

**PATIENT INFORMATION LEAFLET
TESAR RANGE**

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM:

TESAR 20 mg* uncoated tablets

TESAR 40 mg uncoated tablets

TESAR 80 mg uncoated tablets

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **TESAR** 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 TESAR CONTAINS:

The active substance is telmisartan.

Each tablet contains 20 mg*, 40 mg or 80 mg telmisartan respectively.

The other ingredients are crospovidone, magnesium stearate, mannitol, meglumine, povidone and sodium hydroxide.

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TESAR contains sugar (mannitol) in the following quantities;

TESAR 20 mg (81,9 mg), **TESAR 40 mg** (163,8 mg), **TESAR 80 mg** (327,7 mg).

2. WHAT TESAR IS USED FOR:

Treatment of mild to moderate high blood pressure.

3. BEFORE YOU USE TESAR:**Do not take TESAR:**

- if you are hypersensitive (allergic) to telmisartan or any of the other ingredients of **TESAR** (see **WHAT TESAR CONTAINS**)
- if you have any heart or blood circulation conditions
- if you are taking an antibiotic of the fluoroquinolone group of antibiotics (e.g. ciprofloxacin, moxifloxacin and levofloxacin), to treat a bacterial infection (such as respiratory tract infections, urinary tract infections and skin infections), as taking these medicines while taking Angiotensin receptor blockers, such as **TESAR**, may result in kidney injury, especially if you have kidney problems or if you are elderly.
Contact your doctor to re-evaluate your treatment if you are treated with an Angiotensin receptor blocker, such as **TESAR**, together with a fluoroquinolone antibiotic
- if you have an abnormally functioning kidney or narrowing of any kidney arteries
- if you have narrowing of the aorta (biggest artery in the body)
- if you are being treated with any medication which increases urination or fluid loss
- if you have condition called porphyria

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- if you are undergoing lithium therapy: Simultaneous administration with **TESAR** may lead to toxic blood concentrations of lithium
- if you are pregnant or breastfeeding
- if you are taking renin-inhibiting (aliskiren-containing) medicines used for the treatment of high blood pressure.

Take special care with TESAR:

- if you are taking an antibiotic of the fluoroquinolone group of antibiotics (e.g. ciprofloxacin, moxifloxacin and levofloxacin), to treat a bacterial infection (such as respiratory tract infections, urinary tract infections and skin infections), as taking these medicines while treated with **TESAR** may result in kidney injury, especially if you have kidney problems or if you are elderly.

Contact your doctor to re-evaluate your treatment if you are treated with an Angiotensin receptor blocker, such as **TESAR**, together with a fluoroquinolone antibiotic

- if you are taking renin-inhibiting (aliskiren-containing) medicines for treatment of high blood pressure, as the risk of low blood pressure, low blood potassium levels and kidney problems may be increased if these medicines are taken in combination with **TESAR**
- if you have low blood pressure
- if you have kidney problems, heart failure, are on kidney replacement therapy, on potassium supplements, potassium sparing medication, and other medications that increase potassium levels

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- if you have a condition called aldosteronism which is characterised by the overproduction of the hormone aldosterone by the adrenal glands
- if you are sodium depleted (this may result from dietary salt restriction, diarrhoea, vomiting or if you are on medication that increases urination)
- if you have narrowing of renal arteries or the main artery
- if you have any liver problems or conditions
- as dehydration may occur due to side effects such as excess sweating, diarrhoea and vomiting.

Pregnancy and breastfeeding:

Safety in pregnancy and while breastfeeding has not been established. Use of medicines affecting the renin-angiotensin system, such as **TESAR**, during second and third trimesters of pregnancy may cause injury or even death to the foetus.

DO NOT take **TESAR** if you are pregnant, planning to become pregnant or breastfeeding. If you become pregnant while taking **TESAR**, the treatment should be stopped immediately and switched to a different class of antihypertensives by your doctor.

Woman of childbearing age should use effective contraception.

Driving and using machinery:

TESAR can cause low blood pressure and dizziness, and caution should be taken while driving or using heavy machinery.

Important information about some of the ingredients of TESAR:

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TESAR contains mannitol and may have a laxative effect.

Using other medicines with TESAR:

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

Consult with your doctor, pharmacist or healthcare professional, if you need to take any other medicines, for advice. If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **TESAR** with these medicines may cause undesirable interactions.

TESAR may interact with fluoroquinolone antibiotics (e.g. ciprofloxacin, moxifloxacin and levofloxacin), which are used in treatment of bacterial infections such as respiratory tract infections, urinary tract infections and skin infections.

Contact your doctor to re-evaluate your treatment if you are treated with a fluoroquinolone antibiotic together with **TESAR**.

TESAR should not be taken with renin inhibiting (aliskiren-containing) medicines, used to treat high blood pressure.

TESAR can cause an excessive low blood pressure effect when used with other blood pressure medication.

Medicines such as digoxin (heart medicine), warfarin (medicine used to prevent blood clots),

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hydrochlorothiazide (medicine used to increase urination and reduce blood pressure), glibenclamide (medicine used to treat high blood sugar / diabetes), paracetamol (pain killer), ibuprofen (medicine used to treat pain and inflammation), simvastatin (medicine used to treat high cholesterol levels in the blood) and amlodipine (medicine used to treat high blood pressure) have been known to interact with **TESAR**.

TESAR causes the increase of lithium absorption in the body when used in lithium therapy.

4. HOW TO TAKE TESAR:

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

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

The recommended dosage for an adult is 40 mg once a day.

A dosage of 20 mg may already be beneficial for some patients.

The maximum dosage of **TESAR** is 80 mg once daily.

The best blood pressure lowering result is achieved four to eight weeks after the start of treatment with **TESAR**.

Your doctor will tell you how long your treatment with **TESAR** will last. If you have the impression that the effect of **TESAR** is too strong or too weak, tell your doctor or pharmacist.

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Children and adolescents up to the age of 18:

Safety and efficacy has not been established in children and adolescents, and it is therefore not recommended that anyone younger than 18 years of age use **TESAR**.

If you take more TESAR than you should:

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 TESAR:

Take one tablet as soon as you remember. If it is almost time for your next usual dose, skip the missed dose and continue taking **TESAR** at your regular time.

DO NOT take a double dose of **TESAR**.

5. POSSIBLE SIDE EFFECTS:

TESAR can have side effects.

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

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

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- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- skin rash, hives, itchiness, skin blistering, redness of the skin (signs of infection/inflammation).

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

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

- heart failure (symptoms include tightness or pain in the chest, neck, back or arms, as well as fatigue, dizziness or feeling faint, abnormal heartbeat and anxiety), abnormal heart rhythm (heart beating faster or slower than normal), chest pain
- trouble breathing, breathlessness
- sweating.

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:

- urinary tract infection, respiratory tract infection.

Less frequent side effects:

- changes in the number of red and white blood cells determined by blood tests (eosinophilia), symptoms such as bruising and bleeding easily due to a reduced number of blood platelets (thrombocytopenia)

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- nervousness, depression, difficulty sleeping
- headache, dizziness, light headedness
- change in vision
- problems with balance, pounding in the ears
- low blood pressure
- coughing, sinusitis
- trouble digesting food (discomfort after meals), stomach cramps, nausea, vomiting, diarrhoea, dry mouth, flatulence
- weakness, muscle aches, pain or cramps, tendon pain
- flu-like symptoms, fatigue.

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

6. STORING AND DISPOSING OF TESAR:

Store all medicines out of reach of children.

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

Do not pop a tablet out of the blister pack until you need to take it.

Keep the blisters in the outer carton 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).