

**APPROVED PATIENT INFORMATION LEAFLET:
INFORMATION FOR THE PATIENT ABOUT FORTZAAR™**

Read all of this leaflet carefully before you start taking FORTZAAR

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or your pharmacist.
- FORTZAAR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

FORTZAAR™ TABLET

(100 mg losartan potassium and 25 mg hydrochlorothiazide)

WHAT FORTZAAR CONTAIN

FORTZAAR (losartan potassium-hydrochlorothiazide) are film-coated tablets containing 100 mg of losartan potassium and 25 mg of hydrochlorothiazide as the active ingredients.

In addition, FORTZAAR contain the following inactive ingredients:

Quinoline yellow aluminium lake; carnauba wax; hydroxypropyl cellulose; hypromellose; lactose hydrous; magnesium stearate; microcrystalline cellulose; pregelatinised starch; titanium dioxide.

FORTZAAR contains lactose hydrous

WHAT FORTZAAR IS USED FOR

FORTZAAR is a combination of angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide).

Losartan and hydrochlorothiazide work together to lower high blood pressure.

Your doctor has prescribed FORTZAAR because you have a condition known as hypertension or high blood pressure.

BEFORE YOU TAKE FORTZAAR

Do not take FORTZAAR:

- If you are allergic to any of its ingredients (see **WHAT FORTZAAR CONTAIN**)
- If you have previously been treated with a medication in the same group of medicines as FORTZAAR (angiotensin receptor antagonists) or with a medication in the group of medicines known as ACE inhibitors and have had allergic reactions with swelling of the face, lips, tongue, and/or throat with difficulty in swallowing or breathing.
- If you have hereditary or idiopathic angioedema
- If you have hypertrophic obstructive cardiomyopathy, a heart disorder in which the walls of the ventricles (lower heart chambers) thicken (hypertrophy) and become stiff and the thickened muscle blocks the flow of blood out of the heart.
- If you have severe kidney disease
- If you have narrowing of the blood vessels to both kidneys or to a single kidney.
- If you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of the heart) and the aorta (the main artery leading away from the heart)
- If you are taking diuretics (water pills) that cause your body to retain potassium such as spironolactone, triamterene and amiloride.
- If you have porphyria
- Thiazide water tablets in (fixed dose) combination as with FORTZAAR should not be given to patients with Addison's disease. This therapy should also not be used in patients with severe kidney disease or patients not passing urine, and in patients who show allergy to other sulphonamide-derived medicines (ask your doctor if you are not sure what sulphonamide-derived medicines are).
- Lithium therapy: Concomitant administration with FORTZAAR may lead to toxic blood concentrations of lithium
- If you are pregnant or breastfeeding (see **Pregnancy and Breastfeeding**)
- If you have liver disease

Take special care with FORTZAAR

- If you have or have had medical problems, any allergies, or if you have recently suffered from vomiting or diarrhoea

- If you have any liver or kidney problems, gout, sugar diabetes, lupus erythematosus, or if you are being treated with diuretics (water tablets). In these cases, your doctor may need to adjust the dose of your medication.
- Before surgery and any anaesthesia (even at a dentist's office), tell the doctor or dentist that you are taking FORTZAAR, as there may be a sudden fall in blood pressure associated with the anaesthetic.
- If you are taking lithium (a medicine used to treat a certain kind of depression)

Use in children

As there is no experience with the use of FORTZAAR in children, FORTZAAR should not be given to children.

Taking FORTZAAR with food and drink

FORTZAAR can be taken with or without food. For convenience and to help you remember, try to take FORTZAAR at the same time each day.

Pregnancy and Breastfeeding

You should not use FORTZAAR while you are pregnant or breastfeeding your baby, as FORTZAAR may harm your baby. If you are pregnant or become pregnant while taking FORTZAAR, stop taking FORTZAAR and tell your doctor as soon as possible.

If you are pregnant or breastfeeding your baby while taking FORTZAAR please consult your doctor, pharmacist or other health care professional for advice

Driving and using machinery

You should be careful in performing tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate FORTZAAR.

Important information about some of the ingredients of FORTZAAR

FORTZAAR contains lactose. If you have been told by our doctor that you have an intolerance to some sugars, contact your doctor before taking FORTZAAR.

Taking other medicines with FORTZAAR

You should tell your doctor about all medicines that you are taking or plan to take, including those obtained without a prescription. It is especially important for your doctor to know if you are taking other medicines to reduce blood pressure, other diuretics (water tablets), medications to treat diabetes including insulin, resins which reduce high cholesterol, muscle relaxants, pressor amines such as adrenaline, steroids, certain pain and arthritis medicines, or lithium (a medicine used to treat a certain kind of depression). Sedatives, tranquilizers, narcotics, alcohol and analgesics may increase the blood pressure-lowering effect of FORTZAAR, so tell your doctor if you take any of these medicines.

If you are taking other medicines on a regular basis including complementary or traditional medicines the use of FORTZAAR with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO TAKE FORTZAAR

Take FORTZAAR every day, exactly as your doctor has instructed. It is important to continue taking FORTZAAR for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

The usual dose of FORTZAAR is 1 tablet of FORTZAAR per day.

Do not share FORTZAAR prescribed for you with others

If you take more FORTZAAR than you should:

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre

If you forget to take FORTZAAR

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

POSSIBLE SIDE EFFECTS

FORTZAAR can have side effects. Side effects may include dizziness, hives, rash, or increased sensitivity of the skin to the sun. Your doctor or pharmacist has a more complete list. Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

If you develop an allergic reaction involving swelling of the face, lips, throat and/or tongue, stop taking FORTZAAR and contact your doctor immediately.

Not all side effects reported for FORTZAAR are included in this leaflet. Should your general health worsen while taking FORTZAAR, please consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF FORTZAAR

Do not use this medicine after the month and year following EXPIRES/VERVAL on the container.

Return all unused medicine to your pharmacist.

Store FORTZAAR at room temperature

Keep the container tightly closed.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not dispose of unused medicine in drains or the sewerage system (eg.Toilets)

PRESENTATION OF FORTZAAR

FORTZAAR tablets are supplied in blister packs of 30

IDENTIFICATION OF FORTZAAR

FORTZAAR Tablets are light yellow, oval-shaped, film-coated tablets with '747' on one side and plain on the other side.

REGISTRATION NUMBER

34/7.1.3/0281

**THE NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE
OF REGISTRATION**

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