

PATIENT INFORMATION LEAFLET
ZARTAN RANGE

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM:

ZARTAN 12,5 mg film coated tablets

ZARTAN 25 mg film coated tablets

ZARTAN 50 mg film coated tablets

ZARTAN 100 mg film coated tablets

Read all of this leaflet carefully before you start taking ZARTAN.

Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor or your pharmacist.
- **ZARTAN** 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.

1. WHAT ZARTAN CONTAINS:

The active substance is losartan potassium.

The other ingredients are croscarmellose sodium, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, propylene glycol, povidone, purified talc and titanium dioxide.

ZARTAN contains mannitol (50,95 mg, 101,90 mg, 203,80 mg and 407,60 mg in **ZARTAN** 12,5 mg, 25 mg, 50 mg and 100 mg).

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ZARTAN has been prescribed to you by your doctor or healthcare provider because you have a condition known as hypertension “high blood” or high blood pressure.

3. BEFORE YOU TAKE ZARTAN:**Do not take ZARTAN:**

- if you are hypersensitive (allergic) to losartan potassium or any of the other ingredients of **ZARTAN** (see **WHAT ZARTAN CONTAINS**)
- If you are taking fluoroquinolones (type of antibiotic) such as ciprofloxacin or levofloxacin with **ZARTAN**, contact your doctor to re-evaluate your treatment
- if you or your family have a history of serious allergic reaction which includes swelling of the face or throat
- if you have abnormally thickened heart muscles
- if you have severe kidney disease
- if you only have one kidney
- if you have a heart condition
- if you are taking other medicines which retain potassium, such as spironolactone, triamterene or amiloride (see **Taking other medicines with ZARTAN**)
- if you suffer from porphyria (a rare blood disorder)
- if you are taking lithium medicines (see **Taking other medicines with ZARTAN**)
- if you are pregnant or breastfeeding (see **Pregnancy and breastfeeding**)

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- if you are taking high blood pressure medicines which are in the renin inhibitors or aliskiren-containing group (see **Take special care with ZARTAN**).

Take special care with ZARTAN:

- if you fall pregnant while taking **ZARTAN**, you should stop taking **ZARTAN** immediately and inform your doctor as soon as possible (see **BEFORE YOU TAKE ZARTAN** and **Pregnancy and breastfeeding**)
- If you are currently on any fluoroquinolones, such as ciprofloxacin or levofloxacin, as the concomitant use of fluoroquinolone and Angiotensin receptor blockers such as **ZARTAN** may cause acute kidney injury, contact your doctor to re-evaluate your treatment
- If you are currently being treated for hypertension with other medicines used to lower blood pressure
- if you have recently suffered from excessive vomiting or diarrhoea
- if you have liver or kidney disease
- If you are taking high-dose diuretics (water tablets)
- If you are an elderly patient or if you have problems with your kidneys, the potassium levels in your body should be carefully monitored
- If you have problems with your liver.

Taking ZARTAN with food and drink:

ZARTAN does not interact with food or drink.

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The use of **ZARTAN** while you are pregnant or breast feeding is not recommended. If you are pregnant or suspect that you are pregnant while taking **ZARTAN**, stop taking **ZARTAN** and talk to your doctor or healthcare provider as soon as possible (see **Take special care with ZARTAN**).

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking **ZARTAN**.

Driving and using machinery:

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 **ZARTAN**.

Important information about some of the ingredients of Zartan:

Zartan contains mannitol and may have a laxative effect.

Taking other medicines with ZARTAN:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Combinations containing any of the following medications, depending on the amount present, may also interact with **ZARTAN** tablets:

- fluoroquinolones (type of antibiotic) such as ciprofloxacin or levofloxacin may lead to acute kidney injury, contact your doctor to re-evaluate your treatment
- anti-inflammatory medicines, NSAIDs, especially indomethacin

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- potassium-sparing diuretics (water tablets), potassium containing medicine, potassium supplements, medicines which retain potassium (amoloride, triameterene, spironolactone) or increases potassium levels (heparin)
- lithium (to treat depression).

4. HOW TO TAKE ZARTAN:

Do not share medicines prescribed for you with any other person.

Always take **ZARTAN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual starting dose of **ZARTAN** is 50 mg per day to control blood pressure over the 24-hour period.

The dose may be increased to 100 mg once daily.

A starting dose of 25 mg once daily may be used in the elderly patient over 75 years, and for patients with renal impairment.

A reduced dose should also be considered for patients with hepatic impairment.

For convenience and to help you remember, try to take **ZARTAN** at the same time each day.

If you have the impression that the effect of **ZARTAN** is too strong or too weak, tell your doctor or pharmacist.

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

If you forget to take a dose of ZARTAN:

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

5. POSSIBLE SIDE EFFECTS:

ZARTAN can have side effects.

Not all side effects reported for **ZARTAN** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **ZARTAN**, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking **ZARTAN** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- hives, rash, itching skin

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ZARTAN**. You may need urgent medical attention or hospitalisation.

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Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- heart pounding, fast heartbeat, chest pain, irregular heartbeat
- fainting from low blood pressure
- difficulty breathing
- pancreas infection (you may experience a few of the following symptoms: abdomen pain in the upper middle or upper left belly, the pain may get worse after eating or when you lay flat on your back)
- liver damage (you may feel very tired, nauseous, pain on your right side just below your ribs, no appetite, fever)
- kidney failure (you may experience the following symptoms: less urine than normal, legs, ankles and feet swelling, shortness of breath, tiredness, nausea, confusion, chest pain, seizures).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- head spinning sensation (vertigo)
- kidney problems (you may experience the following symptoms: nausea, vomiting, less urine than normal, ankles swelling, puffiness around the eyes, unpleasant taste in the mouth, stinky breath, tiredness, shortness of breath, no appetite)

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- increased potassium level in blood, low blood sugar which will be seen in a blood test (you may feel weak, tired, numbness, nausea, shortness of breath, chest pain, fast or skipped heartbeat).

Less frequent side effects:

- lack of iron in blood, low white blood cells, low platelet count which will be seen in a blood test (you may experience the following symptoms: tiredness, weakness, pale skin, shortness of breath, dizziness, tingling sensation in your legs, tongue swelling, fever, sore mouth, swollen gums, sinus infection, ear infection, cough)
- dizziness, difficulty falling asleep, migraine, sleepiness, tingling sensation on skin, metallic taste in mouth
- ringing in the ear
- cough, stuffy nose, throat infection, sinus infection, upper airway infection, shortness of breath
- diarrhoea, heartburn, nausea, change in sense of taste, losing sense of taste, stomach pain, severe constipation, vomiting
- increased liver enzymes which will be seen in a blood test
- severe itching of the skin, sun sensitivity
- back pain, muscle cramps, leg pain, muscle pain, joint pain
- inability to develop or sustain an erection
- tiredness, swelling from water retention

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- decrease sodium level in blood which will be seen in a blood test (you may experience the following symptoms: weakness, tiredness, headache, nausea, vomiting, muscle cramps or spasms, confusion, irritability).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF ZARTAN:

Store all medicines out of reach of children.

Store **ZARTAN** in a dry place at or below 25 °C.

Do not store your medicine in the bathroom.

Keep the tablets in the original packaging until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).