

PACKAGE LEAFLET: INFORMATION FOR THE USER

COZAAR® Comp 100mg/25mg film-coated tablets

(losartan potassium and hydrochlorothiazide)

Read all of this leaflet carefully before 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- What COZAAR Comp is and what it is used for
- What you need to know before you take COZAAR Comp
- How to take COZAAR Comp
- Possible side effects
- How to store COZAAR Comp
- Contents of the pack and other information

1. What COZAAR Comp is and what it is used for

COZAAR Comp is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). Angiotensin II is a substance produced in the body which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure. Losartan prevents the binding of angiotensin II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Hydrochlorothiazide works by making the kidneys pass more water and salt. This also helps to reduce blood pressure.

COZAAR Comp is indicated for the treatment of essential hypertension (high blood pressure).

2. What you need to know before you take COZAAR Comp

Do not take COZAAR Comp

- if you are allergic to losartan, hydrochlorothiazide or to any of the other ingredients of this medicine (listed in section 6),
- if you are allergic to other sulfonamide-derived substances (e.g. other thiazides, some antibacterial drugs such as co-trimoxazole, ask your doctor if you are not sure),
- if you have severely impaired liver function,
- if you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment,
- if you are suffering from gout,
- if you are more than 3 months pregnant. (It is also better to avoid COZAAR Comp in early pregnancy - see Pregnancy section),
- if you have severely impaired kidney function or your kidneys are not producing any urine,
- if you have diabetes or impaired kidney function and are taking a medicine called aliskiren to reduce blood pressure.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking **Cozaar Comp**

You must tell your doctor if you think you are (or might become) pregnant. COZAAR Comp is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

It is important to tell your doctor before taking COZAAR Comp:

- if you have previously suffered from swelling of the face, lips, throat or tongue
- if you take diuretics (water pills)
- if you are on a salt-restricted diet
- if you have or have had severe vomiting and/or diarrhoea
- if you have heart failure
- if your liver function is impaired (see section 2 "Do not take COZAAR Comp")
- if you have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning kidney, or you have recently had a kidney transplant
- if you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to poor heart function)
- if you have 'aortic or mitral valve stenosis' (narrowing of the valves of the heart) or 'hypertrophic cardiomyopathy' (a disease causing thickening of heart muscle)
- if you are diabetic
- if you have had gout

- if you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus)
- if you have high calcium or low potassium levels or you are on a low potassium diet
- if you need to have an anaesthetic (even at the dentist) or before surgery, or if you are going to have tests to check your parathyroid function, you must tell the doctor or medical staff that you are taking losartan potassium and hydrochlorothiazide tablets
- if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland)
- if you are taking a medicine called aliskiren to reduce blood pressure.

Children and adolescents

There is no experience with the use of COZAAR Comp in children. Therefore, COZAAR Comp should not be given to children.

Other medicines and Cozaar Comp

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Diuretic agents such as the hydrochlorothiazide contained in COZAAR Comp may interact with other medicines.

Preparations containing lithium should not be taken with COZAAR Comp without close supervision by your doctor.

Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines, other diuretics ("water tablets"), some laxatives, medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral agents or insulins).

It is also important for your doctor to know if you are taking

- other medicines to reduce your blood pressure,
- steroids
- medicines to treat cancer
- pain killers
- drugs for treatment of fungal infections
- arthritis medicines
- resins used for high cholesterol, such as colestyramine
- medicines which relax your muscles
- sleeping tablets
- opioid medicines such as morphine
- 'pressor amines' such as adrenaline or other drugs from the same group
- oral agents for diabetes or insulins.

Please also inform your doctor if you are taking COZAAR Comp if you will be undergoing a radiographic procedure and will be given iodine contrast media.

COZAAR Comp with food and drink

You are advised not to drink alcohol whilst taking these tablets: alcohol and COZAAR Comp tablets may increase each other's effects.

Dietary salt in excessive quantities may counteract the effect of COZAAR Comp tablets.

COZAAR Comp tablets may be taken with or without food.

Pregnancy and breast-feeding

Pregnancy

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

Your doctor will normally advise you to stop taking COZAAR Comp before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of COZAAR Comp. COZAAR Comp is not recommended during pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding.

