

TELMIDIP-H Tablets

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

What is in this leaflet

1. What is TELMIDIP-H used for
2. How TELMIDIP-H works
3. Before you use TELMIDIP-H
4. How to use TELMIDIP-H
5. While you are using it
6. Side effects
7. Storage and Disposal of TELMIDIP-H
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What TELMIDIP-H is used for

TELMIDIP-H 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 TELMIDIP-H works

TELMIDIP-H is a combination of two active substances, telmisartan and hydrochlorothiazide in one tablet. Both of these substances help to control high blood pressure.

- ☐ Telmisartan belongs to a group of medicines called angiotensin II receptor blockers. 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.

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.

Before you use TELMIDIP-H

- When you must not use it

- if you are allergic (hypersensitive) to telmisartan or any other ingredients of this medicine.
- if you are allergic (hypersensitive) to hydrochlorothiazide or to any other sulfonamide-derived medicines.
- if you are more than 3 months pregnant. (It is also better to avoid TELMIDIP-H in early pregnancy.)
- if you have severe liver problems such as cholestasis or biliary obstruction (problems with drainage of the bile from the gall bladder) or any other severe liver disease.
- if you have severe kidney disease.
- if your doctor determines that you have low potassium levels or high calcium levels in your blood that do not get better with treatment.

If any of the above applies to you, tell your doctor or pharmacist before taking TELMIDIP-H.

- 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:

- 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, vomiting, or haemodialysis.
- Kidney disease or kidney transplant.
- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- Liver disease.
- Heart trouble.
- 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.
- The active ingredient hydrochlorothiazide can cause an unusual reaction, resulting in a

decrease in vision and eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking TELMIDIP-H. This can lead to permanent vision impairment, if not treated.

- Inform your healthcare providers before taking TELMIDIP-H if 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 TELMIDIP-H.

Talk to your doctor before taking TELMIDIP-H:

- if you are taking any of the following medicines used to treat high blood pressure:
 - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes related kidney problems.
 - aliskiren.
 Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.
- if you are taking digoxin.

Treatment with hydrochlorothiazide may cause electrolyte imbalance in your body. Typical symptoms of fluid or electrolyte imbalance include dry mouth, weakness, lethargy, drowsiness, restlessness, muscle pain or cramps, nausea (feeling sick), vomiting, tired muscles, and an abnormally fast heart rate (faster than 100 beats per minute). If you experience any of these, you should tell your doctor.

You should also tell your doctor, if you experience an increased sensitivity of the skin to the sun with symptoms of sunburn (such as redness, itching, swelling, blistering) occurring more quickly than normal.

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In case of surgery or anaesthetics, you should tell your doctor that you are taking TELMIDIP-H.

As with all other angiotensin II receptor blockers, telmisartan may be less effective in lowering the blood pressure in black patients.

Before taking TELMIDIP-H, tell your doctor:

- 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 TELMIDIP-H, seek medical attention immediately.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken or might take 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 TELMIDIP-H:

- Lithium containing medicines to treat some types of depression.
- Medicines associated with low blood potassium (hypokalemia) such as other diuretics, ('water tablets'), laxatives (e.g. castor oil), corticosteroids (e.g. prednisone), ACTH (a hormone), amphotericin (an antifungal medicine), carbenoxolone (used to treat mouth ulcers), penicillin G sodium (an antibiotic), and salicylic acid and derivatives.
- Medicines that may increase blood potassium levels such as potassium sparing diuretics, potassium supplements, salt substitutes containing potassium, ACE inhibitors, and other medicinal products such as heparin sodium (an anticoagulant).
- Medicines that are affected by changes of the blood potassium level such as heart medicines (e.g. digoxin) or medicines to control the rhythm of your heart (e.g. digitalis glycosides),

- Medicines for the treatment of diabetes (insulins or oral agents such as metformin).
- Cholestyramine and colestipol, medicines for lowering blood fat levels.
- Medicines to increase blood pressure, such as noradrenaline.
- Muscle relaxing medicines, such as tubocurarine.
- Calcium supplements and/or vitamin D supplements.
- Anti-cholinergic medicines (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anaesthesia) such as atropine and biperiden.
- Amantadine (medicine used to treat Parkinson's disease and also used to treat or prevent certain illnesses caused by viruses).
- Other medicines used to treat high blood pressure, corticosteroids, painkillers (such as non-steroidal anti-inflammatory drugs [NSAIDs]), medicines to treat cancer, gout or arthritis.
- If you are taking an ACE-inhibitor or aliskiren.
- Digoxin.

TELMIDIP-H may increase the blood pressure lowering effect of other medicines and low blood pressure may be aggravated by alcohol, barbiturates, or narcotics. You should consult with your doctor if you need to adjust the dose of your other medicine while taking TELMIDIP-H.

The effect of TELMIDIP-H may be reduced when you take NSAIDs (nonsteroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen).

