

Telmicos® AMH (Tablets) Ref. No.:INS354/04.19

Telmisartan	Angiotensin II antagonist
Hydrochlorothiazide	Thiazide Diuretic
Amlodipine Besilate	Calcium channel blocker

TELMICOS® AMH 40/12.5/5MG TABLETS

PRESENTATION

Telmicos®AMH Tablets 40/12.5/5 mg: Yellow and white circular biconvex shaped two layer tablet. Each tablet contains: Telmisartan 40 mg, Hydrochlorothiazide 12.5 mg, Amlodipine Besilate 5mg, Lactose and other excipients.

CLINICAL PHARMACOLOGY

Telmicos® AMH Tablet works by inhibiting the influx of calcium ions into vascular smooth muscle and cardiac muscles; eliminating the fluid and salts from the body and blocking the action of a substance responsible for narrowing the blood vessels.

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 1.5 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.

Amlodipine After oral administration of therapeutic doses, amlodipine is well absorbed with peak blood levels between 6-12 hours post dose. Absolute bioavailability has been estimated to be between 64 and 80%. The terminal plasma elimination half-life is about 35-50 hours and is consistent with once daily dosing. In vitro studies have shown that approximately 97.5% of circulating amlodipine is bound to plasma proteins Amlodipine is extensively metabolised by the liver to inactive metabolites with 10% of the parent compound and 60% of metabolites excreted in the urine

USES

Telmicos® AMH tablet is used for hypertension, coronary artery disease, chronic stable angina, vasospastic angina, fluid retention, heart failure, liver failure, kidney failure.

DOSAGE AND ADMINISTRATION

Telmicos® AMH Should be taken once daily preferably in the morning.

Telmicos® AMH may be substituted for its individually titrated components for patients on Telmisartan, Amlodipine, and Hydrochlorothiazide. Telmicos® AMH may be used as add-on/switch therapy to provide additional blood pressure lowering for patients not adequately controlled on agents from two of the following antihypertensive classes: angiotensin receptor blockers, calcium channel blockers, and diuretics at their maximally tolerated, labeled, or usual dose.

CONTRA-INDICATIONS

Telmicos® AMH is contraindicated in patients with known hypersensitivity to any component of this product.

Precautions and warnings

Before using Telmicos® AMH Tablet, inform your doctor about any medications you are taking, .), any allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Take as directed by your doctor as the dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Avoid taking hydrochlorothiazide at bedtime because it makes you urinate more often
- Consult your doctor if you experience dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, confusion, muscle pains or cramps
- Do not chew, divide or crush the tablets
- Drink adequate amount of liquid to avoid becoming dehydrated or overheated
- Get your blood pressure, potassium and kidney function checked 1 week after starting this medicine
- Hepatic impairment
- Inform your doctor of any other medications you may be taking

Telmicos® AMH (Tablets)

- Seek medical attention immediately if you experience increased chest pain or any of the side effects listed below for a longer duration.
- Severe aortic stenosis
- Severe obstructive coronary artery disease

Adverse Effects

The following are possible side-effects that may occur when taking Telmicos® AMH Tablet. Consult your doctor if you observe any of the following side-effects, especially if they persist for a long time

- Cough
- Swelling of legs and feet
- Drowsiness
- Nausea
- Abdominal pain
- Dizziness
- Flushing
- Arrhythmia
- Rapid heartbeat
- Hypotension, Visual disturbances

WARNING

Telmicos® AMH Tablets should not be taken during pregnancy.

Overdosage

Telmisartan Limited data are available with regard to overdosage in humans. The most likely manifestations of overdosage would be hypotension, dizziness and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation.

Hydrochlorothiazide The most common signs and symptoms observed in patients are those caused by electrolyte depletion (hypokalemia, hypochloremia, hyponatremia) and dehydration resulting from excessive diuresis. If digitalis has also been administered, hypokalemia may accentuate cardiac arrhythmias.

Amlodipine Overdosage might be expected to cause excessive peripheral vasodilation with marked hypotension and possibly a reflex tachycardia. In humans, experience with intentional overdosage of amlodipine is limited. If massive overdose should occur, initiate active cardiac and respiratory monitoring. Frequent blood pressure measurements are essential. Should hypotension occur, provide cardiovascular support including elevation of the extremities and the judicious administration of fluids.

Interactions

If you use other drugs or over the counter products at the same time, the effects of Telmicos® AMH Tablet may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that your doctor can help you prevent or manage drug interactions. Telmicos® AMH Tablet may interact with the following drugs and products:

- Acetylsalicylic acid, Alcohol, Amifostine, Amiloride, Aspirin, CYP3A4 inhibitors, Cholestyramine, Colestipol, Corticosteroids, Cyclosporine etc

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)

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