

TELSTRAN PLUS[®] TABLET

Telmisartan & Hydrochlorothiazide (40mg+12.5mg & 80mg+12.5mg)

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What TELSTRAN PLUS[®] Tablet is used for

TELSTRAN PLUS[®] Tablet is a combination of two active substances, Telmisartan and Hydrochlorothiazide in one tablet. Both of these substances help to control high blood pressure.

It is always important to regularly measure the blood pressure to verify if it is within the normal range.

TELSTRAN PLUS[®] Tablet is used to treat high blood pressure (essential hypertension) in patients whose blood pressure is not controlled enough when either Telmisartan or Hydrochlorothiazide is used alone.

How TELSTRAN PLUS[®] Tablet works

Telmisartan is an orally effective and specific angiotensin II receptor antagonist.

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.

Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics, which cause your urine output to increase, leading to a lowering of your blood pressure.

Before you use TELSTRAN PLUS[®]

- When you must not use it

Do not take this medicine if:

- you are allergic to Telmisartan and/or Hydrochlorothiazide (or other sulphonamide-derived substances) or any other ingredients of this medicine (listed in Product Description).
- You are in second or third trimesters of pregnancy.
- You have severe liver problems such as cholestasis and biliary obstructive disorders. (Problems with drainage of the bile from gall bladder)
- You have severe hepatic impairment.
- You have severe renal impairment.
- You have Hypokalaemia (low potassium levels) and/or Hypercalcaemia (high calcium levels).
- The package is torn or shows signs of tampering.
- The expiry date printed on the pack has passed.
- If you are not sure if you should be taking TELSTRAN PLUS[®] Tablet, talk to your doctor.

- Before you start to use it

Check with your doctor or pharmacist before taking TELSTRAN PLUS[®] Tablet if you:

- You are pregnant or plan to become pregnant.
- TELSTRAN PLUS[®] Tablet are 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 the baby.
- You are breast-feeding or about to start breast-feeding.
- TELSTRAN PLUS[®] Tablet are not recommended for mothers who are breast-feeding and your doctor may choose another treatment for you if you wish to breast-feed.
- You have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma

skin cancer). Protect your skin from sun exposure and UV rays while taking TELSTRAN PLUS[®] Tablet.

- You are suffering or have ever suffered from any of the following conditions or illnesses:
- Low blood pressure (hypotension), likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy, low-salt diet, diarrhoea, vomiting, or haemodialysis.
- Kidney disease or kidney transplant.
- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- Liver disease.
- Diabetes.
- Gout.
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- Systemic lupus erythematosus (also called “lupus” or “SLE”) a disease where the body’s immune system attacks the body.
- Non-melanoma skin cancer (NMSC)
- You are allergic to any other medicines, foods, dyes or preservatives.
- If you experience breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking TELSTRAN PLUS[®] Tablet, seek medical attention immediately.

Pregnancy and lactation

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

- 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.

Inform your doctor or pharmacist if you are taking:

- Lithium containing medicines to treat some types of depression.
- Medicinal products associated with potassium loss and hypokalaemia. Such as laxatives (e.g. castor oil), corticosteroids (e.g. prednisolone), ACTH, (a hormone) amphotericin (an antifungal medicine), carbenoxolone (used to treat mouth ulcers), penicillin G sodium (an antibiotic), salicylic acid and derivatives.
- Heart medicines such as digitalis glycosides.
- Other antihypertensive agents.
- Antidiabetic medicinal products (oral agents and insulin).
- Non-steroidal anti-inflammatory medicinal products.
- Other medicines like steroids, painkillers, medicines to treat cancer, gout, or arthritis, and vitamin D supplements.

You may need to use different amounts of the medicine, or you may need to take different medicines. Your doctor will advise you.

How to use TELSTRAN PLUS® Tablet

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.

