

SCHEDULING STATUS

S3

TENSIOTEL 40/5 tablets

TENSIOTEL 40/10 tablets

TENSIOTEL 80/5 tablets

TENSIOTEL 80/10 tablets

Telmisartan and Amlodipine

Contains sweetener: mannitol

TENSIOTEL 40/5 contains mannitol 353,79 mg per tablet

TENSIOTEL 40/10 contains mannitol 346,14 mg per tablet

TENSIOTEL 80/5 contains mannitol 531,04 mg per tablet

TENSIOTEL 80/10 contains mannitol 516,89 mg per tablet

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

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor pharmacist, nurse or other health care provider.
- **TENSIOTEL** 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 **TENSIOTEL** is and what it is used for
2. What you need to know before you take **TENSIOTEL**
3. How to take **TENSIOTEL**
4. Possible side effects



5 How to store **TENSIOTEL**

6. Contents of the pack and other information

1. What **TENSIOTEL** is and what is it used for:

TENSIOTEL tablets contain two active substances called telmisartan and amlodipine. Both of these substances help to control your high blood pressure:

- Telmisartan belongs to a group of substances called “angiotensin-II receptor antagonists”.

Angiotensin II is a substance produced in the body which causes blood vessels to narrow, thus increasing blood pressure. Telmisartan works by blocking the effect of angiotensin II.

- Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.

This means that both of these active substances work together to help stop your blood vessels tightening. As a result, the blood vessels relax, and blood pressure is lowered.

TENSIOTEL 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 TENSIOTEL:

Do not take TENSIOTEL:

- if you are allergic (hypersensitive) to telmisartan, amlodipine or any of the other ingredients of TENSIOTEL (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 (ACE) inhibitors or angiotensin receptor blockers (ARBs).
- if you have a narrowing of the aortic blood vessel.
- 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 suffer from severe liver problems.
- if you suffer from biliary obstruction (a problem with the drainage of the bile from the liver and gall bladder).
- if you suffer from porphyria.
- if you are currently taking potassium sparing water tablets containing spironolactone, triamterene or amiloride.
- if you are currently taking lithium.
- if you suffer from low heart output because of a serious heart problem.
- if you suffer from severe kidney impairment.
- if you are currently taking aliskiren-containing medicines.
- if you are currently taking fluoroquinolone antibiotics and you are elderly or have kidney problems.



- if you are pregnant or breast-feeding.

Warnings and precautions

Tell your doctor or healthcare professional before taking TENSIOTEL:

Take special care with TENSIOTEL:

- if you suffer from kidney disease or have had a kidney transplant.
- if you suffer from liver problems.
- if you have heart problems.
- if you have heart-associated chest pain also at rest or with minimal effort (unstable angina pectoris).
- If you had a heart attack (myocardial infarction) one month ago
- if you are taking any of the following medicines used to treat high blood pressure:
 - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes related kidney problems.
 - aliskiren.
- 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 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 high potassium levels in your blood or use salt substitutes that contain potassium.
- if you have diabetes.



- if you are treated with Angiotensin-converting enzyme (ACE) inhibitors/Angiotensin receptor blockers (ARBs) together with a fluoroquinolone antibiotic.

Children and adolescents:

The use of TENSIOTEL in children and adolescents up to the age of 18 years is not recommended.

Other medicines and TENSIOTEL:

Always tell your health care provider if you are taking any other medicine. (This includes all

complementary or traditional medicines.)

Please consult your health care provider for advice. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below when taken together with TENSIOTEL:

- 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')
- Digoxin which is a heart medicine.
- Lithium-containing medicines used to treat some types of depression.
- Fluoroquinolones (Antibiotic)
- Erythromycin, clarithromycin (Antibiotic)



- Verapamil or diltiazem (Used to lower blood pressure)
- Dantrolene infusion used to treat an anaesthetic complication called malignant hyperthermia
- Anticonvulsant medicines (e.g. carbamazepine, phenobarbitone, phenytoin, fosphenytoin, primidone).
- Rifampicin used for treatment of tuberculosis.
- St. John's wort used for treatment of depression.
- Medicines used for HIV/AIDS (e.g. ritonavir) or for treatment of fungal infections (e.g. ketoconazole, itraconazole).
- Simvastatin used to lower your cholesterol levels.
- Ciclosporin or tacrolimus used to suppress your immune system.

The effect of TENSIOTEL may be reduced when you take NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids.

TENSIOTEL may increase the blood pressure lowering effect of other medicines used to treat high blood pressure or of medicines with blood pressure lowering potential (e.g. antidepressants, barbiturates, narcotics) or alcohol.

