

Telmicos® (Tablets)

Telmisartan



21100

Ref. No: B2121100/22.01

Angiotensin II Receptor antagonists

TELMICOS® 40MG TABLETS (FILM COATED)

TELMICOS® 80MG TABLETS (FILM COATED)

PRESENTATION:

Telmicos® 40mg Tablets: White to off-white, circular biconvex tablet embossed 'C' on one side and a breakline on the other side. Each film coated tablet contains: Telmisartan 40mg.

Telmicos® 80mg Tablets: White to off-white, circular biconvex tablet embossed 'COSMOS' on one side and plain on the other side. Each film coated tablet contains: Telmisartan 80mg.

CLINICAL PHARMACOLOGY:

Telmisartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT₁ receptor in a number of tissues. It does not cause persistent dry cough that normally complicates ACE inhibitors therapy. This is due to the fact that it does not inhibit the breakdown of Kinins.

Pharmacokinetics:

Telmisartan is rapidly absorbed from the gastrointestinal tract; the absolute oral bioavailability is dose dependent and is about 42% following a 40mg dose and 58% following a 160mg dose. Peak plasma concentrations of Telmisartan are reached about 0.5 to 1 hour after oral dose. Telmisartan is over 99% bound to plasma proteins. It is excreted almost entirely in faeces via bile, mainly as unchanged drug. The terminal elimination half-life of Telmisartan is about 24 hours.

USES:

Hypertension

Treatment of essential hypertension in adults.

Cardiovascular prevention

Reduction of cardiovascular morbidity in adults with:

- Manifest atherothrombotic cardiovascular disease (history of coronary heart disease, stroke, or peripheral arterial disease) or
- Type 2 diabetes mellitus with documented target organ damage.

DOSAGE AND ADMINISTRATION:

The usual starting dose of Telmisartan is 40mg once a day; blood pressure response is dose related over the range of 20-80mg. Patients with depletion of intravascular volume should have the condition corrected or Telmisartan tablets should be initiated under close medical supervision.

Dosage

Treatment of essential hypertension

The usually effective dose is 40mg once daily. Some patients may already benefit at a daily dose of 20mg. In cases where the target blood pressure is not achieved, the dose of telmisartan can be increased to a maximum of 80mg once daily. Alternatively, telmisartan may be used in combination with thiazide-type diuretics such as hydrochlorothiazide, which has been shown to have an additive blood pressure lowering effect with telmisartan.

Cardiovascular prevention

The recommended dose is 80mg once daily.

Elderly patients

No dose adjustment is necessary for elderly patients.

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Paediatric population

The safety and efficacy of Telmisartan in children and adolescents aged below 18 years have not been established.

Method of Administration

Telmisartan tablets are for once-daily oral administration and should be taken with liquid, with or without food.

Precautions to be taken before handling or administering the medicinal product. Tablets should be taken out of the blister shortly before administration.

CONTRA-INDICATIONS AND WARNINGS:

Telmisartan is contra-indicated in Hypersensitivity; Second and third trimesters of pregnancy; Biliary obstructive disorders and Severe hepatic impairment.

The concomitant use of Telmisartan with aliskiren is contraindicated in patients with diabetes mellitus or renal impairment. (GFR < 60mL/min/1.73m²)

Adverse Effects:

Adverse effects occurring in 1% or more of patients receiving Telmisartan include upper respiratory tract infection, sinusitis, pharyngitis, back pain and diarrhoea.

WARNING

Telmicos[®] is not recommended in 1st trimester and contra-indicated in 2nd and 3rd trimesters of pregnancy.

Drug Interactions:

Drugs Affecting Hepatic Microsomal inhibitors or inducers of the cytochrome P-450 (CYP) isoenzyme system; pharmacokinetic interactions unlikely.

Digoxin pharmacokinetic interactions (increased plasma digoxin concentrations). It is recommended that serum digoxin concentration be monitored when Telmisartan therapy is initiated, adjusted, or discontinued in patients stabilized on digoxin. Concomitant use is not recommended.

Warfarin Pharmacokinetic interactions (decreased plasma warfarin concentrations; international normalized ratio (INR) not affected)

Acetaminophen, amlodipine, glyburide, ibuprofen, simvastatin pharmacological interactions unlikely.

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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