COZAAR Comp is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

Use in elderly patients

COZAAR Comp works equally well in and is equally well tolerated by most older and younger adult patients. Most older patients require the same dose as younger patients.

Driving and using machines

When you begin treatment with this medication, you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate your medicine.

COZAAR Comp contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take COZAAR Comp

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on the appropriate dose of COZAAR Comp depending on your condition and whether you are taking other medicines. It is important to continue taking COZAAR Comp for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

High Blood Pressure

The usual dose of COZAAR Comp for most patients with high blood pressure is 1 tablet of COZAAR Comp 50mg/12.5mg per day to control blood pressure over the 24-hour period. This can be increased to 2 tablets once daily of Losartan/Hydrochlorothiazide 50mg/12.5mg Film-Coated Tablets or changed to 1 tablet daily of Losartan/Hydrochlorothiazide 100mg/25mg Film-Coated Tablets (a stronger strength) per day. The maximum daily dose is 2 tablets per day of Losartan/Hydrochlorothiazide 50mg/12.5mg Film-Coated Tablets or 1 tablet daily of Losartan/Hydrochlorothiazide 100mg/25mg Film-Coated Tablets

If you take more COZAAR Comp than you should

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. Overdose can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition and dehydration.

If you forget to take COZAAR Comp

Try to take COZAAR Comp daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

4. Possible side effects

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

If you experience the following, stop taking COZAAR Comp tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

This is a serious but rare side effect, which affects more than 1 out of 10,000 patients but fewer than 1 out of 1,000 patients. You may need urgent medical attention or hospitalisation.

The following side effects have been reported:

Common (may affect up to 1 in 10 people):

- Cough, upper airway infection, congestion in the nose, sinusitis, sinus disorder
- Diarrhoea, abdominal pain, nausea, indigestion
- Muscle pain or cramps, leg pain, back pain
- Insomnia, headache, dizziness
- Weakness, tiredness, chest pain
- Increased potassium levels (which can cause an abnormal heart rhythm), decreased haemoglobin levels
- Changes in kidney function including kidney failure
- Too low sugar in the blood (hypoglycaemia)

Uncommon (may affect up to 1 in 100 people):

- Anaemia, red or brownish spots on the skin (sometimes especially on the feet, legs, arms and buttocks, with joint pain, swelling of the hands and feet and stomach pain), bruising, reduction in white blood cells, clotting problems, reduced number of platelets
- Loss of appetite, increased uric acid levels or frank gout, increased blood sugar levels, abnormal blood electrolyte levels
- Anxiety, nervousness, panic disorder (recurring panic attacks), confusion, depression, abnormal dreams, sleep disorders, sleepiness, memory impairment
- Pins and needles or similar sensations, pain in the extremities, trembling, migraine, fainting
- Blurred vision, burning or stinging in the eyes, conjunctivitis, worsening eyesight, seeing things in yellow
- Ringing, buzzing, roaring or clicking in the ears, vertigo
- Low blood pressure, which may be associated with changes in posture (feeling light-headed or weak when you stand up), angina (chest pain), abnormal heartbeat, cerebrovascular accident (TIA, "mini-stroke"), heart attack, palpitations

- Inflammation of blood vessels, which is often associated with a skin rash or bruising
- Sore throat, breathlessness, bronchitis, pneumonia, water on the lungs (which causes difficulty breathing), nosebleed, runny nose, congestion
- Constipation, obstipation, wind, stomach upsets, stomach spasms, vomiting, dry mouth, inflammation of a salivary gland, toothache
- Jaundice (yellowing of the eyes and skin), inflammation of the pancreas
- Hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, flushing, sweating, hair loss
- Pain in the arms, shoulders, hips, knees or other joints, joint swelling, stiffness, muscle weakness
- Frequent urination including at night, abnormal kidney function including inflammation of the kidneys, urinary tract infection, sugar in the urine
- Decreased sexual appetite, impotence
- Swelling of the face, localised swelling (oedema), fever

Rare (may affect up to 1 in 1,000 people):

- Hepatitis (inflammation of the liver), abnormal liver function tests

Not known (frequency cannot be estimated from the available data):

- Flu-like symptoms
- Unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis)
- Low levels of sodium in the blood (hyponatraemia)
- Generally feeling unwell (malaise)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

