

Teva Pharmaceuticals (Pty) Ltd.	Product: TENSITEV 40/5; 40/10; 80/5; 80/10 Dosage Form: Tablets
Reg. No.: 57/7.1.3/0340 57/7.1.3/0341 57/7.1.3/0342 57/7.1.3/0343	Strength: Each tablet contains 40 mg telmisartan and 5 mg or 10 mg amlodipine (as besilate), respectively Each tablet contains 80 mg telmisartan and 5 mg or 10 mg amlodipine (as besilate), respectively

PATIENT INFORMATION LEAFLET
SCHEDULING STATUS: S3 TENSITEV 40/5, 40/10, 80/5, 80/10, Tablets Telmisartan; amlodipine (as besilate) TENSITEV contains sugar (mannitol: 98,505 mg, 98,36 mg, 197,01 mg and 196,72 mg per tablet) respectively Read all of this leaflet carefully before you start taking TENSITEV. • 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. • TENSITEV 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 TENSITEV IS AND WHAT IT IS USED FOR 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TENSITEV 3. HOW TO TAKE TENSITEV 4. POSSIBLE SIDE EFFECTS 5. HOW TO STORE TENSITEV 6. CONTENTS OF THE PACK AND OTHER INFORMATION

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1. WHAT TENSITEV IS AND WHAT IT IS USED FOR:

TENSITEV tablets contain two active substances called telmisartan and amlodipine.

TENSITEV is used to treat high blood pressure (also known as essential hypertension) in patients using the same components as individual components, or when treatment with amlodipine alone did not lower your blood pressure enough.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TENSITEV:

Do not take TENSITEV if you are pregnant, are considering becoming pregnant or are breastfeeding. A switch to a suitable alternative treatment should be carried out in advance of planned pregnancy.

Do not take TENSITEV:

- if you are hypersensitive (allergic) to telmisartan or amlodipine or to any of the other ingredients of TENSITEV (listed in **section 6**)
- if you are allergic to other medicines of the dihydropyridine type (one type of calcium channel blocker)
- if you have developed swelling and giant wheals on your skin when having previously taken medicines called angiotensin converting enzyme inhibitors (ACE inhibitors) or angiotensin receptor blockers (ARBs)
- if you have an inherited disorder or of unknown origin you suffer from recurrent episodes of the accumulation of fluids outside of the blood vessels, blocking the normal flow of blood or lymphatic fluid

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and causing rapid swelling of tissues in the hands, feet, limbs, face, intestinal tract, or airway (hereditary or idiopathic angioedema)

- if you have a heart condition called hypertrophic obstructive cardiomyopathy
- if you suffer from severe renal impairment
- if both blood vessels to the kidneys are narrowed or if you have a single kidney and the blood vessel to the kidney is narrowed
- if you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body)
- if you are currently taking lithium or potassium sparing water tablets containing spironolactone, triamterene or amiloride
- if you suffer from porphyria
- if you are currently taking aliskiren-containing medicines
- if you suffer from biliary obstruction (a problem with the drainage of the bile from the liver and gall bladder)
- if you suffer from severe liver problems
- if you suffer from severe low blood pressure (hypotension)
- if the blood circulation to your heart has not fully recovered following a recent heart attack
- if you have to use fluoroquinolones (antibiotic) concomitantly with TENSITEV and you have moderate to severe renal impairment or if you are elderly.

Warnings and precautions:

Take special care with TENSITEV:

- if you suffer from liver problems

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- if you suffer from kidney disease or have ever had a kidney transplant
- if you have low blood pressure (hypotension), which is likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy ('water tablets'), low-salt diet, diarrhoea, or vomiting
- if you have heart failure and kidney problems affecting the renin-angiotensin-aldosterone system
- if you are treated with TENSITEV and a fluoroquinolone antibiotic (see **section 4.3**)
- if you have been told that you have raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals)
- if the valve of your heart is narrowed (aortic and mitral valve stenosis) or your heart muscle is enlarged (hypertrophic obstructive cardiomyopathy)
- if you have heart-associated chest pain also at rest or with minimal effort (unstable angina pectoris)
- if you have high potassium levels in your blood or use salt substitutes that contain potassium
- if you have diabetes
- if you are elderly and your dose needs to be increased.

Children and adolescents:

Do not give TENSITEV to children under the age of 18 years.