TENSIOTEL can interfere with ACE-inhibitors.

TENSIOTEL with food, drink and alcohol

You can take TENSIOTEL tablets with water or other non-alcoholic drinks and with or without food.

Grapefruit and grapefruit juice:

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

Alcohol:

Do not take TENSIOTEL with alcohol.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking TENSIOTEL.

Do not take TENSIOTEL if you are pregnant, are considering becoming pregnant or are breastfeeding.

If you are a woman of childbearing age, you must use effective contraception.

Driving and using machines:

No information is available on the effect of TENSIOTEL on the ability to drive or operate machinery.

Some people may experience side effects such as fainting, sleepiness, dizziness or a feeling of

spinning (vertigo) when they are treated for high blood pressure. If you experience these side effects, do not drive or operate machinery.

3. How to take TENSIOTEL:

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

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

The usual dose of TENSIOTEL is one tablet per day. Try to take the tablet at the same time each day.

Remove your TENSIOTEL tablet from the blister only immediately prior to intake.

You can take TENSIOTEL with or without food. The tablets should be swallowed with some water or other non-alcoholic drinks. It is important that you take

TENSIOTEL every day until your health care provider tells you otherwise. If you have the impression that the effect of TENSIOTEL is too strong or too weak, talk to your health care provider.

If your liver is not working properly, the usual dose should not exceed TENSIOTEL 40/5 mg or TENSIOTEL 40/10 mg once daily.

TENSIOTEL tablets are only for adults and should not be taken by children and adolescents up to 18 years.

If you take more TENSIOTEL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. You might experience low blood pressure and a rapid heartbeat.

Slow heartbeat, dizziness, reduced kidney function including kidney failure, marked and prolonged low blood pressure including shock and death have also been reported.

If you forget to take TENSIOTEL

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten dose.

Effects when treatment with TENSIOTEL is stopped:

It is important that you take TENSIOTEL every day until your doctor tells you otherwise.

4. Possible side effects

TENSIOTEL can have side effects.

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

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

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

These are all very serious side effects. If you have them, you may have had a serious reaction to TENSIOTEL. 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), rapid swelling of the skin and mucosa (angioedema); these side effects are extremely serious, and you should stop taking TENSIOTEL and see their doctor immediately. If these effects are not treated, they could be fatal. Increased incidence of sepsis has been observed with telmisartan only, however cannot be ruled out for TENSIOTEL

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



Tell your doctor if you notice any of the following with TENSIOTEL which is a combination of Telmisartan and Amlodipine:

Frequent:

- dizziness,
- ankle swelling (oedema).

Less frequent:

- sleepiness, migraine, headache, tingling or numbness of the hands or feet, feeling of spinning (vertigo), slow heart rate, palpitations (awareness of your heart beat), low blood pressure (hypotension), dizziness on standing up (orthostatic hypotension), flushing, cough, stomach ache (abdominal pain), diarrhoea, feeling sick (nausea), itching, joint pain, muscle cramps, muscle pain, inability to obtain an erection, weakness, chest pain, tiredness, swelling (oedema), increased levels of hepatic enzymes;
- urinary bladder infection, feeling sad (depression), feeling anxious, sleeplessness, fainting, nerve damage in the hands or feet, reduced sense of touch, taste abnormalities, trembling, vomiting, enlarged gums, indigestion, dry mouth, eczema (a skin disorder), redness of skin, rash, back pain, leg pain, urge to urinate during the night, feeling unwell (malaise), increased levels of uric acid in the blood;
- progressive scarring of lung tissue (interstitial lung disease [mainly pneumonia of the interstitium and pneumonia with excess eosinophils]).
- hives (urticaria), medicine rash, inflammation of the tendons, flu-like illness (for example muscle pain, feeling generally unwell), decreased haemoglobin

(a blood protein), and increased levels of creatinine phosphokinase in the blood.

The following side effects have been observed with the components telmisartan or amlodipine and may occur also with TENSIOTEL:

Telmisartan

In patients taking telmisartan alone the following additional side effects have been reported:

Less frequent:

- urinary tract infections, upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), high potassium levels in the blood, shortness of breath, bloating, increased sweating, kidney damage including sudden inability of the kidneys to work, increased levels of creatinine.
- increase in certain white blood cells (eosinophilia), low platelet count (thrombocytopenia), allergic reaction (e.g. rash, itching, difficulty of breathing, wheezing, swelling of the face or low blood pressure), low blood sugar levels (in diabetic patients), impaired vision, fast heartbeat, upset stomach, abnormal liver function.