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

5. How to store Cozaar Comp

Keep out of the reach and sight of children.
Do not store above 30°C. Store in the original package in order to protect from light and moisture.
Do not use COZAAR Comp after the expiry date (Exp) which is stated on the container. The expiry date refers to the last day of that month.
Do not open the blister pack until you are ready to take the medicine.
If your tablets appear discoloured, damaged or show any other signs of deterioration, please return these to your pharmacist who will advise you further.
Medicines should not be disposed of via wastewater or household waste.
Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
If you have any left-over/unused tablets, please return these to your pharmacist for safe disposal.

6. Contents of the pack and other information

What COZAAR Comp contains

The active substances are losartan potassium and hydrochlorothiazide.

COZAAR Comp 100mg/25mg contains 100mg of losartan potassium and 25mg of hydrochlorothiazide as the active ingredients.

COZAAR Comp 100mg/25mg contains the following inactive ingredients: microcrystalline cellulose, lactose monohydrate, pregelatinised maize starch, magnesium stearate, hydroxypropyl cellulose, hypromellose, 8.48mg (0.216 mEq) of potassium, titanium dioxide (E171), quinoline yellow aluminium lake (E104) and carnauba wax (E903).

What COZAAR Comp looks like and contents of the pack

COZAAR Comp are oval, yellow, film-coated tablets with '747' on one side and plain on the other.

Your medicine is available in blister packs containing 28 film-coated tablets in an outer cardboard carton.

Manufacturer

Manufactured by: Merck Sharp & Dohme B.V.,
Waarderweg 39, 2031 BN, Haarlem, The Netherlands.

Procured from within the EU by the Parallel Product Authorisation holder:
Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by:
Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/95/1

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	COSAAR Plus – Filmtabletten, FORTZAAR-Filmtabletten
Belgium	COZAAR PLUS FORTE, LOORTAN PLUS FORTE
Cyprus	FORTZAAR, HYZAAR
Denmark	COZAAR Comp, . COZAAR Comp Forte, FORTZAAR
Estonia	HYZAAR, FORTZAAR
Finland	COZAAR Comp, COZAAR Comp Forte
France	FORTZAAR film-coated tablets, HYZAAR film-coated tablets
Germany	FORTZAAR Filmtabletten
Greece	HYZAAR, HYZAAR Extra Forte, HYZAAR Forte
Hungary	HYZAAR Forte.
Ireland	COZAAR Comp film-coated tablets
Italy	HIZAAR compresse rivestite con film, FORZAAR compresse rivestite con film, LOSAZID compresse rivestite con film
Lithuania	FORTZAAR plevele dengtos tabletes
Luxembourg	COZAAR PLUS FORTE , LOORTAN PLUS FORTE
Malta	COZAAR Comp pilloli miksjija b'rita
Netherlands	FORTZAAR
Poland	HYZAAR, HYZAAR FORTE
Portugal	COZAAR Plus, FORTZAAR, SIAARA, LORTAAN PLUS
Romania	FORTZAAR comprimate filmate
Slovenia	HYZAAR, FORTZAAR
Spain	COZAAR Plus, FORTZAAR
Sweden	COZAAR Comp Forte
United Kingdom	COZAAR-COMP FILM COATED TABLETS
Iceland	COZAAR COMP FORTE
Norway	COZAAR Comp, COZAAR Comp Forte

Leaflet issue and revision date (ref): 03.07.14

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1. What COZAAR Comp is and what it is used for

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COZAAR Comp is indicated for the treatment of essential hypertension (high blood pressure).

2. What you need to know before you take COZAAR Comp

Do not take COZAAR Comp

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- if you have severely impaired liver function,
- if you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment,
- if you are suffering from gout,
- if you are more than 3 months pregnant. (It is also better to avoid COZAAR Comp in early pregnancy - see Pregnancy section),
- if you have severely impaired kidney function or your kidneys are not producing any urine,
- if you have diabetes or impaired kidney function and are taking a medicine called aliskiren to reduce blood pressure.

