Telma®

Telmisartan

Tablet

Description

Telma® belongs to a class of medicines known as angiotensin II receptor antagonists. Angiotensin II is produced in the body which causes the blood vessels to narrow, thus increasing the blood pressure. Telma® blocks the effect of angiotensin II so that the blood vessels relax, and the blood pressure become lower.

Indications

Telma® is used to lower high blood pressure (hypertension). It may be used alone or with other medicines to treat high blood pressure. It is also indicated for reduction of the risk of myocardial infarction, stroke, or death from cardiovascular causes in patients 55 years of age or older are unable to take ACE inhibitors.

Dosage and Administration

Hypertension:

Dosage must be individualized. The usual starting dose of Telma® tablets is 40 mg once a day. Blood pressure response is dose-related over the range of 20 to 80 mg. Most of the antihypertensive effect is apparent within 2 weeks and maximal blood pressure reduction is generally attained after 4 weeks.

Cardiovascular Risk Reduction:

The recommended dose of Telma® tablet is 80 mg once a day and can be administered with or without food. It is not known whether doses lower than 80 mg of Telmisartan are effective in reducing the risk of cardiovascular morbidity and mortality. When initiating Telmisartan therapy for cardiovascular risk reduction, monitoring of blood pressure is recommended, and if appropriate, adjustment of medications that lower blood pressure may be necessary.

Use in Special Populations

Paediatric Use

Safety and effectiveness of Telmisartan in paediatric patients have not been established.

Pregnancy

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

Nursing Mothers

Tell your doctor if you are breast-feeding or about to start breast-feeding. Telma® is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Contraindications

Telma® is contraindicated in patients with known hypersensitivity (e.g., anaphylaxis or angioedema) to Telmisartan or any other component of this product.

Warning and Precaution

Pregnancy (Pregnancy Category D) and Lactation

Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios can be associated with fetal lung hypoplasia and skeletal deformations. When pregnancy is detected, discontinue Telmisartan as soon as possible.

Because no information is available regarding the use of Telmisartan during breast-feeding, it is not recommended and alternative treatments with better established safety profiles during breast-feeding are preferable, especially while nursing a newborn or preterm infant.

Hypotension

In patients with an activated renin-angiotensin system, such as volume- or salt-depleted patients (e.g., those being treated with high doses of diuretics), symptomatic hypotension may occur after initiation of therapy with Telmisartan.

Impaired Hepatic Function

As the majority of Telmisartan is eliminated by biliary excretion, patients with biliary obstructive disorders or hepatic insufficiency can be expected to have reduced clearance. Initiate Telma® at low doses and titrate slowly in these patients.

Adverse Effects

Adverse effects are similar to other angiotensin II receptor antagonists and include tachycardia and bradycardia (fast or slow heartbeat), hypotension (low blood pressure), edema and allergic reactions.

Drug Interactions

Aliskiren: Do not co-administer Aliskiren with Telmisartan in patients with diabetes. Avoid use of Aliskiren with Telmisartan in patients with renal impairment (GFR <60 mL/min).

Digoxin: When Telmisartan was co-administered with digoxin, median increases in digoxin peak plasma concentration (49%) and in trough concentration (20%) were observed and therefore, monitor digoxin levels.

Non-Steroidal Anti-Inflammatory Agents including Selective Cyclooxygenase-2 Inhibitors (COX-2 Inhibitors): In patients who are elderly, volume-depleted (including those on diuretic therapy), or with compromised renal function, co-administration of NSAIDs, including selective COX-2 inhibitors, with angiotensin II receptor antagonists, including Telmisartan, may result in deterioration of renal function, including possible acute renal failure.

Ramipril: Co-administration of Telmisartan 80 mg once daily and Ramipril 10 mg once daily to healthy subjects increases steady-state Cmax and AUC of Ramipril 2.3- and 2.1-fold, respectively. Concomitant use of Telmisartan and Ramipril is not recommended.

Other Drugs: Co-administration of Telmisartan did not result in a clinically significant interaction with acetaminophen, amlodipine, glyburide, simvastatin, hydrochlorothiazide, warfarin, or ibuprofen. Telmisartan is not metabolized by the cytochrome P450 system and had no effects in vitro on cytochrome P450 enzymes, except for some inhibition of CYP2C19.

Overdose

Limited data are available with regard to overdosage in humans. The most likely manifestation of overdosage with Telmisartan tablets would be hypotension, dizziness and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted. Telmisartan is not removed by hemodialysis.

Pharmaceutical Precautions

Keep out of the reach of children. Keep in a cool and dry place. Protect from light.

Commercial Pack

Telma® 40 Tablet: Box containing 30 tablets in 3 x 10's Alu-Alu form packs. Each film coated tablet contains Telmisartan USP 40 mg.

Telma® 80 Tablet: Box containing 30 tablets in 3 x 10's Alu-Alu form packs. Each film coated tablet contains Telmisartan USP 80 mg.

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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