

# TOLURA TABLETS

Telmisartan (40 mg, 80 mg)

Consumer Medication Information Leaflet (RiMUP)

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## What Tolura is used for

**Tolura 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.

High blood pressure, if not treated, can damage blood vessels in several organs, which could lead sometimes to 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.

**Tolura is also used to** reduce cardiovascular events (i.e. heart attack or stroke) in adults 55 years of age or older 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.

## How Tolura works

Tolura 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. Tolura blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

## Before you use Tolura

- When you must not use it

- if you are allergic to telmisartan or any other ingredients of this medicine.
- if you are more than 3 months pregnant. (It is also better to avoid Tolura in early pregnancy – see pregnancy section.)
- if you have severe liver problems such as cholestasis or biliary

obstruction (problems with the drainage of the bile from the liver and gall bladder) or any other severe liver disease.

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

- Before you start to use it

Talk to your doctor 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.
- 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 information under the heading "Do not take Tolura".
  - if you are taking digoxin.
- In case of surgery or anaesthesia, you should tell your doctor that you are taking Tolura.
- Tolura may be less effective in lowering the blood pressure in black patients.

## Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

Your doctor will normally advise you to stop taking Tolura before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Tolura. Tolura 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.

Tolura 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 new born, or was born prematurely.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

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 Tolura:

- 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 Tolura, may lead to excessive loss of body water and low blood pressure (hypotension).

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

Tolura may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

Patient should inform their doctors if they are on other medication – aliskiren and digoxin.

## How to use Tolura

### - How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

For treatment of high blood pressure, the usual dose of Tolura 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. Tolura may also be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with Tolura.

For reduction of cardiovascular events, the usual dose of Tolura is one 80 mg tablet once a day. At the beginning of the preventive therapy with Tolura 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

Use as directed by your doctor or pharmacist.

Try to take the tablet at the same time each day. You can take Tolura with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. If you have the impression that the effect of Tolura is too strong or too weak, talk to your doctor or pharmacist.

### - How long to use it

Continue using Tolura for the duration that the doctor recommends.

### - If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. **Do not** take a double dose to make up for the missed dose.

### - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause hypotension (low blood pressure) and tachycardia (abnormally fast heartbeat); bradycardia (slow heart rate), dizziness, increase in serum creatinine, and acute renal failure.

## While you are using it

### - Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Tolura.

Tell your doctor immediately if you become pregnant while using this medication.

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

### - Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

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

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

### - Things to be careful of

#### *Driving and using machines*

Some people feel dizzy or tired when taking Tolura. If you feel dizzy or tired, do not drive or operate machinery.

Tolura may be less effective in lowering the blood pressure in black patients.

## Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

## 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 medicine and see their doctor immediately. If these effects are not treated they could be fatal.

Possible side effects of Tolura:

### Common side effects:

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

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

## Storage and Disposal of Tolura

### - Storage

Keep out of the reach and sight of children.

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Do not store above 30 °C.  
Store in the original package in order to protect from light.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- 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.

## Product Description

- What it looks like

Tolura 40 mg tablets are presented as white to almost white, biconvex, oval tablets.

Tolura 80 mg tablets are presented as white to almost white, biconvex, capsule shaped tablets.

Blisters packs: 28 or 30 tablets in a folding box.  
Not all pack sizes may be marketed.

- Ingredients

- Active ingredient

Tolura 40 mg: Each tablet contains 40 mg telmisartan.

Tolura 80 mg: Each tablet contains 80 mg telmisartan.

- Inactive ingredients

Povidone, meglumine, sodium hydroxide, lactose monohydrate, sorbitol and magnesium stearate.

- MAL number(s):

Tolura 40 mg: MAL18046163AZ

Tolura 80 mg: MAL18046162AZ

## Manufacturer

KRKA, d.d., Novo mesto,  
Šmarješka cesta 6,  
8501 Novo mesto, Slovenia

## Product Registration Holder

Pahang Pharmacy Sdn. Bhd.  
Lot 5979, Jalan Teratai,  
5 ½ Miles off Jalan Meru,  
41050 Klang, Selangor, MALAYSIA.

## Date of revision

01/09/2023

## Serial Number

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