Warnings and precautions

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- if you are on a salt-restricted diet
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- if you have heart failure
- if your liver function is impaired (see section 2 "Do not take COZAAR Comp")
- if you have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning kidney, or you have recently had a kidney transplant
- if you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to poor heart function)
- if you have 'aortic or mitral valve stenosis' (narrowing of the valves of the heart) or 'hypertrophic cardiomyopathy' (a disease causing thickening of heart muscle)
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- if you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus)
- if you have high calcium or low potassium levels or you are on a low potassium diet
- if you need to have an anaesthetic (even at the dentist) or before surgery, or if you are going to have tests to check your parathyroid function, you must tell the doctor or medical staff that you are taking losartan potassium and hydrochlorothiazide tablets
- if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland)
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Children and adolescents

There is no experience with the use of COZAAR Comp in children. Therefore, COZAAR Comp should not be given to children.

Other medicines and Cozaar Comp

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Diuretic agents such as the hydrochlorothiazide contained in COZAAR Comp may interact with other medicines.

Preparations containing lithium should not be taken with COZAAR Comp without close supervision by your doctor.

Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines, other diuretics ("water tablets"), some laxatives, medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral agents or insulins).

It is also important for your doctor to know if you are taking

- other medicines to reduce your blood pressure,
- steroids
- medicines to treat cancer
- pain killers
- drugs for treatment of fungal infections
- arthritis medicines
- resins used for high cholesterol, such as colestyramine
- medicines which relax your muscles
- sleeping tablets
- opioid medicines such as morphine
- 'pressor amines' such as adrenaline or other drugs from the same group
- oral agents for diabetes or insulins.

Please also inform your doctor if you are taking COZAAR Comp if you will be undergoing a radiographic procedure and will be given iodine contrast media.

COZAAR Comp with food and drink

You are advised not to drink alcohol whilst taking these tablets: alcohol and COZAAR Comp tablets may increase each other's effects.

Dietary salt in excessive quantities may counteract the effect of COZAAR Comp tablets.

COZAAR Comp tablets may be taken with or without food.

Pregnancy and breast-feeding

Pregnancy

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

Your doctor will normally advise you to stop taking COZAAR Comp before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of COZAAR Comp. COZAAR Comp is not recommended during pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding.

COZAAR Comp is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

Use in elderly patients

COZAAR Comp works equally well in and is equally well tolerated by most older and younger adult patients. Most older patients require the same dose as younger patients.

Driving and using machines

When you begin treatment with this medication, you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate your medicine.

COZAAR Comp contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take COZAAR Comp

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on the appropriate dose of COZAAR Comp depending on your condition and whether you are taking other medicines. It is important to continue taking COZAAR Comp for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

High Blood Pressure

The usual dose of COZAAR Comp for most patients with high blood pressure is 1 tablet of COZAAR Comp 50mg/12.5mg per day to control blood pressure over the 24-hour period. This can be increased to 2 tablets once daily of Losartan/Hydrochlorothiazide 50mg/12.5mg Film-Coated Tablets or changed to 1 tablet daily of Losartan/Hydrochlorothiazide 100mg/25mg Film-Coated Tablets (a stronger strength) per day. The maximum daily dose is 2 tablets per day of Losartan/Hydrochlorothiazide 50mg/12.5mg Film-Coated Tablets or 1 tablet daily of Losartan/Hydrochlorothiazide 100mg/25mg Film-Coated Tablets

If you take more COZAAR Comp than you should

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. Overdose can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition and dehydration.

If you forget to take COZAAR Comp

Try to take COZAAR Comp daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

4. Possible side effects

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

If you experience the following, stop taking COZAAR Comp tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

This is a serious but rare side effect, which affects more than 1 out of 10,000 patients but fewer than 1 out of 1,000 patients. You may need urgent medical attention or hospitalisation.