Other medicines and TENSITEV:

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

Tell your doctor if you are taking:

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- Other antihypertensive medicines
- Medicines with the potential to lower blood pressure (baclofen, amifostine, barbiturates, narcotics or antidepressants or alcohol)
- Corticosteroids
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain 'water tablets')
- Lithium-containing medicines to treat some types of depression
- Digitalis glycosides (digoxin) which is a heart medication
- Anticonvulsant medicines (e.g. carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone)
- ACE-inhibitors, angiotensin II receptor antagonists or aliskiren (see **Do not take TENSITEV** and **Take special care with TENSITEV**)
- NSAIDs (non-steroidal anti-inflammatory medicines, e.g. acetylsalicylic acid or ibuprofen), heparin, immunosuppressives (e.g. ciclosporin or tacrolimus)
- Fluoroquinolones (an antibiotic)
- Grapefruit and grapefruit juice
- Strong or moderate CYP3A4 inhibitors (ketoconazole, erythromycin, clarithromycin, verapamil or diltiazem)
- Rifampicin
- St. John's wort (*Hypericum perforatum*)
- Dantrolene infusion used to treat an anaesthetic complication called malignant hyperthermia
- Ciclosporin, tacrolimus, sirolimus, temsirolimus or everolimus used to suppress your immune system or to treat certain types of cancer

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- Simvastatin (used to lower cholesterol)

TENSITEV with food and drink:

You can take TENSITEV with water or other non-alcoholic drink and with or without food.

You should not eat grapefruit or drink grapefruit juice when you take TENSITEV because this can increase the blood pressure lowering effect in some people.

Do not take TENSITEV with alcohol.

Pregnancy, breastfeeding and fertility:

Do not take TENSITEV and consult your doctor, pharmacist or other healthcare provider for advice if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby. A switch to a suitable alternative treatment should be carried out in advance of planned pregnancy.

Driving and using machines:

You may experience side effects such as fainting, sleepiness, dizziness or a feeling of spinning (vertigo) when you are treated for high blood pressure. If you experience these side effects, do not drive or use machines.

It is not always possible to predict to what extent TENSITEV may interfere with your daily activities. You should ensure that you do not engage in driving or use machines until you are aware of the measure to which TENSITEV affects you.

TENSITEV contains sodium:

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This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. HOW TO TAKE TENSITEV:

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

Always take TENSITEV exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet a day. Your doctor will start you on the lowest dose, 40/5 mg and will increase the dose if necessary.

Try to take the tablet at the same time each day.

You can take TENSITEV with or without food. The tablets should be swallowed with some water or other non-alcoholic drink.

If your liver is not working properly, the usual dose should not exceed one 40 mg/5 mg tablet or one 40 mg/10 mg tablet per day.

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

If you take more TENSITEV than you should:

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

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You might experience low blood pressure and rapid heartbeat. Slow heartbeat, dizziness, marked and prolonged low blood pressure including shock and death have also been reported.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24 to 48 hours after intake.

If you forget to take TENSITEV:

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

TENSITEV can have side effects.

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

If any of the following symptoms occur, stop taking the TENSITEV 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
- rash or itching
- fainting
- yellowing of the skin and eyes, also called jaundice.

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These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TENSITEV. 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:

- sepsis (often called ‘blood poisoning’, is a severe infection of the whole-body with high fever and the feeling of being severely ill)
- severe allergic reactions with blistering eruptions of the skin and mucous membranes (exfoliative dermatitis, Stevens-Johnson-Syndrome).

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

Tell your doctor if you notice any of the following:

Fixed dose combination:

Frequent side effects:

- dizziness
- swelling in your lower legs and hands.

Less frequent side effects:

- bladder inflammation
- depression, feeling anxious, sleeplessness
- fainting, sleepiness, migraine, headache
- tingling or numbness of the hands or feet
- weakness, numbness from nerve damage in the hands or feet

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- taste disorder, tremors
- feeling of spinning
- palpitations (awareness of your heartbeat), slow heartbeat
- low blood pressure, dizziness on standing up
- flushing
- cough
- stomach pain, diarrhoea, being sick (vomiting), feeling sick (nausea)
- indigestion, dry mouth, overgrowth of gum tissue around the teeth
- eczema (a skin disorder), redness of skin, rash
- joint stiffness, back pain, pain in arms and legs, muscle spasms, muscle aches and pain
- urge to urinate during the night
- inability to obtain an erection
- chest pain, excess of watery fluid collecting in the cavities or tissues of the body
- weakness, tiredness, feeling unwell (malaise)
- increased liver enzymes, increased levels of uric acid in the blood.

Telmisartan component of TENSITEV:

Less frequent side effects:

- sepsis (often called ‘blood poisoning’, is a severe infection of the whole-body with high fever and the feeling of being severely ill)
- urinary tract infections, upper respiratory tract infections (e.g., sore throat, inflamed sinuses, common cold), bladder inflammation

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- low platelet count (thrombocytopenia)
- deficiency in red blood cells (anaemia)
- increase in certain white blood cells (eosinophilia)
- allergic reaction (rash, itching, difficulty of breathing, wheezing, swelling of face or low blood pressure)
- high potassium levels in blood, low blood sugar levels
- depression, anxiety, sleeplessness
- fainting
- visual disturbance
- feeling of spinning
- slow or fast heartbeat
- low blood pressure, dizziness on standing up
- difficulty breathing
- stomach pain, diarrhoea, being sick (vomiting), indigestion, dry mouth, flatulence, upset stomach
- abnormal liver function, liver disorder
- skin rash caused by a medicine
- hives, eczema (a skin condition), redness of skin, rash
- increased sweating
- joint stiffness, back pain, pain in arms and legs, inflammation of the tendons, muscle spasms, muscle aches and pain
- kidney impairment
- chest pain, weakness, flu-like illness (for example muscle pain, feeling generally unwell)

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- increase liver enzymes, increased levels of creatinine, increased levels of creatinine phosphokinase in the blood, decreased haemoglobin (a blood protein), increased blood uric acid.