Most cases of abnormal liver function and liver disorder from post-marketing experience with telmisartan occurred in Japanese patients. Japanese patients are more likely to experience this side effect.

Amlodipine

In patients taking amlodipine alone the following additional side effects have been reported:

Frequent:

- altered bowel habits, diarrhoea, constipation, visual disturbances, double vision, ankle swelling.

Less frequent:

- mood changes, confusion, impaired vision, ringing in the ears, shortness of breath, sneezing/running nose, hair loss, unusual bruising and bleeding (red blood cell damage), skin discolouration, increased sweating, difficulty passing urine, increased need to pass urine especially at night, pain, weight increased, weight decreased.
- reduced number of white blood cells (leucopenia), low platelet count (thrombocytopenia), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure), excess sugar in blood, uncontrollable twitching or jerking movements, heart attack, irregular heartbeat, inflammation of the blood vessels, inflamed pancreas, inflammation of the stomach lining (gastritis), rapid swelling of skin and mucosa (angioedema), severe skin reactions, hives (urticaria), severe allergic reactions with blistering eruptions of the skin and mucous membranes (exfoliative dermatitis, Stevens-Johnson Syndrome), increased sensitivity of the skin to sun.

Frequency unknown:

- severe allergic reactions with blistering eruptions of the skin and mucous membranes (toxic epidermal necrolysis).

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TENSIOTEL.

Contact Innovata Pharmaceuticals: regulatory@innovata.co.za

HOTLINE for reporting of side effects directly to Innovata Pharmaceuticals (Pty)

Ltd: 086 999 0912

5. How to store TENSIOTEL

STORE ALL MEDICINE OUT OF REACH OF CHILDREN

- Store at or below 25 °C.
- Store in the original package in order to protect from light and moisture.
- Remove the tablets from the blister only when required for administration.
- Do not use after the expiry date stated on the carton / label.
- 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 TENSIOTEL contains:

The active substances are telmisartan and amlodipine.

TENSIOTEL 40/5: Each tablet contains 40 mg telmisartan and 5 mg amlodipine (as amlodipine besylate).

Contains sugar: mannitol 353,79 mg per tablet.

TENSIOTEL 40/10: Each tablet contains 40 mg telmisartan and 10 mg amlodipine (as amlodipine besylate).

Contains sugar: mannitol 346,14 mg per tablet.

TENSIOTEL 80/5: Each tablet contains 80 mg telmisartan and 5 mg amlodipine (as amlodipine besylate).

Contains sugar: mannitol 531,04 mg per tablet.

TENSIOTEL 80/10: Each tablet contains 80 mg telmisartan and 10 mg amlodipine (as amlodipine besylate).

Contains sugar: mannitol 516,89 mg per tablet.

The other ingredients are:

Brilliant Blue FCF, Colloidal SiO₂, Iron oxide Black, Iron oxide Yellow E172, Magnesium Stearate, Mannitol, Meglumine, Povidone, Sodium Hydroxide, Sodium Stearyl Fumarate and Purified Talc

What TENSIOTEL looks like and contents of the pack

TENSIOTEL 40/5: Oval shaped biconvex, bilayer, uncoated tablets with one white to off white colour layer and one blue colour mottled layer debossed with 'L389'.

TENSIOTEL 40/10: Oval shaped biconvex, bilayer, uncoated tablets with one white to off white colour layer and one blue colour mottled layer debossed with 'L390'.

TENSIOTEL 80/5: Oval shaped biconvex, bilayer, uncoated tablets with one white to off white colour

layer and one blue colour mottled layer debossed with 'L391'.

TENSIOTEL 80/10: Oval shaped biconvex, bilayer, uncoated tablets with one white to off white colour

layer and one blue colour mottled layer debossed with 'L388'.

Contents of the pack:

30 Tablets in aluminium blister strips of 10 tablets per strip with 3 blisters packed in a unit carton along with leaflet.

Holder of Certificate of Registration

Innovata Pharmaceuticals Pty Ltd

Crownwood Office Park

100 Northern Parkway

Building D

Ormonde

Johannesburg

2091

This leaflet was revised in 02/06/2026.

Registration number

TENSIOTEL 40/5: 61/7.1.3/0738

TENSIOTEL 40/10: 61/7.1.3/0739

TENSIOTEL 80/5: 61/7.1.3/0740

TENSIOTEL 80/10: 61/7.1.3/0741



Access to the corresponding Professional information is contained in the
packaging or

Follow the link for the corresponding Professional Information for

TENSIOTEL:

pi-pil-repository.innovata.co.za,

alternatively, please scan the QR code below:

PLACE HOLDER:

The QR code to
be included after
approval.