The following side effects have been reported:

Common (may affect up to 1 in 10 people):

- Cough, upper airway infection, congestion in the nose, sinusitis, sinus disorder
- Diarrhoea, abdominal pain, nausea, indigestion
- Muscle pain or cramps, leg pain, back pain
- Insomnia, headache, dizziness
- Weakness, tiredness, chest pain
- Increased potassium levels (which can cause an abnormal heart rhythm), decreased haemoglobin levels
- Changes in kidney function including kidney failure
- Too low sugar in the blood (hypoglycaemia)

Uncommon (may affect up to 1 in 100 people):

- Anaemia, red or brownish spots on the skin (sometimes especially on the feet, legs, arms and buttocks, with joint pain, swelling of the hands and feet and stomach pain), bruising, reduction in white blood cells, clotting problems, reduced number of platelets
- Loss of appetite, increased uric acid levels or frank gout, increased blood sugar levels, abnormal blood electrolyte levels
- Anxiety, nervousness, panic disorder (recurring panic attacks), confusion, depression, abnormal dreams, sleep disorders, sleepiness, memory impairment
- Pins and needles or similar sensations, pain in the extremities, trembling, migraine, fainting
- Blurred vision, burning or stinging in the eyes, conjunctivitis, worsening eyesight, seeing things in yellow
- Ringing, buzzing, roaring or clicking in the ears, vertigo
- Low blood pressure, which may be associated with changes in posture (feeling light-headed or weak when you stand up), angina (chest pain), abnormal heartbeat, cerebrovascular accident (TIA, "mini-stroke"), heart attack, palpitations

- Inflammation of blood vessels, which is often associated with a skin rash or bruising
- Sore throat, breathlessness, bronchitis, pneumonia, water on the lungs (which causes difficulty breathing), nosebleed, runny nose, congestion
- Constipation, obstipation, wind, stomach upsets, stomach spasms, vomiting, dry mouth, inflammation of a salivary gland, toothache
- Jaundice (yellowing of the eyes and skin), inflammation of the pancreas
- Hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, flushing, sweating, hair loss
- Pain in the arms, shoulders, hips, knees or other joints, joint swelling, stiffness, muscle weakness
- Frequent urination including at night, abnormal kidney function including inflammation of the kidneys, urinary tract infection, sugar in the urine
- Decreased sexual appetite, impotence
- Swelling of the face, localised swelling (oedema), fever

Rare (may affect up to 1 in 1,000 people):

- Hepatitis (inflammation of the liver), abnormal liver function tests

Not known (frequency cannot be estimated from the available data):

- Flu-like symptoms
- Unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis)
- Low levels of sodium in the blood (hyponatraemia)
- Generally feeling unwell (malaise)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
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Website: www.hpra.ie E-mail: medsafety@hpra.ie

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5. How to store Cozaar Comp

Keep out of the sight and reach of children.
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If you have any left-over/unused tablets, please return these to your pharmacist for safe disposal.

6. Contents of the pack and other information

What COZAAR Comp contains

The active substances are losartan potassium and hydrochlorothiazide.

COZAAR Comp 100mg/25mg contains 100mg of losartan potassium and 25mg of hydrochlorothiazide as the active ingredients.

COZAAR Comp 100mg/25mg contains the following inactive ingredients: microcrystalline cellulose, lactose monohydrate, pregelatinised maize starch, magnesium stearate, hydroxypropyl cellulose, hypromellose, 8.48mg (0.216 mEq) of potassium, titanium dioxide (E171), quinoline yellow aluminium lake (E104) and carnauba wax (E903).

What COZAAR Comp looks like and contents of the pack

COZAAR Comp are oval, yellow, film-coated tablets with '747' on one side and plain on the other.

Your medicine is available in blister packs containing 28 film-coated tablets in an outer cardboard carton.

Manufacturer

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Waarderweg 39, 2031 BN, Haarlem, The Netherlands.

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Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by:
Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/95/1

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	COZAAR Plus – Filmtabletten, FORTZAAR-Filmtabletten
Belgium	COZAAR PLUS FORTE, LOORTAN PLUS FORTE
Cyprus	FORTZAAR, HYZAAR
Denmark	COZAAR Comp, . COZAAR Comp Forte, FORTZAAR
Estonia	HYZAAR, FORTZAAR
Finland	COZAAR Comp, COZAAR Comp Forte
France	FORTZAAR film-coated tablets, HYZAAR film-coated tablets
Germany	FORTZAAR Filmtabletten
Greece	HYZAAR, HYZAAR Extra Forte, HYZAAR Forte
Hungary	HYZAAR Forte.
Ireland	COZAAR Comp film-coated tablets
Italy	HIZAAR compresse rivestite con film, FORZAAR compresse rivestite con film, LOSAZID compresse rivestite con film
Lithuania	FORTZAAR plevele dengtos tabletes
Luxembourg	COZAAR PLUS FORTE , LOORTAN PLUS FORTE
Malta	COZAAR Comp pilloli miksija b'rita
Netherlands	FORTZAAR
Poland	HYZAAR, HYZAAR FORTE
Portugal	COZAAR Plus, FORTZAAR, SIAARA, LORTAAN PLUS
Romania	FORTZAAR comprimate filmate
Slovenia	HYZAAR, FORTZAAR
Spain	COZAAR Plus, FORTZAAR
Sweden	COZAAR Comp Forte
United Kingdom	COZAAR-COMP FILM COATED TABLETS
Iceland	COZAAR COMP FORTE
Norway	COZAAR Comp, COZAAR Comp Forte