- How much to use

- TELSTRAN PLUS® should be taken once daily. The dose of telmisartan could be up-titrated before switching to TELSTRAN PLUS®. Direct change from monotherapy to the fixed combinations may be considered.
- TELSTRAN PLUS® 40/12.5 mg may be administered in patients whose blood pressure is not adequately controlled by telmisartan 40 mg or hydrochlorothiazide.
- TELSTRAN PLUS® 80/12.5 mg may be administered in patients whose blood pressure is not adequately controlled by telmisartan 80 mg or by TELSTRAN PLUS® 40/12.5 mg.

- TELSTRAN PLUS® may be taken with or without food.

- When to use it

Use as directed by your doctor or pharmacist.

It is always advisable to take doses at the same time each day. It will have the best effect and it will also help you to remember when to take TELSTRAN PLUS® Tablet.

- How long to use it

Use this medicine for the duration that your doctor recommends.

TELSTRAN PLUS® Tablet should be taken every day exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The maximum antihypertensive effect is generally attained with TELSTRAN PLUS® 4 – 8 weeks after the start of treatment.

- 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 or anyone else may have used 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 TELSTRAN PLUS® Tablet

- 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 TELSTRAN PLUS® Tablet.

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

Take TELSTRAN PLUS® Tablet only with a doctor's prescription.

- 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 TELSTRAN PLUS® Tablet to anyone else, even if they have the same symptoms or condition as you.

Do not use TELSTRAN PLUS® Tablet to treat other complaints unless your doctor says so.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting with a pharmacist.

- Things to be careful of

You should regularly check your skin for any new lesions and promptly report any suspicious skin lesions when taking TELSTRAN PLUS® Tablet. Limit your exposure to sunlight and UV rays. In case of exposure, adequate protection is advised to minimize the risk of skin cancer. Suspicious skin lesions should be promptly examined potentially including histological examinations of biopsies.

Side effects

Like all medicines, TELSTRAN PLUS® Tablet can cause side effects, although not everybody gets them.

- **Common Side effects:** dizziness.
- **Uncommon Side effects:** Hypokalaemia (decreased blood potassium levels), Anxiety, Syncope (fainting), paraesthesia (sensation of tingling, pins and needles), Vertigo (feeling of spinning), Tachycardia (increased heartbeats), Arrhythmias, Hypotension (low blood pressure), Orthostatic hypotension (a sudden fall in blood pressure when you stand up), Dyspnoea (shortness of breath), Diarrhoea, dry mouth, flatulence, Back pain, Muscle spasms, Myalgia, Erectile dysfunction, Chest pain, Blood uric acid increased.

- **Rare Side effects:** Serious Angioedema (swelling of the area beneath the skin), Bronchitis (inflammation of the lungs), Pharyngitis (inflammation of the pharynx), Sinusitis (inflammation of the sinus), Exacerbation or activation of systemic lupus erythematosus (a disease where the body's immune system attacks the body, which causes joint pain, skin rashes and fever), Hyperuricaemia (increased uric acid in blood), hyponatraemia (decreased sodium level in blood), Depression, Insomnia (difficulty in falling asleep), sleep disorders, Visual disturbance, vision blurred, Respiratory distress (including pneumonitis and pulmonary oedema), Abdominal pain, constipation, dyspepsia, vomiting, gastritis, erythema (redness of the skin), pruritus (allergic reactions such as itching), rash, hyperhidrosis (increased sweating), urticaria (hives), Arthralgia (joint pain), muscle cramps, pain in limb, Influenza-like illness, pain, Blood creatinine increased, blood creatine phosphokinase increased, hepatic enzyme increased, abnormal hepatic function or liver disorder.

