

Presart

Telmisartan Tablet

Presentation

Presart 20 Tablet: Each tablet contains Telmisartan USP 20 mg

Presart 40 Tablet: Each tablet contains Telmisartan USP 40 mg

Presart 80 Tablet: Each tablet contains Telmisartan USP 80 mg

Description

Telmisartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland. Its action is therefore independent of the pathways for angiotensin II synthesis. Telmisartan has much greater affinity (>3,000 fold) for the AT1 receptor than for the AT2 receptor. Because Telmisartan does not inhibit ACE (kininase II), it does not affect the response to bradykinin. Telmisartan does not bind to or block other hormone receptors or ion channels known to be important in cardiovascular regulation.

Indications

- Treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal & nonfatal cardiovascular events, primarily strokes and myocardial infarctions.
- Cardiovascular risk reduction- Reduction of cardiovascular morbidity in adults with:
 - 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

Indication	Starting Dose	Dose Range
Hypertension	20-40 mg once daily	20 to 80 mg once daily
Cardiovascular Risk Reduction	80 mg once daily	80 mg once daily

The usual starting dose of Presart 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 reduction is generally attained after 4 weeks. When additional blood pressure reduction beyond that achieved with Presart 80 mg is required, may switch to combination.

Initial therapy with Presart is not recommended in patients ≥ 75 years old or with hepatic impairment

Pediatric use

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

Geriatric use

No overall differences in effectiveness and safety were observed in these patients compared to younger patients.

Hepatic impairment

Monitor carefully in patients with impaired hepatic or renal function.

Side Effects

In hypertensive patients: The most common side effects of Presart tablets include sinus pain and congestion (sinusitis), back pain, diarrhea etc.

For patients of cardiovascular risk reduction: The most common side effects of Presart tablets in CV risk reduction include intermittent claudication and skin ulcer.

Precautions

Telmisartan should be used with caution in Patients with-

- Avoid fetal or neonatal exposure
- Hypotension
- Monitor carefully in patients with impaired hepatic or renal function
- Avoid concomitant use of an ACE inhibitor and angiotensin receptor blocker

Contraindications

Presart is contraindicated in patients with known hypersensitivity to this product or any of its components.

Overdose

The most likely manifestation of overdosage with Presart tablets would be hypotension, dizziness and tachycardia; bradycardia, increase in serum creatinine and acute renal failure could occur from parasympathetic (vagal) stimulation.

Drug Interactions

- NSAIDs: Increased risk of renal impairment and loss of antihypertensive effect
- Co-administration with aliskiren with Presart in patients with diabetes should be avoided

Use in Pregnancy & Lactation

Pregnancy Category D

Pregnancy: Telmisartan should not be used in second and third trimesters of pregnancy because it can cause fetal death. When pregnancy is detected, discontinue this combination as soon as possible.

Lactation: It is not known whether the Telmisartan is excreted in human milk, but Telmisartan is secreted at low concentration in the milk of lactating rats. Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Storage

Store below 30°C and dry place, away from light. Keep out of the reach of children.

Packing

Presart 20 Tablet: Each box contains 3 blister packs with each blister of 10 tablets.

Presart 40 Tablet: Each box contains 3 blister packs with each blister of 10 tablets.

Presart 80 Tablet: Each box contains 3 blister packs with each blister of 10 tablets.

Manufactured by:

 **GENERAL**
Pharmaceuticals Ltd.
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