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PACKAGE LEAFLET: INFORMATION FOR THE USER

COZAAR® Comp 100mg/25mg film-coated tablets

(losartan potassium and hydrochlorothiazide)

Read all of this leaflet carefully before 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- What COZAAR Comp is and what it is used for
- What you need to know before you take COZAAR Comp
- How to take COZAAR Comp
- Possible side effects
- How to store COZAAR Comp
- Contents of the pack and other information

1. What COZAAR Comp is and what it is used for

COZAAR Comp is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). Angiotensin II is a substance produced in the body which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure. Losartan prevents the binding of angiotensin II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Hydrochlorothiazide works by making the kidneys pass more water and salt. This also helps to reduce blood pressure.

COZAAR Comp is indicated for the treatment of essential hypertension (high blood pressure).

2. What you need to know before you take COZAAR Comp

Do not take COZAAR Comp

- if you are allergic to losartan, hydrochlorothiazide or to any of the other ingredients of this medicine (listed in section 6),
- if you are allergic to other sulfonamide-derived substances (e.g. other thiazides, some antibacterial drugs such as cotrimoxazole, ask your doctor if you are not sure)
- if you have severely impaired liver function,
- if you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment,
- if you are suffering from gout,
- if you are more than 3 months pregnant. (It is also better to avoid COZAAR Comp in early pregnancy - see Pregnancy section),
- if you have severely impaired kidney function or your kidneys are not producing any urine,
- if you have diabetes or impaired kidney function and are taking a medicine called aliskiren to reduce blood pressure.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking **Cozaar Comp**

You must tell your doctor if you think you are (or might become) pregnant. COZAAR Comp is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

It is important to tell your doctor before taking COZAAR Comp:

- if you have previously suffered from swelling of the face, lips, throat or tongue
- if you take diuretics (water pills)
- if you are on a salt-restricted diet
- if you have or have had severe vomiting and/or diarrhoea
- if you have heart failure
- if your liver function is impaired (see section 2 "Do not take COZAAR Comp")
- if you have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning kidney, or you have recently had a kidney transplant
- if you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to poor heart function)
- if you have 'aortic or mitral valve stenosis' (narrowing of the valves of the heart) or 'hypertrophic cardiomyopathy' (a disease causing thickening of heart muscle)
- if you are diabetic
- if you have had gout

- if you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus)
- if you have high calcium or low potassium levels or you are on a low potassium diet
- if you need to have an anaesthetic (even at the dentist) or before surgery, or if you are going to have tests to check your parathyroid function, you must tell the doctor or medical staff that you are taking losartan potassium and hydrochlorothiazide tablets
- if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland)
- if you are taking a medicine called aliskiren to reduce blood pressure.

Children and adolescents

There is no experience with the use of COZAAR Comp in children. Therefore, COZAAR Comp should not be given to children.

Other medicines and Cozaar Comp

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Diuretic agents such as the hydrochlorothiazide contained in COZAAR Comp may interact with other medicines.

Preparations containing lithium should not be taken with COZAAR Comp without close supervision by your doctor.

Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines, other diuretics ("water tablets"), some laxatives, medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral agents or insulins).

It is also important for your doctor to know if you are taking

- other medicines to reduce your blood pressure
- steroids
- medicines to treat cancer
- pain killers
- drugs for treatment of fungal infections
- arthritis medicines
- resins used for high cholesterol, such as colestyramine
- medicines which relax your muscles
- sleeping tablets
- opioid medicines such as morphine
- 'pressor amines' such as adrenaline or other drugs from the same group
- oral agents for diabetes or insulins.

