

TELDAY TABLETS

Telmisartan (40mg , 80mg)

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What TELDAY is used for

TELDAY contains Telmisartan. It is used to treat essential hypertension (high blood pressure). '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.

How TELDAY 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 TELDAY

- When you must not use it

If you are allergic (hypersensitive) to Telmisartan or any other ingredients included in TELDAY tablets.

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.

Pregnancy and lactation

Do not take TELDAY if you are pregnant, trying to get pregnant or think you may be pregnant. TELDAY 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.

Do not take TELDAY if you are breast-feeding. TELDAY 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.

- Before you start use it

Please tell 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.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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 TELDAY:

- 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.
- Immune-suppressives (e.g. cyclosporin or tacrolimus).
- The antibiotic trimethoprim.
- Diuretics ('water tablets'), especially if taken in high doses together with TELDAY, may lead to excessive loss of body water and low blood pressure (hypotension).
- As with other blood pressure lowering medicines, the effect of TELDAY may be reduced when you take NSAIDs (nonsteroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids.
- TELDAY may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

How to use TELDAY

- How much to use

- Always take TELDAY exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- *High blood pressure:*
 - The usual dose of TELDAY 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 lower dose of 20 mg or a higher dose of 80 mg.
 - Alternatively, TELDAY 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 TELDAY.
- Cardiovascular prevention:
 - The recommended dose is 80 mg once daily.

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

- How long to use it

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

- 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 use too much (overdose)

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

While you are using it

- Things you must do

- Take TELDAY at about the same time each day.
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking TELDAY.
- You must tell your doctor if you think you are (or might become) pregnant.
- Tell your doctor if you are breast-feeding or about to start breast-feeding.
- In case of surgery or anesthesia, you should tell your doctor that you are taking TELDAY.

- 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 TELDAY 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 TELDAY. If you feel dizzy or tired, do not drive or operate machinery.

Side effects

Like all medicines, TELDAY 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.

Possible side effects of TELDAY:

- 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.
- Urinary tract infections (including cystitis (inflammation of the bladder)).
- Upper respiratory tract infections including pharyngitis (inflammation in the back of the throat) and sinus infection.
- Anaemia (lack of red blood cells in blood), eosinophilia (high number of eosinophils in the blood), thrombocytopenia (low blood platelet count).
- Allergic reaction, hypersensitivity.
- Hyperkalaemia (high blood potassium).
- Hypoglycaemia (low blood sugar).
- Anxiety.
- Insomnia (difficult to sleep).
- Depression.
- Faint.
- Somnolence.
- Visual disturbance.
- Vertigo (sensation of spinning dizziness).
- Bradycardia (abnormally slow heart rate).
- Tachycardia (abnormally rapid heart rate).
- Hypotension, postural hypotension (occurs when a person's blood pressure falls when suddenly standing up from a lying or sitting position).
- Dyspnoea (difficult breathing), cough, lung disease.

- Abdominal pain, diarrhoea, dry mouth, dyspepsia (indigestion), flatulence, stomach discomfort, vomiting.
- Abnormal liver function or liver disorder.
- Angioedema (swelling caused by a build-up of fluid in deeper layers of the skin often near the eyes, lips, hands, and feet). Angioedema can cause fatal outcome. Eczema, erythema (redness of the skin), pruritus (severe itching of the skin), excessive sweating, hives, drug eruption, toxic skin eruption, rash.
- Joint pain, back pain, muscle spasms, pain in extremity, muscle pain, tendon pain.
- Kidney impairment including acute kidney failure.
- Chest pain, influenza-like illness, asthenia (weakness).

These are not all the possible side effect of TELDAY. 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website <http://npra.moh.gov.my> (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of TELDAY

- Storage

- Store below 30°C. Protect from moisture.
- Keep medicines 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.

TELDAY TABLETS

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Product Description

- *What it looks like*

TELDAY TABLETS 40 MG:

White or off-white to yellowish oblong biconvex uncoated tablets with break line on one side and plain on the other side.

TELDAY TABLETS 80 MG:

White or off-white to yellowish oval biconvex uncoated tablets with break line on one side and plain on other side.

Ingredients

Active ingredient:

- Telmisartan.

Inactive ingredients:

- Mannitol.
- Sodium Hydroxide.
- Meglumine.
- Povidone.
- Sodium Stearyl Fumarate.

- *MAL numbers:*

TELDAY TABLETS 40 MG:

MAL*****

TELDAY TABLETS 80 MG:

MAL*****

Manufacturer

Torrent Pharmaceuticals Ltd. - Indrad Plant
Near Indrad Village, Taluka-Kadi,
District Mehsana Gujarat 382721
INDIA.

Product Registration Holder

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