

STAMLO T 80/10 (Telmisartan and Amlodipine Tablets 80/10mg)

Telmisartan/Amlodipine (80mg/10mg)

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What STAMLO T is used for

Stamlo T is used to treat high blood pressure.

- in adult patients whose blood pressure is not controlled enough with amlodipine or telmisartan alone.
- in adult patients who already receive telmisartan and amlodipine from separate tablets and who wish to take instead the same doses in one tablet for convenience.

High blood pressure, if not treated, can damage blood vessels in several organs, which puts patients at risk of serious events such as heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus it is important to regularly measure blood pressure to verify if it is within the normal range

How STAMLO T works

Stamlo T tablets contain two active substances called telmisartan and amlodipine besilate. 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.

Before you take STAMLO T

-When you must not take it

- if you are allergic to telmisartan or amlodipine or any of the other ingredients of this medicine
- if you are allergic to other medicines of the dihydropyridine type (one type of calcium channel blocker).
- if you are more than 3 months pregnant. (It is also better to avoid Stamlo T in early pregnancy – see Pregnancy section.)
- if you have severe liver problems or biliary obstruction (problems with drainage of the bile from the liver and gall bladder).
- 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 suffer from heart failure after a heart attack.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of the above applies to you, tell your doctor or pharmacist before taking Stamlo T.

-Before you start to take it

Warnings and precautions

Talk to your doctor before taking Stamlo T if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant.
- Narrowing of the blood vessels to one or both kidneys (renal artery stenosis).
- Liver disease.
- Heart trouble.
- Raised aldosterone levels (which lead to water and salt retention in the body along with imbalance of various blood minerals).

- Low blood pressure (hypotension), 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.
- Elevated potassium levels in your blood.
- Diabetes.
- Narrowing of the aorta (aortic stenosis).
- Heart-associated chest pain also at rest or with minimal effort (unstable angina pectoris).
- A heart attack within the last four weeks.

Talk to your doctor before taking Stamlo T:

- 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. Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. See also “When you must not take it”.
- if you are elderly and your dose needs to be increased.

In case of surgery or anaesthesia, you should tell your doctor that you are taking Stamlo T.

Children and adolescents

STAMLO T is not recommended for use in children or adolescents under 18 years.

Pregnancy, breastfeeding and fertility

Pregnancy

You must tell your doctor if you think you might be pregnant or are planning to have a baby. Your doctor will normally advise you to stop taking Stamlo T before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Stamlo T. Stamlo T is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

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Breast-feeding

Amlodipine has been shown to pass into breast milk in small amounts.

Tell your doctor if you are breast-feeding or about to start breast-feeding. Stamlo T is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

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 use machines.

-Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may need to change the dose of these other medicines or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below:

- Lithium-containing medicines to treat some types of depression.
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain 'water tablets').
- Angiotensin II receptor antagonists.
- ACE-inhibitors or aliskiren (see also information under the headings "When you must not take it" and "Before you start to take it").
- NSAIDs (non steroidal anti-inflammatory medicines, e.g. acetylsalicylic acid or ibuprofen), heparin, immunosuppressives (e.g. cyclosporin or tacrolimus), and the antibiotic trimethoprim.
- Rifampicin, erythromycin, clarithromycin (antibiotics).
- St. John's wort.
- Dantrolene (infusion for severe body temperature abnormalities).
- Medicines used to alter the way your immune system works (e.g. sirolimus, temsirolimus and everolimus).
- Medicines used for HIV/AIDS (e.g. ritonavir) or for treatment of fungal

infections (e.g. ketoconazole).

- Diltiazem (cardiac medicine).
- Simvastatin to treat elevated levels of cholesterol.
- Digoxin.

As with other blood pressure lowering medicines, the effect of Stamlo T may be reduced when you take NSAIDs (non steroidal anti-inflammatory medicines, e.g. acetylsalicylic acid or ibuprofen) or corticosteroids.

Stamlo T 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. baclofen, amifostine, neuroleptics or antidepressants).

Low blood pressure may be aggravated by alcohol. You may notice this as dizziness when standing up

STAMLO T with food, drink and alcohol
Grapefruit juice and grapefruit should not be consumed when you take Stamlo T. This is because grapefruit and grapefruit juice may lead to increased blood levels of the active ingredient amlodipine in some patients and may increase the blood pressure lowering effect of Stamlo T.

How to take STAMLO T

-How much to take

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The doctor will advise you on the right dosing.

The recommended dose is one tablet a day. Remove your Stamlo T tablet from the blister only directly prior to intake.

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.

-When to take it

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

-How long to take it

It is important that you take Stamlo T every day until your doctor tells you otherwise. If you have the impression that the effect of Stamlo T is too strong or too weak, talk to your doctor or pharmacist.

-If you forget to take it

If you forget to take a dose, take it as soon as you remember and then carry on as before. If you do not take your tablet on one day, take your normal dose on the next day. Do not take a double dose to make up for forgotten individual doses.

-If you have taken too much (overdose)

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately. You might experience low blood pressure and rapid heart beat. Slow heart beat, dizziness, reduced kidney function including kidney failure, 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 24-48 hours after intake

While you are taking STAMLO T

-Things you must do

Always follow your doctor's instructions carefully.

-Things you must not do

- Do not give STAMLO T to anyone else, even if they have the same condition as you.
- Do not use STAMLO T to treat any other medical complaints unless your doctor tells you to.
- Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects can be serious and need immediate medical attention

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You should see your doctor immediately if you experience any of the following symptoms:

Common side effects (may affect up to 1 in 10 people)
Dizziness, ankle swelling (oedema).

Uncommon side effects (may affect up to 1 in 100 people)
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.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of STAMLO T

-Storage

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.
- Store below 30°C. Store in the original package in order to protect from light and moisture

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will

help protect the environment.

Product description

What it looks like

Stamlo T is oblong shaped, uncoated, bilayered tablet with off white to white layer on one side and pale yellow to yellow layer on other side. Pack Size: One or three blisters containing 10 tablets each are packed into an outer carton with a pack insert.

Ingredients

The active substance is Amlodipine (as besilate) and Telmisartan
Each tablet contains 80 mg telmisartan and 10 mg amlodipine (as amlodipine besilate).

Inactive ingredients: Sodium Hydroxide, Meglumine, Povidone, Polysorbate 80, Mannitol, Magnesium Stearate, Iron Oxide Yellow

MAL number:

XXXXX

Manufacturer

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Product Registration Holder

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Date of revision

19/06/2024

Serial number

NPRA (R2) 23/239