Cozaar (losartan potassium) - Drug Summary

Merck Sharp & Dohme Corp.

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Cozaar
(losartan potassium)

BOXED WARNING

D/C when pregnancy is detected. Drugs that act directly on the renin-angiotensin system (RAS) can cause injury/death to the developing fetus.

THERAPEUTIC CLASS

Angiotensin II receptor blocker (ARB)

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Hypertension

Initial: 50mg qd
Usual Range: 25-100mg/day given qd or bid
May add a low dose diuretic if BP not controlled

Hypertension with Left Ventricular Hypertrophy

Reduction in Risk of Stroke:
Initial: 50mg qd
Titrate: Add HCTZ 12.5mg qd and/or increase losartan to 100mg qd, followed by an increase in HCTZ to 25mg qd based on BP response

This may not apply to black patients

Diabetic Nephropathy

Elevated SrCr/Proteinuria (Urinary Albumin to Creatinine Ratio ≥300mg/g) in Patients w/ Type 2 Diabetes and a History of HTN:
Initial: 50mg qd
Titrate: Increase to 100mg qd based on BP response

PEDIATRIC DOSAGE & INDICATIONS

Hypertension

≥6 Years:
Initial: 0.7mg/kg qd (up to 50mg total) administered as a tab or sus
Titrate: Adjust dose according to BP response
Max: 1.4mg/kg/day (or 100mg/day)

DOSING CONSIDERATIONS

Hepatic Impairment
Initial: 25mg qd

Other Important Considerations
Patients w/ Intravascular Volume Depletion:
Initial: 25mg qd

ADMINISTRATION

Oral route

Take w/ or w/o food

Preparation of Sus (for 200mL of a 2.5mg/mL sus)
1. Add 10mL of Purified Water USP to an 8 oz (240mL) amber polyethylene terephthalate (PET) bottle containing ten 50mg Cozaar tabs. Immediately shake for at least 2 min
2. Let the concentrate stand for 1 hr and then shake for 1 min to disperse the tab contents
3. Separately prepare a 50/50 volumetric mixture of Ora-Plus and Ora-Sweet SF
4. Add 190mL of the 50/50 Ora-Plus/Ora-Sweet SF mixture to the tab and water slurry in the PET bottle and shake for 1 min to disperse the ingredients
5. The sus should be refrigerated at 2-8°C (36-46°F) and can be stored for up to 4 weeks
6. Shake the sus prior to each use and return promptly to the refrigerator

HOW SUPPLIED

Tab: 25mg, 50mg*, 100mg *scored

CONTRAINDICATIONS

Coadministration with aliskiren in patients with diabetes.

WARNINGS/PRECAUTIONS

Symptomatic hypotension may occur in patients who are intravascularly volume-depleted (eg, treated with diuretics); correct volume depletion before therapy or start therapy at a lower dose. Hypersensitivity, including angioedema, reported. Consider a lower dose in patients with hepatic dysfunction. Changes in renal function reported. Oliguria and/or progressive azotemia and (rarely) acute renal failure and/or death may occur in patients whose renal function is dependent on the RAS (eg, severe CHF). Increases in SrCr or BUN reported in patients with unilateral/bilateral renal artery stenosis. Electrolyte imbalances reported with renal impairment, with or without DM. Hyperkalemia reported in type 2 diabetics with proteinuria. Not recommended in pediatric patients with GFR <30mL/min.

ADVERSE REACTIONS

Dizziness, cough, URI, diarrhea, asthenia/fatigue, chest pain, hypotension, hypoglycemia, anemia, back pain, UTI, cataract, diabetic vascular disease, cellulitis, influenza-like disease.

DRUG INTERACTIONS

See Contraindications. Increases in lithium levels and lithium toxicity reported; monitor lithium levels. Dual blockade of the RAS is associated with increased risks of hypotension, syncope, hyperkalemia, and changes in renal function (including acute renal failure); closely monitor BP, renal function, and electrolytes with concomitant agents that affect the RAS. Avoid with aliskiren in patients with renal impairment (GFR <60mL/min). May increase serum K^+ with K^+-sparing diuretics (eg, spironolactone, triamterene, amiloride), K^+ supplements, or salt substitutes containing K^+. NSAIDs, including selective COX-2 inhibitors, may attenuate antihypertensive effect and deteriorate renal function. Rifampin may decrease levels. Fluconazole may decrease levels of the active metabolite and increase levels of losartan.

PREGNANCY AND LACTATION

Category D, not for use in nursing.

MECHANISM OF ACTION

Angiotensin II receptor antagonist; blocks vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to AT_1 receptor in many tissues (eg, vascular smooth muscle, adrenal gland).

PHARMACOKINETICS

Absorption: Well-absorbed. Systemic bioavailability (33%); T_{max}=1 hr, 3-4 hrs (active metabolite). **Distribution:** V_d=34L, 12L (active metabolite); plasma protein binding (98.7%, 99.8% active metabolite). **Metabolism:** Liver via CYP2C9, 3A4; carboxylic acid (active metabolite). **Elimination:** Urine (35%, 4% unchanged, 6% active metabolite), feces (60%); $T_{1/2}$=2 hrs, 6-9 hrs (active metabolite).

ASSESSMENT

Assess for history of hypersensitivity, volume depletion, CHF, DM, unilateral or bilateral renal artery stenosis, hepatic/renal impairment, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of electrolyte imbalance, hypotension, hypersensitivity reactions, oliguria, azotemia, hepatic dysfunction, and other adverse reactions. Monitor BP, serum electrolytes, and renal function periodically.

PATIENT COUNSELING

Inform of pregnancy risks and discuss treatment options with women planning to become pregnant; instruct to report pregnancy to physician as soon as possible. Instruct not to use K^+ supplements or salt substitutes containing K^+ without consulting physician.

STORAGE

(Tab) 25°C (77°F); excursions permitted to 15-30°C (59-86°F). Protect from light. (Sus) 2-8°C (36-46°F) for up to 4 weeks.

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