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Patient Information

Telmisartan and Hydrochlorothiazide Tablets, USP

(TEL-mi-SAR-tan and HYE-droe-KLOR-oh-THYE-a-zide)

Read this Patient Information before you start taking telmisartan and hydrochlorothiazide tablets and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information I should know about telmisartan and hydrochlorothiazide tablets?

Telmisartan and hydrochlorothiazide tablets can cause harm or death to an unborn baby. Talk to your doctor about other ways to lower your blood pressure if you plan to become pregnant. If you get pregnant while taking telmisartan and hydrochlorothiazide tablets, tell your doctor right away.

What are telmisartan and hydrochlorothiazide tablets?

Telmisartan and hydrochlorothiazide tablets are a prescription medicine used to treat high blood pressure (hypertension). Telmisartan and hydrochlorothiazide tablets contain:

- telmisartan, an angiotensin receptor blocker (ARB)
- hydrochlorothiazide, a water pill or diuretic

Your doctor may prescribe other medicines for you to take along with telmisartan and hydrochlorothiazide tablets to treat your high blood pressure.

It is not known if telmisartan and hydrochlorothiazide tablets are safe and effective in children.

Do not take telmisartan and hydrochlorothiazide tablets if you:

- have low or no urine output
- are allergic (hypersensitive) to the active ingredients (telmisartan or hydrochlorothiazide) or any of the other ingredients listed at the end of this leaflet

What should I tell my doctor before using telmisartan and hydrochlorothiazide tablets?

Before you take telmisartan and hydrochlorothiazide tablets, tell your doctor if you:

- are pregnant or are planning to become pregnant. See "**What is the most important**

information I should know about telmisartan and hydrochlorothiazide tablets?"

- are breast-feeding or plan to breast-feed. Telmisartan and hydrochlorothiazide can pass into your breast milk and may harm your baby. You and your doctor should decide if you will take telmisartan and hydrochlorothiazide tablets or breast-feed. You should not do both. Talk with your doctor about the best way to feed your baby if you take telmisartan and hydrochlorothiazide tablets.
- have been told that you have abnormal body salt (electrolytes) levels in your blood
- have liver problems
- have asthma or history of asthma
- have lupus
- have diabetes
- have kidney problems
- have any other medical conditions

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Also, tell your doctor if you drink alcohol.

Telmisartan and hydrochlorothiazide tablets may affect the way other medicines work, and other medicines may affect how telmisartan and hydrochlorothiazide tablets work. Especially tell your doctor if you take:

- aliskiren
- digoxin (Lanoxin[®])
- lithium (Lithobid[®], lithium carbonate, lithium citrate)
- other medicines used to treat your high blood pressure or a heart problem
- water pills (diuretic)
- aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs)
- potassium supplements or a salt substitute containing potassium
- medicine used to treat diabetes, including insulin
- narcotic pain medicines
- sleeping pills
- steroid medicine or Adrenocorticotrophic Hormone (ACTH)
- barbiturates
- certain cholesterol lowering medicines (resins that are used for cholesterol reduction, e.g., cholestyramine and colestipol resins)

Ask your doctor if you are not sure if you are taking one of the medicines listed above.

Know the medicines you take. Keep a list of them and show it to your doctor or pharmacist when you get a new medicine.

How should I take telmisartan and hydrochlorothiazide tablets?

- Take telmisartan and hydrochlorothiazide tablets exactly as your doctor tells you to take it.
- Your doctor will tell you how many telmisartan and hydrochlorothiazide tablets to take and when to take it.
- Do not change your dose unless your doctor tells you to.
- Take telmisartan and hydrochlorothiazide tablets once each day.
- Take telmisartan and hydrochlorothiazide tablets with or without food.
- If you take too many telmisartan and hydrochlorothiazide tablets, call your doctor, or go to the nearest hospital emergency room right away.

What are the possible side effects of telmisartan and hydrochlorothiazide tablets?