Amlodipine component of TENSITEV:

Frequent side effects:

- sleepiness, dizziness
- headache
- impaired vision, double vision
- quivering or irregular heartbeat
- flushing
- difficulty breathing
- stomach pain, diarrhoea, indigestion, constipation, (feeling sick) nausea, change of bowel habit
- joint swelling, cramps in legs
- excess of watery fluid collecting in the cavities or tissues of the body, weakness, tiredness.

Less frequent side effects:

- reduced number of white blood cells (leukopenia), low platelet count (thrombocytopenia)
- hypersensitivity, painless swelling under the skin, triggered by an allergy
- high blood sugar levels
- depression, anxiety, confusional state, sleeplessness, altered mood
- fainting
- muscle overactivity, numbness from nerve damage in the hands or feet, pins and needles sensation

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- numbness, taste disorder, tremors
- ringing in the ears
- heart attack, irregular and often abnormally fast heart rate
- low blood pressure
- slow heart rate
- inflammation of the blood vessels
- cough, runny nose
- inflamed pancreas, inflammation of the stomach lining (gastritis), being sick (vomiting), overgrowth of gum tissue around the teeth, dry mouth
- inflammation of the liver (hepatitis), yellow skin caused by the build-up of bilirubin in the blood, increased levels of hepatic enzymes
- Stevens-Johnson syndrome (SJS) is a rare, serious disorder of the skin and mucous membranes. It's usually a reaction to medication that starts with flu-like symptoms, followed by a painful rash that spreads and blisters, skin condition with bull's eye shaped lesions, severe skin condition that causes extreme shedding of the top layers of your skin
- increased sensitivity of the skin to sun, hives
- skin rash, hair loss, purple-coloured spots and patches on the skin, skin discolouration, increased sweating
- joint stiffness, back pain, muscle aches and pain
- urge to urinate during the night, difficulty passing urine, frequent daytime urination
- inability to obtain an erection, enlarging of male breasts
- chest pain, pain

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- feeling unwell (malaise)
- increased weight, decreased weight.

Side effects with unknown frequency:

- involuntary or uncontrollable movements. tremors, muscle contractions, toxic epidermal necrolysis – a life-threatening skin disorder characterized by a blistering and peeling of the skin.

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

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TENSITEV.

5. HOW TO STORE TENSITEV:

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package to protect from light.

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:

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What TENSITEV contains:

The active substance is telmisartan and amlodipine.

TENSITEV 40/5 contains 40 mg telmisartan and amlodipine besilate equivalent to 5 mg amlodipine.

TENSITEV 40/10 contains 40 mg telmisartan and amlodipine besilate equivalent to 10 mg amlodipine.

TENSITEV 80/5 contains 80 mg telmisartan and amlodipine besilate equivalent to 5 mg amlodipine.

TENSITEV 80/10 contains 80 mg telmisartan and amlodipine besilate equivalent to 10 mg amlodipine.

The other ingredients are:

Telmisartan layer: Cellulose, microcrystalline, crospovidone, iron oxide red (E172) (40/5 and 80/5 strength), iron oxide yellow (E172) (40/10 and 80/10 strength), magnesium stearate, mannitol, meglumine, povidone K-25, sodium hydroxide.

Amlodipine layer: Cellulose, microcrystalline, magnesium stearate, silica, colloidal anhydrous, starch, pregelatinized (maize), starch (maize).

What TENSITEV looks like and contents of the pack:

TENSITEV 40/5: bilayer tablets, white to off-white on one side and pink on the other side, acceptable slight speckles on the pink side, oblong, biconvex.

TENSITEV 40/10: bilayer tablets, white to off-white on one side and yellow on the other side, acceptable slight speckles on the yellow side, oblong, biconvex.

TENSITEV 80/5: bilayer tablets, white to off-white on one side and pink on the other side, acceptable slight speckles on the pink side, oblong, biconvex.

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TENSITEV 80/10: bilayer tablets, white to off-white on one side and yellow on the other side, acceptable slight speckles on the yellow side, oblong, biconvex.

TENSITEV tablets are packed in Aluminium/OPA/Aluminium/PVC blister packs. The blisters are placed together with a patient information leaflet into cardboard boxes with imprinted label text.

Pack size: 28 or 30 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd

Maxwell Office Park

Magwa Crescent West

Waterfall City

Midrand

2090

South Africa

Tel: +27 11 055 0200

This leaflet was last revised in:

24 June 2025

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