

TELMISARTAN TABLETS USP 40mg/80mg

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1. What Telmisartan Tablets is used for

Telmisartan is used to treat essential hypertension (high blood pressure) in adults. 'Essential' means that the high blood pressure is not caused by any other condition.

Also used to reduce cardiovascular events (i.e. heart attack or stroke) in adults who are at risk because they have a reduced or blocked blood supply to the heart or legs or have had a stroke or have high risk diabetes. Your doctor can tell you if you are at high risk for such events.

2. How Telmisartan Tablets works

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

3. Before you use Telmisartan Tablets

-When you must not use it

Do not take Telmisartan

- if you are allergic to telmisartan or any other ingredients of this medicine
- if you are more than 3 months pregnant.
- if you have severe liver problems such as cholestasis or biliary obstruction (problems with drainage of the bile from the liver and gall bladder) or any other severe liver disease.
- 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 Telmisartan.

-Before you start to use it

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

- Kidney disease or kidney transplant.
- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- Liver disease.
- Heart trouble.
- Raised aldosterone levels (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.

You must tell your doctor if you think you are (or might become) pregnant. Telmisartan is not recommended in early pregnancy and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage.

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

Children and adolescents

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

- 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 taken at the same time with telmisartan;

- 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'), ACE inhibitors, angiotensin II

receptor antagonists, NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen), heparin, immunosuppressives (e.g. cyclosporin or tacrolimus), and the antibiotic trimethoprim.

- Diuretics ('water tablets'), especially if taken in high doses together with Telmisartan, may lead to excessive loss of body water and low blood pressure (hypotension).
- If you are taking an ACE-inhibitor or aliskiren.
- Digoxin.

4. How to use Telmisartan Tablets

- How much to use

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

For treatment of high blood pressure, the usual dose of telmisartan for most patients is one 40 mg tablet once a day to control blood pressure over the 24 hour period. However, sometimes your doctor may recommend a higher dose of 80 mg. Alternatively, Telmisartan may be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with telmisartan.

For reduction of cardiovascular events, the usual dose of Telmisartan is one 80 mg tablet once a day. At the beginning of the preventive therapy with Telmisartan 80 mg, blood pressure should be frequently monitored.

If your liver is not working properly, the usual dose should not exceed 40 mg once daily.

- When to use it

Try to take the tablet at the same time each day. You can take it with or without food. The tablets should be swallowed with some water or other non- alcoholic drink.

- How long to use it

Management of high blood pressure and cardiovascular events patients required to treat for a long time with required dose, hence your doctor will decide the duration of treatment on the basis response of the drug to maintain of normal blood pressure.

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- If you forget to use it

If you forget to take a dose, do not worry. Take it as soon as you remember 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 any further questions on the use of this medicine, ask your doctor or pharmacist

- If you use too much (overdose)

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately

5. While you are using it:

- Things you must do

If you are a diabetic patient using Insulin or medication to reduce glucose, check your blood glucose regularly as recommended by your doctor

- Things you must not do

Do not stop taking your medicine unless your doctor tells you to.

Do not take any new medicines without consulting your doctor.

Do not give it to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines
Some people feel dizzy or tired when taking Telmisartan. If you feel dizzy or tired, do not drive or operate machinery

6. 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:

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

-Sepsis (often called "blood poisoning", is a severe infection with whole-body inflammatory response), rapid swelling of the skin and mucosa (angioedema). These side effects are rare but are extremely serious and patients should stop taking the product and see their doctor immediately. If these effects are not treated, they could be fatal.

Possible side effects of Telmisartan *Common*

Low blood pressure (hypotension) in users treated for reduction of cardiovascular events

Uncommon

- Urinary tract infection
- Upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold)
- Deficiency in red blood cells (anaemia)
- High potassium levels,
- Difficulty falling asleep
- Depression,
- Fainting (syncope), feeling of spinning (vertigo)
- Slow heart rate (bradycardia)
- Dizziness on standing up (orthostatic hypotension)
- Shortness of breath, cough
- Abdominal pain, diarrhoea, discomfort in the abdomen, bloating, vomiting
- Itching,
- Increased sweating
- Rash
- Back pain
- Muscle cramps, muscle pain (myalgia)
- Kidney impairment including acute kidney failure, Increased level of creatinine in the blood.
- Pain in the chest
- Feeling of weakness

Rare

- Eosinophilia (increase level of eosinophils in blood)
- Thrombocytopenia (reduced level of thrombocytes in blood)
- Hypersensitivity, Anaphylactic reaction (allergy reaction)
- Hypoglycemia (low levels of glucose in blood)
- Anxiety
- Somnolence (drowsiness)
- Visual Disturbances (disturbances in sight)
- Tachycardia (fast heart rate)

These are not all the possible side effect of TSART. For a complete list, ask your doctor or pharmacist. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects:

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 [Public --> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and disposal Of Telmisartan Tablets

Storage

Store at a temperature not exceeding 30°C. Store in a dry place and protect from light. Keep out of reach of children

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product Description

What it looks like and contents of the pack

TSART 40: White to off white oblong shaped biconvex, uncoated tablets debossed with TEL on one side and 40 on other side.

TSART 80: White to off white oblong shaped biconvex, uncoated tablets debossed with TEL on one side and 80 on other side

Available as an Aluminum Blister of 10's Tablets and such 3 or 6 blisters packed in a carton along with pack insert.

What TSART contains

- Active Ingredient: Telmisartan

- Inactive Ingredient: Lactose Monohydrate, Crospovidone, Meglumine, Sodium Hydroxide, Povidone, Colloidal anhydrous Silicon, Magnesium Stearate

- MAL number(s):

TSART 40: MAL19056110AZ

TSART 80: MAL19056113AZ

9. Manufacturer

Alkem Laboratories Ltd.

Plot No. 167/2, 164, 165/1, 165/2, 165/3, Mahatma Gandhi Udyog Nagar, Village Dabhel, Daman - 396 210, INDIA.

H.O: ALKEM HOUSE, Senapati Bapat Marg, Lower Parel, Mumbai 400 013, India

10. Product Registration Holder

Ascend Laboratories Sdn Bhd, Level 25, Menara Hong Leong, No. 6, Jalan Damanlela, 50490 Bukit Damansara Malaysia

11. Date of revision: 19/12/2022

12. Serial Number: NPRA (R2) 19/77.