How to use TELMIDIP-H

- How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of TELMIDIP-H is one tablet a day. Try to take a tablet at the same time each day. You can take TELMIDIP-H with or without food. The tablets should be swallowed with

some water or other non-alcoholic drink. It is important that you take TELMIDIP-H every day until your doctor tells you otherwise.

If your liver is not working properly, the usual dose should not exceed 40mg/12.5 mg once a day.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking TELMIDIP-H for as long as your doctor recommends.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember and 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 your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking TELMIDIP-H.

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 TELMIDIP-H to anyone else, even if they have the same symptoms or condition as you.

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- Things to be careful of

Pregnancy and lactation

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking TELMIDIP-H before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of TELMIDIP-H.

TELMIDIP-H 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.

Breast-feeding

Tell your doctor if you are breastfeeding or about to start breast-feeding. TELMIDIP-H is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breastfeed.

Children and adolescents

The use of TELMIDIP-H in children and adolescents up to the age of 18 years is not recommended.

Driving and using machines

Some people feel like dizzy, fainting (syncope) or spinning (vertigo) when taking TELMIDIP-H. If you experience these symptoms, do not drive or operate machinery.

TELMIDIP-H contains lactose and sorbitol

If you are intolerant to some sugars, consult your doctor before taking TELMIDIP-H.

Side effects

Like all medicines, TELMIDIP-H 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 TELMIDIP-H: Common side effects (may affect up to 1 in 10 people):

➤ Dizziness

Uncommon side effects (may affect up to 1 in 100 people):

Decreased blood potassium levels, anxiety, fainting (syncope), sensation of tingling, pins and needles (paraesthesia), feeling of spinning (vertigo), fast heart beat (tachycardia), heart rhythm disorders, low blood pressure, a sudden fall in blood pressure when you stand up, shortness of breath (dyspnoea), diarrhoea, dry mouth, flatulence, back pain, muscle spasm, muscle pain, erectile dysfunction (inability to get or keep an erection), chest pain, increased blood uric acid levels.

Rare side effects (may affect up to 1 in 1,000 people):

Inflammation of the lung (bronchitis), activation or worsening of systemic lupus erythematosus (a disease where the body's immune system attacks the body, which causes joint pain, skin rashes and fever); sore throat, inflamed sinuses, feeling sad (depression), difficulty falling asleep (insomnia), impaired vision, difficulty breathing, abdominal pain, constipation, bloating (dyspepsia), feeling sick (vomiting), inflammation of the stomach (gastritis), abnormal liver function (Japanese patients are more likely to experience this side effect), redness of the skin (erythema), allergic reactions such as itching or rash, increased sweating, hives (urticaria), joint pain (arthralgia) and pain in extremities, muscle cramps, flu-like illness, pain, increased levels of uric acid, low levels of sodium, increased levels of creatinine, hepatic enzymes or creatine phosphokinase in the blood.

Adverse reactions reported with one of the individual components may be potential adverse reactions with TELMIDIP-H, even if not observed in clinical trials with this product.

Hydrochlorothiazide:

Side effects of frequency 'not known':

- ☐ 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;
- ☐ Acute angle-closure glaucoma: a rapid increased pressure in your eyes, eye pain. If left untreated, it may lead to permanent vision loss.

Very Rare:

- ☐ Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).

If any of the side effects get 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 visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of TELMIDIP-H

- Storage

Keep out of the reach and sight of children.

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

TELMIDIP-H is sensitive to moisture. Remove your TELMIDIP-H tablet from the blister only directly prior to intake.

- 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

TELMIDIP-H 40 mg + 12.5 mg Tablets: Oblong shaped biconvex, bilayered, uncoated tablets with one

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white to off white color layer and one pink color mottled layer debossed with 'L199'. White to off white color layer may contain pink color specks.

TELMIDIP-H 80 mg + 12.5 mg Tablets: Oblong shaped biconvex, bilayered, uncoated tablets with one white to off white color layer and one pink color mottled layer debossed with 'L200'. White to off white color layer may contain pink color specks.

- Ingredients

Active ingredient:

- Telmisartan
- Hydrochlorothiazide

Inactive ingredients:

- Mannitol
- Sodium Hydroxide
- Meglumine
- Povidone K-25
- Sodium Stearyl Fumarate
- Magnesium Stearate
- Lactose Monohydrate
- Pigment Blend PB-24880 Pink

- MAL numbers:

TELMIDIP-H 40 mg + 12.5 mg Tablets: MAL24046029AZ

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Manufacturer

Alembic Pharmaceuticals Limited
(Formulation Division),
Village Panelav, P.O. Tajpura,
Near Baska, Taluka Halol, Panchmahal,
Gujarat – 389350 India.

Product Registration Holder

GENPHARMA SDN. BHD.
Lot 5016, Jalan Teratai,
5 ½ Mile Off Jalan Meru,
41050 Klang, Selangor, Malaysia

Date of revision

9th May 2024

Serial Number

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