent organ transplant rejection
- certain antibiotics (tetracyclines), anaesthetics and sedatives
- carbamazepine, a medicine used to treat seizures conditions.

Co-Cinfaval with food, drink and alcohol

Co-Cinfaval can be taken with or without food.

Avoid drinking alcohol until you have checked with your doctor. Alcohol can reduce your blood pressure even more and/or increase the possibility of dizziness and feeling of weakness.

Pregnancy and breast-feeding

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

- **If you are pregnant, think you may be pregnant, or are planning to have a baby you must tell your doctor.** In general, your doctor will advise you to stop taking **Co-Cinfaval** before getting pregnant or as soon as you are pregnant and you will be advised to take another antihypertensive medicine instead. Use of **Co-Cinfaval** is not recommended at the start of pregnancy and under no circumstances must be administered from the third month of pregnancy because it can cause serious damage to your baby when given after this time.
- **Tell your doctor if you are going to start or are already breast-feeding,** as administration of **Co-Cinfaval** is not recommended for women at this time. Your doctor may decide to give you another treatment that is more suitable if you wish to breast-feed, especially for new-borns or premature babies.

Driving and using machines

Before driving a vehicle, using tools or handling machines, or carrying out any other activities that require concentration ensure you know how you react to the effects of **Co-Cinfaval**. As with many medicines used to treat high blood pressure, on rare occasions, **Co-Cinfaval** can cause dizziness and affect the ability to concentrate.

Important information about some of the ingredients of Co-Cinfaval:

This medicine contains hydrochlorothiazide which may give a positive result in blood tests for performance drugs.

This medication contains sorbitol and lactose. If your doctor has indicated that you suffer from intolerance to some sugars, ask him or her before taking this medicinal product.

3. How to take Co-Cinfaval

Always take this medicine exactly as your doctor has told you. This will help to obtain the best results and reduce the risk of side effects. 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.

Your doctor will prescribe the exact number of tablets of **Co-Cinfaval** you must take. Depending on how you respond to the treatment, your doctor may suggest increasing or decreasing the dose.

- The standard dose of **Co-Cinfaval** is one tablet a day.

- Do not change the dose or stop taking the treatment without asking your doctor.
- This medicine must be taken at the same time every day, usually in the morning.
- **Co-Cinfaval** can be taken with or without food.
- Swallow the tablet with a glass of water.

If you take more Co-Cinfaval than you should

If you experience severe dizziness and/or faint, lie down and contact your doctor immediately. In case of overdose or accidental intake, notify your doctor or pharmacist immediately.

If you forget to take Co-Cinfaval

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, do not take the forgotten dose.

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

If you stop taking Co-Cinfaval

If you stop taking **Co-Cinfaval** your high blood pressure may become worse. Do not stop taking the medicine unless your doctor tells you to.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, though 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 1,000 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 side effects may be severe and require immediate medical attention:

You should immediately inform your doctor if you notice symptoms of angioedema such as:

- swelling in your face, tongue or pharynx
- difficulty in swallowing
- hives and breathing difficulties.

Other side effects include:

Uncommon

- cough
- low blood pressure
- light-headedness
- dehydration (with symptoms such as thirst, dry mouth and tongue, reduced rate of urination, dark-coloured urine, dry skin)
- muscle pain
- tiredness
- tingling or numbness
- blurred vision
- noises (i.e. hissing or buzzing) in the ears

Very rare

- dizziness

- diarrhoea
- joint pain

Not known

- breathing difficulties
- severely decreased urine output
- low blood sodium level (sometimes accompanied by nausea, tiredness, confusion, malaise, convulsions)
- low blood potassium level (sometimes with muscular weakness, muscle spasms, abnormal heart rhythm)
- low level of white blood cells (with symptoms such as fever, skin infections, sore throat or mouth ulcers from infections, weakness)
- increase in the blood bilirubin level (which in serious cases can cause the skin and eyes to turn yellow)
- increase in blood urea nitrogen level and increase in creatinine in the blood (which can indicate kidney function abnormalities)
- increase in uric acid level in blood (which can, in serious cases, trigger gout)
- syncope (fainting)

Adverse effects seen with valsartan or hydrochlorothiazide taken separately, but not observed in Co-Cinfaval:

Valsartan

Uncommon

- spinning sensation
- abdominal pain

Not known frequency

- rash, with or without itching, together with any of the following signs or symptoms: fever, joint pain, muscular pain, swelling of the lymph nodes and/or flu-like symptoms
- rash, purplish-red spots, fever, itching (signs of inflammation of the blood vessels)
- low platelet levels (sometimes with more frequent bleeding or bruising than usual)
- high blood potassium level (sometimes with muscle spasms, abnormal heart rhythm)
- allergic reactions (with symptoms such as rash, itching, hives, difficulty in breathing or swallowing, dizziness)
- swelling, mainly of the face and throat, rash, itching
- increased liver function values
- reduction of the level of haemoglobin and reduction of the percentage of red blood cells in blood (that, in severe cases, may cause anaemia),
- kidney failure

Hydrochlorothiazide

Common

- skin rash with itching and other types of rash
- loss of appetite
- vomiting and slight nausea
- faintness, fainting on standing up
- impotence

Rare

- swelling and blisters (due to increased sensitivity to the sun)
- constipation, stomach or intestinal discomfort, liver disorders (yellow skin or eyes)
- irregular heartbeat

- headache
- sleep disorders
- sad mood (depression)
- low platelet levels (sometimes with bleeding or bruising underneath the skin)

Very rare

- inflammation of the blood vessels with symptoms such as rash, purplish-red spots, fever
- itching or skin reddening
- blisters on the lips, eyes or mouth
- skin peeling
- fever
- face rash associated with joint pain
- muscle disorders
- fever (cutaneous lupus erythematosus)
- severe pain in the upper stomach; absence or low level of different types of blood cells
- serious allergic reactions
- breathing difficulties
- lung infection, shortness of breath

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Co-Cinfaval

- 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 container. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not use this medicine if you notice visible 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. Contents of the pack and other information

What Co-Cinfaval 160 mg/25 mg contains

- The active substances are valsartan and hydrochlorothiazide. Each tablet contains 160 mg of valsartan and 25 mg of hydrochlorothiazide.
 - The other ingredients are: Microcrystalline cellulose (E-460) + colloidal anhydrous silica, sorbitol (E-420i), magnesium carbonate (E-504) + pregelatinised corn starch, pregelatinised corn starch, povidone (E-1201), stearyl and sodium fumarate, sodium lauryl sulphate, crospovidone, colloidal anhydrous silica.
 - The film coating contains: Lactose monohydrate, hypromellose (E-464), titanium dioxide (E-171), macrogol 4000, yellow iron oxide (E-172), brown iron oxide (E-172).

What Co-Cinfaval 160 mg/25 mg looks like and contents of the pack

- The coated tablets of **Co-Cinfaval 160 mg/25 mg** are cylindrical, biconvex brown-coloured tablets.
- The tablets come in packages of 28 tablets (in 7 tablets blister-packs).

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