

**TELSTRAN® TABLET**

Telmisartan (40mg, 80mg)

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**What Telstran® Tablet is used for**

Telstran® Tablet 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.

Telstran® Tablet is 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 Telstran® Tablet works**

Telstran® Tablet is an orally active angiotensin II AT1 receptor antagonist. By selectively blocking the binding of angiotensin II to the AT1 receptors Telstran® Tablet blocks the vasoconstrictor and aldosterone secreting effects of angiotensin II.

**Before you use Telstran® Tablet*****- When you must not use it***

- If you are allergic to Telstran® Tablet or any other ingredients of this medicine.
- If you are more than 3 months pregnant. It is also better to avoid Telstran® Tablet in early pregnancy.
- 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 mellitus or impaired kidney function and you are treated with Aliskiren

Do not take Telstran® Tablet if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

***- Before you start 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.

Talk to your doctor before taking Telstran® Tablet:

- If you are taking Aliskiren, a medicine used to treat high blood pressure.
- If you are taking digoxin.

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

In case of surgery or anesthesia, you should tell your doctor that you are taking Telstran® Tablet.

Telstran® Tablet may be less effective in lowering the blood pressure in black patients.

Children and adolescents:

The use of Telstran® Tablet 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 Telstran® Tablet:

- 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 converting enzyme inhibitors), ARBs (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 Telstran® Tablet, may lead to excessive loss of body water and low blood pressure (hypotension).
- If you are taking an ACE-inhibitor or aliskiren.
- Digoxin.

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

Telstran® Tablet 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).

Furthermore, low blood pressure may be aggravated by alcohol, barbiturates, narcotics or antidepressants. You may notice this as dizziness when standing up. You should consult with your doctor if you need to adjust the dose of your other medicine while taking Telstran® Tablet.

**How to use Telstran® Tablet**

**- How much to use**

Always take Telstran® Tablet exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of Telstran® Tablet is one tablet a day. Try to take the tablet at the same time each day.

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

For treatment of high blood pressure, the usual dose of Telstran® Tablet 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, Telstran® Tablet 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 Telstran® Tablet.

For reduction of cardiovascular events, the usual dose of Telstran® Tablet is one 80 mg tablet once a day. At the beginning of the preventive therapy with Telstran® Tablet 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 Telstran Tablet 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 Telstran Tablet is too strong or too weak, talk to your doctor or pharmacist.

**- How long to use it**

Continue taking Telstran® Tablet for as long as your 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 accidentally take too many tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Symptoms of overdose are 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**

Talk to your doctor about other ways to lower your blood pressure if you plan to become pregnant. If you get pregnant while taking Telstran® Tablet, tell your doctor right away.

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists that are treating you that you are taking Telstran® Tablet.

**- Things you must not do**

You should not take Telstran® Tablet if you are allergic (hypersensitive) to the active ingredient (telmisartan) or any of the other ingredients listed at the end of this leaflet.

For patients with diabetes, if you are taking Telstran® Tablet you should not take aliskiren.

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

Do not take any new medicines without consulting your doctor.

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

**- Things to be careful of**

It is not known if Telstran® Tablet passes into your breast milk. You and your doctor should decide if you will take Telstran® Tablet or breast-feed. You should not do both. Talk with your doctor about the best way to feed your baby if you take Telstran® Tablet.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

For patients with diabetes, if you are taking Telstran® Tablet you should not take Aliskiren.

Telstran® Tablet may affect the way other medicines work, and other medicines may affect how Telstran® Tablet works. Especially tell your doctor if you take:

- Aliskiren
- Digoxin
- Lithium
- Medicines used to treat pain and arthritis, called non-steroidal anti-inflammatory drugs (NSAIDs), including COX-2 inhibitors
- Ramipril or other medicines used to treat your high blood pressure or heart problem.
- Water pills (diuretic).

**-Driving and using machines**

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and

contact your doctor immediately.

**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 Telstran<sup>®</sup>. 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 <http://npra.gov.my/> (Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

**Storage and Disposal of Telstran<sup>®</sup> Tablet**

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Store in the original package in order to protect from moisture.

Tablets should not be removed from blisters until immediately prior to administration.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

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

Telstran<sup>®</sup> Tablet 40 mg: White to off-white, oblong shaped, biconvex, uncoated tablets debossed with 'TL' on one side and plain on other side.

Telstran<sup>®</sup> Tablet 80 mg: White to off-white, oblong shaped, biconvex, uncoated tablets debossed with 'T2' on one side and plain on other side.

- Ingredients

- Active ingredient  
Telmisartan

- Inactive ingredients  
Mannitol  
Sodium Hydroxide Pellets  
Meglumine  
Povidone  
Magnesium Stearate

- MAL number(s):

MAL\*\*\*\*\*

**Manufacturer**

Intas Pharmaceuticals Limited  
Plot No. 457 & 458, Village Matoda, Bavla Road and Plot No. 191/218P, Village: Chacharwadi, Tal- Sanand, Dist: Ahmedabad, Gujarat 382210, India.

**Product Registration Holder**

Y.S.P. Industries (M) Sdn. Bhd.  
Lot 3, 5 & 7, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor D.E., Malaysia.

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28/04/2020

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