

# Telmicos<sup>®</sup> H (Tablets)



1336

Ref. No.:INS336/04.18

## Telmisartan

## Hydrochlorothiazide

Angiotensin II receptor antagonist and Thiazide Diuretic

TELMICOS<sup>®</sup> H 40/12.5MG TABLETS (FILM COATED)

### PRESENTATION:

**Telmicos<sup>®</sup> H 40/12.5mg Tablets:** Pink, circular, biconvex film coated tablets plain on both sides. Each film coated tablet contains: Telmisartan 40 mg and Hydrochlorothiazide 12.5 mg, Lactose and other excipients.

### CLINICAL PHARMACOLOGY:

Telmicos<sup>®</sup> H is a combination of an angiotensin II receptor antagonist, Telmisartan, and a thiazide diuretic, Hydrochlorothiazide. The combination of these ingredients has an additive antihypertensive effect, reducing blood pressure to a greater degree than either component alone.

Telmisartan is an orally effective and specific angiotensin II receptor subtype 1 (AT<sub>1</sub>) antagonist, it displaces angiotensin II with very high affinity from its binding site at the AT<sub>1</sub> receptor subtype, which is responsible for the known actions of angiotensin II. Telmisartan does not exhibit any partial agonist activity at the AT<sub>1</sub> receptor; it selectively binds the AT<sub>1</sub> receptor. The binding is long-lasting. Plasma aldosterone levels are decreased by Telmisartan. Telmisartan does not inhibit human plasma renin or block ion channels. It does not inhibit angiotensin converting enzyme (kininase II), the enzyme which also degrades bradykinin. Therefore, it is not expected to potentiate bradykinin-mediated adverse effects.

Hydrochlorothiazide is a thiazide diuretic. Thiazides are moderately potent diuretics and exert their diuretic effect by reducing the reabsorption of electrolytes from the renal tubules, thereby increasing the excretion of sodium and chloride ions, and consequently water. They act mainly at the beginning of the distal tubules. The excretion of other electrolytes, notably potassium and magnesium, is also increased. The excretion of calcium is reduced. They also reduce carbonic anhydrase activity so that bicarbonate excretion is increased. Their hypotensive effect is probably partly due to a reduction in peripheral resistance; they also enhance the effects of other antihypertensives.

### Pharmacokinetics:

Concomitant administration of Hydrochlorothiazide and Telmisartan does not appear to affect the pharmacokinetics of either substance in healthy subjects.

**Telmisartan** is rapidly absorbed from the gastrointestinal tract; the absolute oral bioavailability is dose dependent and is about 42% after a 40 mg dose and 58% after a 160mg dose.

Peak plasma concentrations of Telmisartan are reached about 0.5 to 1 hour after an oral dose.

Telmisartan is over 99% bound to plasma proteins.

It is excreted almost entirely in the faeces via bile, mainly as unchanged drug. The terminal elimination half-life of Telmisartan is about 24 hours.

**Hydrochlorothiazide** is fairly rapidly absorbed from the gastrointestinal tract. It is reported to have a bioavailability of about 65 to 70%. It has been estimated to have a plasma half life of between about 5 and 15 hours and appears to be preferentially bound to red blood cells. It is excreted mainly unchanged in the urine. Hydrochlorothiazide crosses the placental barrier and is distributed into breast milk.

### USES:

Treatment of essential hypertension.

### DOSAGE AND ADMINISTRATION:

The recommended dose of Telmicos<sup>®</sup> H is 40/12.5 mg once daily in patients whose blood pressure is not adequately controlled by 40mg of Telmisartan.

It is advisable that you take the tablet at the same time each day.

The tablets should be taken with liquid, with or without food.

### CONTRA-INDICATIONS AND WARNINGS:

Telmicos<sup>®</sup> H is contraindicated in patients with hypersensitivity to other sulphonamide-derived substances, second and third trimesters of pregnancy, cholestasis and biliary obstructive disorders, severe hepatic impairment, severe renal impairment (creatinine clearance < 30 ml/min), refractory hypokalaemia, hypercalcaemia.