Telmisartan and hydrochlorothiazide tablets may cause serious side effects, including:

- **Injury or death to your unborn baby.** See "**What is the most important information I should know about telmisartan and hydrochlorothiazide tablets?**"
- **Low blood pressure (hypotension)** is most likely to happen if you also:
 - take water pills (diuretics)
 - are on a low-salt diet
 - get dialysis treatments
 - have heart problems
 - get sick with vomiting or diarrhea
 - do not drink enough fluids
 - sweat a lot

If you feel faint or dizzy, lie down and call your doctor right away.

- **Kidney problems**, which may get worse if you already have kidney disease. You may have changes in your kidney test results, and you may need a lower dose of telmisartan and hydrochlorothiazide tablets. Call your doctor if you get:
 - swelling in your feet, ankles, or hands
 - unexplained weight gain

Call your doctor right away if you get any of the symptoms listed above.

- **Liver problems**, which may get worse in people who already have liver problems and take

telmisartan and hydrochlorothiazide tablets.

- **Eye problems.** One of the medicines in telmisartan and hydrochlorothiazide tablets can cause eye problems that may lead to vision loss. Symptoms of eye problems can happen within hours to weeks of starting telmisartan and hydrochlorothiazide tablets. Tell your doctor right away if you have:
 - decrease in vision
 - eye pain
- **Allergic reactions.** Tell your doctor right away if you get any of these symptoms:
 - swelling of the face, tongue, throat
 - difficulty breathing
- **Worsening of lupus.** Tell your doctor if your lupus gets worse or becomes active while taking telmisartan and hydrochlorothiazide tablets.
- **Change in body salts (electrolytes) level in your blood and fluid problems.** Your doctor may do tests to check your blood. Call your doctor right away if you have:
 - dry mouth
 - thirst
 - tiredness
 - sleepiness
 - restlessness
 - confusion
 - seizures
 - fast heartbeats
 - weakness
 - muscle pain or cramps
 - very low urine output
 - nausea or vomiting
- **Skin Cancer.** One of the medicines in telmisartan and hydrochlorothiazide tablets may increase your risk of getting non-melanoma skin cancer. Protect your skin from the sun and undergo regular skin cancer screening when taking telmisartan and hydrochlorothiazide tablets.

The most common side effects of telmisartan and hydrochlorothiazide tablets include:

- upper respiratory tract infections, including sinus pain/congestion and sore throat
- dizziness
- feeling tired
- flu-like symptoms

- back pain
- diarrhea
- nausea

These are not all the possible side effects with telmisartan and hydrochlorothiazide tablets. Tell your doctor if you have any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store telmisartan and hydrochlorothiazide tablets?

- Store telmisartan and hydrochlorothiazide tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep bottle tightly closed and do not remove telmisartan and hydrochlorothiazide tablets from bottle until immediately before administration.

Keep telmisartan and hydrochlorothiazide tablets and all medicines out of the reach of children.

General information about telmisartan and hydrochlorothiazide tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use telmisartan and hydrochlorothiazide tablets for a condition for which it was not prescribed. Do not give telmisartan and hydrochlorothiazide tablets to other people, even if they have the same condition you have. It may harm them.

This Patient Information leaflet summarizes the most important information about telmisartan and hydrochlorothiazide tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about telmisartan and hydrochlorothiazide tablets that is written for health professionals.

For current prescribing information, call Solco Healthcare US, LLC at 1-866-257-2597.

What are the ingredients in telmisartan and hydrochlorothiazide tablets?

Active Ingredients: telmisartan, USP and hydrochlorothiazide, USP

Inactive Ingredients: sodium hydroxide, meglumine, povidone, mannitol, sodium stearyl fumarate, hypromellose, magnesium stearate, lactose monohydrate, microcrystalline cellulose, crospovidone (Type B), and sodium starch glycolate. The 40 mg/12.5 mg and 80 mg/12.5 mg tablets also contain: ferric oxide red. The 80 mg/25 mg tablets also contain: ferric oxide yellow.

What is high blood pressure (hypertension)?

Blood pressure is the force in your blood vessels when your heart beats and when your heart rests. You have high blood pressure when the force is too much. Medicines that lower your blood pressure lower your chance of having a stroke or heart attack.

High blood pressure makes the heart work harder to pump blood through the body and causes damage to the blood vessels. Telmisartan and hydrochlorothiazide tablets can help your blood vessels relax so your blood pressure is lower.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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