

PATIENT INFORMATION LEAFLET
TESAR RANGE

SCHEDULING STATUS

S3

TESAR 40 mg uncoated tablets

TESAR 80 mg uncoated tablets

Telmisartan

TESAR contains sugar alcohol (mannitol) in the following quantities;

TESAR 40 mg (163,8 mg) and TESAR 80 mg (327,7 mg).

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, pharmacist, nurse or other healthcare provider.
- 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.

What is in this leaflet

1. What TESAR is and what it is used for
2. What you need to know before you take/use TESAR
3. How to take/use TESAR
4. Possible side effects
5. How to store TESAR
6. Contents of the pack and other information

1. What TESAR is and what it is used for

TESAR belongs to a class of medicines known as angiotensin II receptor antagonists.

Angiotensin II is a substance produced in your body which causes your blood vessels to

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narrow, thus increasing your blood pressure. TESAR blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

TESAR is used for the treatment of mild to moderate high blood pressure.

TESAR can also be used to reduce cardiovascular events and death in patients 55 years or older who are at high risk of cardiovascular disease; the benefit of treatment is evident after at least 6 months of continued treatment.

2. What you need to know before you take/use TESAR

Do not take TESAR:

- if you are hypersensitive (allergic) to telmisartan, or to any of the ingredients of TESAR (see section 6)
- have ever developed swelling of the face, lips, mouth, tongue or throat and giant wheals on your skin when previously taking medicines called angiotensin converting enzyme inhibitors (ACE-I) or angiotensin receptor blockers (ARBs) – you should never take these medicines again
- 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 ARB, such as TESAR, together with a fluoroquinolone antibiotic
- if you have an abnormally functioning kidney or narrowing of any kidney arteries

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- if you suffer from severe kidney function impairment
- 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, specifically taking potassium sparing water tablets containing spironolactone, triamterene or amiloride
- if you have a condition called porphyria
- if you are undergoing lithium therapy (used to treat mood disorders), 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
- if you suffer from severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder).

Warnings and precautions

Treatment with TESAR should not be started during pregnancy.

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 ARB, such as TESAR, together with a fluoroquinolone antibiotic

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- 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 suffer from severe kidney function impairment or have had a kidney transplant
- if you have kidney problems, heart failure, are on kidney replacement therapy, potassium supplements, potassium sparing medication, and other medications that increase potassium levels
- if you have narrowing of renal arteries or the main artery
- 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 any liver problems or conditions
- if you have low blood pressure
- if you experience side effects such as excess sweating, diarrhoea, and vomiting, since dehydration may occur
- if you have diabetes.

Other medicines and TESAR

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

- 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

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- 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), 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
- nonsteroidal anti-inflammatory medicines (NSAIDs) like aspirin, when taken with TESAR, may cause kidney problems in dehydrated patients as well as reduce the blood pressure lowering effect of this medicine.

TESAR with food and drink

See section 3 below.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using TESAR.

Safety in pregnancy and while breastfeeding has not been established. Use of medicines

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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 (see section 2 above). 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 machines

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

It is not always possible to predict to what extent TESAR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TESAR affects them.

TESAR contains mannitol

TESAR contains mannitol which may have a laxative effect.

3. How to use TESAR

Do not share medicines prescribed for you with any other person. Always use TESAR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:

TESAR is to be taken once daily with a little water.

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For high blood pressure:

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

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.

To reduce cardiovascular events and death in patients 55 years or older who are at high risk of cardiovascular disease:

The recommended dosage is 80 mg once day.

When initiating treatment, your doctor may wish to monitor your blood pressure and, if appropriate, adjust your blood pressure lowering medicines.

The benefits of therapy are evident after 6 months of continued treatment with TESAR.

Patients with liver impairment:

In patients with mild to moderate liver impairment, the dosage should not exceed 40 mg once daily.

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.

Your doctor will tell you how long your treatment with TESAR will last. Do not stop treatment early because your high blood pressure may return.

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

If you use 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.

Symptoms of overdose may include:

- Abnormal heartbeat, dizziness, low blood pressure.

If you forget to use 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 to make up for forgotten individual doses.

If you stop using TESAR

Do not stop taking TESAR without consulting your doctor first.

4. 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 using TESAR, please consult your healthcare provider for advice.

If any of the following happens, stop using TESAR 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

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difficulty in swallowing or breathing

- rash or itching
- fainting.

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
- skin blistering, redness of the skin (signs of infection/inflammation)
- sepsis (a serious condition resulting from the presence of harmful microorganisms in the blood or other tissues potentially leading to the malfunctioning of various organs, shock, and death. Symptoms include fever, difficulty breathing, low blood pressure, fast heart rate and mental confusion)
- you pass less urine than is normal for you and you notice that your feet are swollen
- faintness, dizziness (for example when standing up quickly)
- liver function problems (symptoms may include yellow eyes and skin i.e. jaundice, nausea, abdominal pain and swelling, and swelling of the legs)

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- urinary tract infection (including inflammation of the bladder), respiratory tract infection

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(e.g. sore throat or sinusitis)

- 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), anaemia
- elevated blood potassium levels in your blood
- nervousness, depression, difficulty sleeping
- headache, dizziness
- 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
- increased sweating, skin rashes
- weakness, muscle aches, pain or cramps, pain in extremities (e.g., leg pain)
- flu-like symptoms, fatigue.

The following side effects have been reported but the frequency for them to occur is not known:

- backflow of undigested food, known as regurgitation, food getting stuck in the esophagus after swallowing
- low blood sugar in diabetic patients
- hives
- tendon pain.

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

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Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: <https://www.sahpra.org.za/Publications/Index/8> or <http://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problemreporting-form/>.

By reporting side effects, you can help provide more information on the safety of TESAR. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store TESAR

Store all medicines out of reach of children.

Store at or below 30 °C in a dry place.

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

Keep blisters in 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).

6. Contents of the pack and other information

What TESAR contains:

The active ingredient is telmisartan.

Each tablet contains 40 mg or 80 mg telmisartan respectively.

The other ingredients are:

Crospovidone, magnesium stearate, mannitol, meglumine (for pH-adjustment), povidone and sodium hydroxide (for pH adjustment).

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What TESAR looks like and contents of the pack

TESAR 40 mg: White, oblong tablet of 12,0 x 5,9 mm approx. with LC debossed on one side.

TESAR 80 mg: White, oblong tablet of 16,0 x 8,0 mm approx. with LC debossed on one side.

TESAR tablets are available in plain silver aluminium/aluminium blister strips. Each pack contains 30 tablets per outer carton.

Holder of Certificate of Registration

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