Side effects associated with Telmisartan alone:

- **Uncommon Side effects:** Upper respiratory tract infection (e.g. sore throat, inflamed sinuses, common cold), urinary tract infection including cystitis, Anaemia (deficiency in red blood cells), Bradycardia (slow heart rate), Cough, Renal impairment (including acute renal failure), Asthenia (weakness), Hyperkalaemia (increased blood potassium levels)
- **Rare Side effects:** Sepsis including fatal outcome (severe infection with whole- body inflammatory response which can lead to death), Eosinophilia (increase in certain white blood cells), thrombocytopenia (low platelet count), Hypersensitivity (serious allergic reaction), Hypoglycaemia - low blood sugar levels (in diabetic

patients), Somnolence (strong desire for sleep), Eczema (a skin disorder), drug eruption, toxic skin eruption, Arthrosis (joint disorder), tendon pain, Hemoglobin decreased

Very Rare Side effects: Interstitial lung disease

Side effects associated with Hydrochlorothiazide alone:

- **Common Side effects:** Decreased magnesium level in the blood, Nausea
- **Rare Side effects:** Low platelet count sometimes with rash of purple spots on skin, increased calcium level in the blood, decreased level of the chloride in the blood, Headache
- **Very Rare Side effects:** Acute respiratory distress (signs include severe shortness of breath, fever, weakness and confusion).
- **Side effects with unidentified frequency:** Sialadenitis (inflammation of a salivary gland), decreases in the number of cells in the blood, including low red and white blood cell count, anaphylactic reaction and hypersensitivity (serious allergic reactions), Diabetes mellitus inadequate control, Anorexia, appetite decreased, electrolyte imbalance, hypercholesterolaemia (high levels of cholesterol in the blood), hyperglycaemia (High blood glucose level), Hypovolaemia (decreased blood volume), Restlessness, Light-headedness, Xanthopsia (color vision deficiency), Vasculitis necrotizing (inflammation of blood vessels), Pancreatitis (inflamed pancreas), stomach discomfort, Jaundice (yellowing of the skin or eyes), Lupus-like syndrome (a condition mimicking a disease called systemic lupus erythematosus where the body's immune system attacks the body), photosensitivity reactions (skin disorder triggered by sunlight), toxic epidermal necrolysis (skin disorders such as inflamed blood vessels in the skin, increased sensitivity to sunlight, or blistering and peeling of the top layer of skin), redness of the skin or mucous

membranes, Weakness, Nephritis interstitial (kidney inflammation or impaired kidney function), renal dysfunction, glycosuria (glucose in the urine), Pyrexia (fever), Triglycerides increased, Skin and lip cancer (Non-melanoma skin cancer). Choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes. Acute myopia: sudden nearsightedness or blurred vision.

This is not a complete list of all possible side effects.

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

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 product name

- Storage

Keep out of the reach and sight of children.

Store below 30°C. Keep TELSTRAN PLUS® Tablet away from moisture and keep the tablets in the original packing where they are protected from light. Tablets should be taken out of the blister shortly before administration.

Do not store them, or any other medicine, in a bathroom or near a sink. Do not leave TELSTRAN PLUS® Tablet in the car or on windowsills.

- 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 PLUS[®] Tablet 40mg+12.5mg are white to off-white on one side and red on other side, biconvex, bilayer, oblong shaped, uncoated tablets debossed with 'T1' on red side and plain on other side, may have mottled appearance on red layer.

TELSTRAN PLUS[®] Tablet 80mg+12.5mg are white to off-white on one side and red on other side, biconvex, bilayer, oblong shaped, uncoated tablets debossed with 'T2' on red side and plain on other side, may have mottled appearance on red layer.

- Ingredients

- Active ingredient(s)

- Telmisartan
- Hydrochlorothiazide

- Inactive ingredients

- Lactose Monohydrate
- Microcrystalline Cellulose
- Mannitol
- Povidone
- Magnesium Stearate
- Sodium Stearyl Fumarate
- Sodium Hydroxide
- Meglumine
- Ferric Oxide Red

- MAL number(s):

TELSTRAN PLUS[®] Tablet 40mg + 12.5mg: MAL20076022ACZ

TELSTRAN PLUS[®] Tablet 80mg + 12.5mg: MAL20076023ACZ

Manufacturer

Intas Pharmaceuticals Ltd.
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Importer and Product Registration

Holder

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