Please also inform your doctor if you are taking COZAAR Comp if you will be undergoing a radiographic procedure and will be given iodine contrast media.

COZAAR Comp with food and drink

You are advised not to drink alcohol whilst taking these tablets: alcohol and COZAAR Comp tablets may increase each other's effects.

Dietary salt in excessive quantities may counteract the effect of COZAAR Comp tablets.

COZAAR Comp tablets may be taken with or without food.

Pregnancy and breast-feeding Pregnancy

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

Your doctor will normally advise you to stop taking COZAAR Comp before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of COZAAR Comp. COZAAR Comp is not recommended during pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding.

COZAAR Comp is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

Use in elderly patients

COZAAR Comp works equally well in and is equally well tolerated by most older and younger adult patients. Most older patients require the same dose as younger patients.

Driving and using machines

When you begin treatment with this medication, you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate your medicine.

COZAAR Comp contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take COZAAR Comp

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on the appropriate dose of COZAAR Comp depending on your condition and whether you are taking other medicines. It is important to continue taking COZAAR Comp for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

High Blood Pressure

The usual dose of COZAAR Comp for most patients with high blood pressure is 1 tablet of COZAAR Comp 50mg/12.5mg per day to control blood pressure over the 24-hour period. This can be increased to 2 tablets once daily of Losartan/Hydrochlorothiazide 50mg/12.5mg Film-Coated Tablets or changed to 1 tablet daily of Losartan/Hydrochlorothiazide 100mg/25mg Film-Coated Tablets (a stronger strength) per day. The maximum daily dose is 2 tablets per day of Losartan/Hydrochlorothiazide 50mg/12.5mg Film-Coated Tablets or 1 tablet daily of Losartan/Hydrochlorothiazide 100mg/25mg Film-Coated Tablets

If you take more COZAAR Comp than you should

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. Overdose can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition and dehydration.

If you forget to take COZAAR Comp

Try to take COZAAR Comp daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

4. Possible side effects

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

If you experience the following, stop taking COZAAR Comp tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

This is a serious but rare side effect, which affects more than 1 out of 10,000 patients but fewer than 1 out of 1,000 patients. You may need urgent medical attention or hospitalisation.

The following side effects have been reported:

Common (may affect up to 1 in 10 people):

- Cough, upper airway infection, congestion in the nose, sinusitis, sinus disorder
- Diarrhoea, abdominal pain, nausea, indigestion
- Muscle pain or cramps, leg pain, back pain
- Insomnia, headache, dizziness
- Weakness, tiredness, chest pain
- Increased potassium levels (which can cause an abnormal heart rhythm), decreased haemoglobin levels
- Changes in kidney function including kidney failure
- Too low sugar in the blood (hypoglycaemia)

Uncommon (may affect up to 1 in 100 people):

- Anaemia, red or brownish spots on the skin (sometimes especially on the feet, legs, arms and buttocks, with joint pain, swelling of the hands and feet and stomach pain), bruising, reduction in white blood cells, clotting problems, reduced number of platelets
- Loss of appetite, increased uric acid levels or frank gout, increased blood sugar levels, abnormal blood electrolyte levels
- Anxiety, nervousness, panic disorder (recurring panic attacks), confusion, depression, abnormal dreams, sleep disorders, sleepiness, memory impairment
- Pins and needles or similar sensations, pain in the extremities, trembling, migraine, fainting
- Blurred vision, burning or stinging in the eyes, conjunctivitis, worsening eyesight, seeing things in yellow
- ringing, buzzing, roaring or clicking in the ears, vertigo
- Low blood pressure, which may be associated with changes in posture (feeling light-headed or weak when you stand up), angina (chest pain), abnormal heartbeat, cerebrovascular accident (TIA, "mini-stroke"), heart attack, palpitations
- Inflammation of blood vessels, which is often associated with a skin rash or bruising
- Sore throat, breathlessness, bronchitis, pneumonia, water on the lungs (which causes difficulty breathing), nosebleed, runny nose, congestion