The concomitant use of Telmicos<sup>®</sup> H with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m<sup>2</sup>).

# Telmicos<sup>®</sup> H (Tablets)

**Precautions and warnings:** Talk to your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses: Low blood pressure (hypotension), low-salt diet, diarrhoea, vomiting, or haemodialysis, kidney disease or kidney transplant, renal artery stenosis, liver disease, heart trouble, diabetes, gout, raised aldosterone levels and systemic lupus erythematosus. Hypersensitivity reactions to Hydrochlorothiazide may occur in patients with or without a history of allergy or bronchial asthma, but are more likely in patients with such a history.

Hydrochlorothiazide, a sulfonamide, can cause an idiosyncratic reaction, resulting in acute transient myopia and acute angle-closure glaucoma. Symptoms include acute onset of decreased visual acuity or ocular pain and typically occur within hours to weeks of drug initiation. Untreated acute angle-closure glaucoma can lead to permanent vision loss. The primary treatment is to discontinue Hydrochlorothiazide as rapidly as possible.

## **Adverse Effects:**

You should see your doctor immediately if you experience any of the following symptoms: Sepsis, rapid swelling of the skin and mucosa (angioedema); these side effects are rare but are extremely serious and patients should stop taking the medicine and see their doctor immediately.

Common side effects: Dizziness

Uncommon side effects: Decreased blood potassium levels, anxiety, fainting, sensation of tingling, paraesthesia, vertigo, tachycardia, heart rhythm disorders, low blood pressure, a sudden fall in blood pressure when you stand up, dyspnoea, diarrhoea, dry mouth, flatulence, back pain, muscle spasm, muscle pain, erectile dysfunction, chest pain, increased blood uric acid levels.

## WARNING

Telmicos<sup>®</sup> H Tablets should not be taken during pregnancy.

**Overdosage:** The most prominent manifestations of Telmisartan overdose were hypotension and tachycardia; bradycardia, dizziness, vomiting, increase in serum creatinine, and acute renal failure have also been reported. Overdose with Hydrochlorothiazide is associated with electrolyte depletion (hypokalaemia, hypochloreaemia) and hypovolaemia resulting from excessive diuresis.

Telmisartan is not removed by haemodialysis. The patient should be closely monitored, and the treatment should be symptomatic and supportive. Suggested measures include induction of emesis and/or gastric lavage. Activated charcoal may be useful in the treatment of overdose.

**Interactions:** 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 Telmicos<sup>®</sup> H: Lithium containing medicines to treat some types of depression, medicines associated with low blood potassium (hypokalaemia) such as other diuretics, laxatives, corticosteroids, ACTH, amphotericin, carbenoxolone, penicillin G sodium, and salicylic acid and derivatives. Potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium, ACE inhibitors that may increase blood potassium levels. Heart medicines (e.g. digoxin, quinidine, disopyramide). Medicines used for mental disorders (e.g. thioridazine, chlorpromazine, levomepromazine etc). Other medicines used to treat high blood pressure, steroids, painkillers, medicines to treat cancer, gout, or arthritis, and vitamin D supplements.

Telmicos<sup>®</sup> H may increase the blood pressure lowering effect of other medicines used to treat high blood pressure (e.g. baclofen, amifostine). Furthermore, low blood pressure may be aggravated by alcohol, barbiturates, narcotics or antidepressants.

The effect of Telmicos<sup>®</sup> H Tablets may be reduced when you take NSAIDs (non steroidal anti-inflammatory drug) e.g. aspirin or ibuprofen.

## **PHARMACEUTICAL PRECAUTIONS:**

Store in a dry place below 30°C. Protect from light. Keep all medicines out of the reach of children.

## **LEGAL CATEGORY:**

Prescription Only Medicine (POM)

®Regd. TM



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