

## PATIENT INFORMATION LEAFLET

Telmisartan and Hydrochlorothiazide Tablets USP  
(80 mg + 12.5 mg)

# TELSARTAN H 80

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

### What is in this leaflet

1. What TELSARTAN H 80 is and what it is used for
2. What you need to know before you take TELSARTAN H 80
3. How to take TELSARTAN H 80
4. Possible side effects
5. How to store TELSARTAN H 80
6. Contents of the pack and other information

#### 1. What TELSARTAN H 80 is and what it is used for

TELSARTAN H 80 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 antagonists. Angiotensin-II is a substance produced in your body that 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.

**TELSARTAN H 80** is used to treat high blood pressure (essential hypertension) in adults whose blood pressure is not controlled enough when telmisartan is used alone.

#### 2. What you need to know before you take TELSARTAN H 80 Do not take TELSARTAN H 80

- ❖ If you are allergic to telmisartan or any of the other ingredients of this medicine.

- ❖ If you are allergic to hydrochlorothiazide or to any other sulfonamide-derived medicines.
- ❖ If you are more than 3 months pregnant. (It is also better to avoid this medicine 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 gallbladder) 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 you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing Aliskiren.

### Warnings and precautions

Talk to your doctor before taking this medicine if you are suffering or have ever suffered from any of the following conditions or illnesses:

- ❖ Low blood pressure (hypotension), is 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).

### Children and adolescents

This medicine is not recommended in children and adolescents up to the age of 18 years.

### Other medicines and TELSARTAN H 80:

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 medications 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 Telmisartan/Hydrochlorothiazide:

- ❖ Medicines associated with low blood potassium (hypokalaemia) 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 cyclosporin (an immunosuppressant drug) and other medicinal products such as heparin sodium (an anticoagulant).

### **TELSARTAN H 80 with food and alcohol**

You can take Telmisartan/Hydrochlorothiazide with or without food. Avoid taking alcohol until you have talked to your doctor. Alcohol may make your blood pressure fall more and/or increase the risk of you becoming dizzy or feeling faint.

### **Pregnancy and breast-feeding**

#### **Pregnancy**

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking this medicine before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of TELSARTAN H 80. These tablets are not recommended during 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 breast-feeding or about to start breast-feeding. These tablets are not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

### **3. How to take TELSARTAN H 80**

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

The recommended dose is one tablet a day. Try to take a tablet at the same time each day. You can take the tablets with or without food. They should be swallowed with some water or other non-alcoholic drink. It is important that you take the tablets every day until your doctor tells you otherwise.

If you forget to take TELSARTAN H 80

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.

### **4. Possible side effects**

#### **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 heartbeat (tachycardia), heart rhythm disorders
- ❖ Low blood pressure, a sudden fall in blood pressure when you stand up
- ❖ Shortness of breath (dyspnoea)
- ❖ Diarrhoea
- ❖ Flatulence
- ❖ Dry mouth
- ❖ Back pain, muscle spasm, muscle pain, chest pain
- ❖ Erectile dysfunction (inability to get or keep an erection)
- ❖ Increased blood uric acid levels.
- ❖ Increased levels of creatinine, liver enzymes or creatine phosphokinase in the blood.

### **5. How to store TELSARTAN H 80**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture. Store in a dry place at or below 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other Information**

#### **What TELSARTAN H 80 contains**

The active substances are Telmisartan and Hydrochlorothiazide

#### **TELSARTAN H 80**

Each uncoated bilayered tablet contains:

Telmisartan IP 80 mg

Hydrochlorothiazide IP 12.5 mg

(Meets Dissolution Test 2)

Colour: Iron Oxide Red

#### **What TELSARTAN H 80 looks like and contents of the pack**

**TELSARTAN H 80** tablets are White/Light Red, Oblong, biconvex, uncoated bilayered tablets. Tablets are packed into Alu-Alu Blister. The pack size is 10 x 10 tablets in a printed paper carton.



Manufactured by :  
**Quest Pharmaceuticals Pvt. Ltd.**  
Chhata Pipara, Bara, Nepal

*For further information*  
**Quest Pharmaceuticals Pvt. Ltd.**  
Tripureshwar, Kathmandu  
Tel. 01-4240304, Email : quest.ktm@quest.com.np,  
Website : www.quest.com.np