- Constipation, obstipation, wind, stomach upsets, stomach spasms, vomiting, dry mouth, inflammation of a salivary gland, toothache
- Jaundice (yellowing of the eyes and skin), inflammation of the pancreas
- Hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, flushing, sweating, hair loss
- Pain in the arms, shoulders, hips, knees or other joints, joint swelling, stiffness, muscle weakness
- Frequent urination including at night, abnormal kidney function including inflammation of the kidneys, urinary tract infection, sugar in the urine
- Decreased sexual appetite, impotence
- Swelling of the face, localised swelling (oedema), fever

Rare (may affect up to 1 in 1,000 people):

- Hepatitis (inflammation of the liver), abnormal liver function tests

Not known (frequency cannot be estimated from the available data):

- Flu-like symptoms
- Unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis)
- Low levels of sodium in the blood (hyponatraemia)
- Generally feeling unwell (malaise)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

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

5. How to store COZAAR Comp

Keep out of the sight and reach of children.
Do not store above 30°C. Store in the original package in order to protect from light and moisture.
Do not use COZAAR Comp after the expiry date (Exp) which is stated on the container and blister. The expiry date refers to the last day of that month.
Do not open the blister pack until you are ready to take the medicine.
If your tablets appear discoloured, damaged or show any other signs of deterioration, please return these to your pharmacist who will advise you further.
Medicines should not be disposed of via wastewater or household waste.
Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
If you have any left-over/unused tablets, please return these to your pharmacist for safe disposal.

6. Contents of the pack and other information

What COZAAR Comp contains

The active substances are losartan potassium and hydrochlorothiazide.

COZAAR Comp 100mg/25mg contains 100mg of losartan potassium and 25mg of hydrochlorothiazide as the active ingredients.

COZAAR Comp 100 mg/25mg contains 8.48 mg (0.216 mEq) of potassium

COZAAR Comp 100mg/25mg contains the following inactive ingredients: microcrystalline cellulose, lactose monohydrate, pregelatinised corn starch, magnesium stearate, hydroxypropyl cellulose, hypromellose, titanium dioxide (E171), quinoline yellow aluminium lake (E104) and carnauba wax (E903).

What COZAAR Comp looks like and contents of the pack

COZAAR Comp are oval, yellow, film-coated tablets with '747' on one side and plain on the other.

Your medicine is available in blister packs containing 28 film-coated tablets in an outer cardboard carton.

Manufacturer

Manufactured by:
Merck Sharp & Dohme Ltd., Cramlington, Northumberland, UK.

Procured from within the EU by the Parallel Product Authorisation holder:
Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by:
Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/95/1

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	COSAAR Plus – Filmtabletten, FORTZAAR-Filmtabletten
Belgium	COZAAR PLUS FORTE, LOORTAN PLUS FORTE
Cyprus	FORTZAAR, HYZAAR
Denmark	COZAAR Comp, . COZAAR Comp Forte, FORTZAAR
Estonia	HYZAAR, FORTZAAR
Finland	COZAAR Comp, COZAAR Comp Forte
France	FORTZAAR film-coated tablets, HYZAAR film-coated tablets
Germany	FORTZAAR Filmtabletten
Greece	HYZAAR, HYZAAR Extra Forte, HYZAAR Forte
Hungary	HYZAAR Forte.
Ireland	COZAAR Comp film-coated tablets
Italy	HIZAAR compresse rivestite con film, FORZAAR compresse rivestite con film, LOSAZID compresse rivestite con film
Lithuania	FORTZAAR plevele dengtos tabletes
Luxembourg	COZAAR PLUS FORTE , LOORTAN PLUS FORTE
Malta	COZAAR Comp pilloli miksjija b'rita
Netherlands	FORTZAAR
Poland	HYZAAR, HYZAAR FORTE
Portugal	COZAAR Plus, FORTZAAR, SIAARA, LORTAAN PLUS
Romania	FORTZAAR comprimate filmate
Slovenia	HYZAAR, FORTZAAR
Spain	COZAAR Plus, FORTZAAR
Sweden	COZAAR Comp Forte
United Kingdom	COZAAR-COMP FILM COATED TABLETS
Iceland	COZAAR COMP FORTE
Norway	COZAAR Comp, COZAAR Comp Forte

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