

Telmisartan (20mg,40mg,80mg)

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What TELSAR is used for

Telmisartan belongs to a group of medicines used:

- To treat essential hypertension (high blood pressure). 'Essential' means that the high blood pressure is not caused by any other condition.
- to reduce cardiovascular events (i.e.heart attack or stroke) in patients who are at risk because they have a reduced or blocked blood supply to the heart or legs, or have a stroke or have high risk of diabetes.

How TELSAR 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.

Before you use

TELSAR When you must not use it **Do not take**

Telmisartan:

- if you are allergic (hypersensitive) to the active substance of this medicine (telmisartan) or to any of the other ingredients of this medicine
- If you are more than 3 months pregnant. (It is better to avoid *Telmisartan* in early pregnancy-see pregnancy section.)
- 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 liver disease.

Pregnancy and lactation

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

You must tell your doctor if you think you are (or might become) pregnant.

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

Breastfeeding

Ask your doctor or pharmacist for advice before taking any medicine. 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 breast-feed, especially if your baby is new born, or was born prematurely.

- Before you start use it

Take special care with *Telmisartan* and check with your doctor or pharmacist before using this medicine 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

In case of surgery or anaesthesia, you should tell your doctor that you are taking *Telmisartan*

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

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. This applies especially to the medicines listed below taken at the same time with

Telmisartan:

- *Digoxin*, used to treat various heart conditions.
- Potassium-sparing diuretics or potassium supplements, used for treatment of hypertension and congestive heart failure.
- *Lithium* containing medicines used to treat some types of depression.
- NSAIDS (non-steroidal anti-inflammatory medicines) used to treat inflammation.
- Diuretics (thiazide or loop diuretics) used to treat hypertension and congestive heart failure.
- Other anti-hypertensive agents

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

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

How to use TELSAR

- 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.

The usual dose of *Telmisartan* is one tablet a day. Try to take the tablet at the same time each day.

You can take *Telmisartan* with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take *Telmisartan* every day until your doctor tells you otherwise. If you have the impression that the effect of *Telmisartan* is too strong or too weak, talk to your doctor or pharmacist.

- High blood pressure 40mg once daily to control blood pressure over the 24-hour period. However, sometimes your doctor will recommend lower doses such as 20 mg or higher doses 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: 80mg once a day. At the beginning of the preventive therapy with *Telmisartan* 80mg, blood pressure should be frequently monitored. If your liver is not working properly, the usual dose should not exceed 40mg once daily.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking **TELSAR** until your doctor tells you to stop. You should not stop taking this medicine without medical advice.

- 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 taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Telmisartan*.

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

- Things you must not do

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

Do not take any new medicines without consulting your doctor.

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

- Things to be careful of
Driving and using machines

No information is available on the effect of *Telmisartan* on the ability to drive or operate machinery. Some people feel dizzy or tired when they are treated for high blood pressure. If you feel dizzy or tired, do not drive or operate machinery

Important information about some of the ingredients of *Telmisartan*:

Telmisartan contains mannitol.

If you are intolerant to some sugars, consult your doctor before taking *Telmisartan*.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking 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 product and see their doctor immediately. If these effects are not treated they could be fatal.

Tell your doctor or pharmacist if you notice any of the following side effects:

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

Uncommon: Urinary tract infections, upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), high potassium levels, difficulty falling asleep, feeling sad (depression), fainting (syncope), feeling of spinning (vertigo), slow heart rate (bradycardia), low blood pressure (hypotension) in users treated for high blood pressure, dizziness on standing up (orthostatic hypotension), shortness of breath, abdominal pain, diarrhoea, discomfort in the abdomen, bloating, vomiting, itching, increased sweating, drug rash, back pain, muscle cramps, muscle pain (myalgia), kidney impairment including acute kidney failure, pain in the chest, feeling of weakness, and increased level of creatinine in the blood.

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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of TELSAR

- Storage

Store below 30°C. Store in original package in order to protect from moisture.

Keep out of the reach and sight of children.

Do not use *Telmisartan* after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions. You should store your medicine in the original package in order to protect the tablets from moisture.

- 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

TELSAR 20 (Telmisartan tablets 20mg): White to off white, round, flat bevel edged tablets, debossed with ‘H’ on one side and ‘162’ on other side. The thickness of the tablet is 2.60±0.40mm.

TELSAR 40 (Telmisartan tablets 40mg): White to off white, oval shaped, biconvex tablets, debossed with ‘H’ on one side and ‘163’ on other side. The thickness of the tablet is 3.80±0.40mm.

TELSAR 80 (Telmisartan tablets 80mg): White to off white, oval shaped, biconvex tablets debossed with ‘H’ on one side and ‘164’ on other side. The thickness of the tablet is 5.00±0.40mm.

- Ingredients

- Active ingredient(s)

Telmisartan

- Inactive ingredients

Meglumine, Mannitol, sodium hydroxide and magnesium stearate.

- MAL number(s):

TELSAR 20 (Telmisartan tablets 20mg):

MAL18116074AZ

TELSAR 40 (Telmisartan tablets 40mg):

MAL18116075AZ

TELSAR 80 (Telmisartan tablets 80mg):

MAL18116076AZ

Manufacturer

Hetero Labs Limited, Unit – V,
Survey No 439,440,441 &458,
TSIC Formulation, SEZ, Polepally
Village,
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Mahaboob Nagar (Dist)-509301,
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Product Registration Holder

UNIMED SDN BHD
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26/11/2021

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