

CaroSpir® (Spironolactone)



Consider this before Crushing/ Compounding

Spironolactone is a NIOSH listed product and is considered hazardous when crushed or compounded.

Crushed/compounded formulations can exhibit a wide variation in potency due to non-uniformity of compounded materials and are not tested for safety and efficacy.



Why CaroSpir®?

CaroSpir is an FDA-approved oral suspension of spironolactone that provides a stable, ready to use, and consistent liquid treatment option for adult patients who have difficulty swallowing, or who cannot swallow tablets, and are suffering from heart failure, edema caused by heart failure and cirrhosis, and hypertension.

Spironolactone Comparison Matrix	CaroSpir®	Crushed/ Compounded Spironolactone
FDA-approved	✓	✗
Tested to ensure potency and consistency in dosing	✓	✗
Tested and proven to ensure proper dosing for bioequivalence	✓	✗
Shelf life of 24-30 months*	✓	✗
Manufactured in GMP-compliant facility	✓	✗
Additional preparation required by pharmacist / patient / caregiver	✗	✓
Requires special safety protocols when crushed or compounded	✗	✓

*See specific shelf life information in Wholesaler section below.

CaroSpir Recommended Dosing & Administration

- Heart Failure: 20 mg once daily
- Hypertension: 20-70 mg daily
- Edema associated with hepatic Cirrhosis: 75 mg

CaroSpir is not therapeutically equivalent to Aldactone tablets. CaroSpir has been shown in studies to have 15 to 37% higher bioavailability than Aldactone tablets. For full dosing instructions, please see the full prescribing information provided in the pocket of this folder.

Available At Your Wholesaler: ORDER TODAY

- 10 x 5mL unit dose cups (24-month shelf life) | NDC: 46287-020-50
- 118mL bottle (24-month shelf life) | NDC: 46287-020-04
- 473mL bottle (30-month shelf life) | NDC: 46287-020-01

Important Safety Information

Contraindications

CAROSPIR is contraindicated for patients with the following conditions: Hyperkalemia, Addison's disease, Concomitant use of eplerenone.

See Next Page for More Important Safety Information

Patients may
pay as little as

\$0*

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Visit cmppharma.com/easypay for
more information

IMPORTANT SAFETY INFORMATION

Indications And Usage

CAROSPIR is an antagonist of aldosterone indicated for:

- the treatment of NYHA Class III-IV heart failure and reduced ejection fraction to increase survival, manage edema, and to reduce the need for hospitalization for heart failure
- use as an add-on therapy for the treatment of hypertension, to lower blood pressure in adult patients. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions
- the management of edema in adult cirrhotic patients when edema is not responsive to fluid and sodium restrictions

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- Addison's disease
- Concomitant use of eplerenone

Warnings And Precautions/ Adverse Reactions

CAROSPIR may cause the following conditions.

- Hyperkalemia
- Hypotension and Worsening Renal Function
- Electrolyte and Metabolic Abnormalities
- Gynecomastia
- Impaired neurological function/ coma in patients with hepatic impairment, cirrhosis and ascites

The most common adverse reaction (incidence > 5%) with CAROSPIR treatment is the increased occurrence of gynecomastia in men.

Talk to your healthcare provider about other possible side effects with CAROSPIR. To report SUSPECTED ADVERSE REACTIONS, contact CMP Pharma, INC. at 1-844-321-1443, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.

Drug Interactions

- Agents increasing serum potassium: Concomitant administration can lead to hyperkalemia.
- Lithium: Increased risk of lithium toxicity.
- NSAIDs: May reduce the diuretic, natriuretic and antihypertensive effect of CAROSPIR.
- Digoxin: CAROSPIR can interfere with radioimmunologic assays of digoxin. Spironolactone and its metabolites increase the apparent exposure to digoxin.
- Cholestyramine: Hyperkalemic metabolic acidosis has been reported with concomitant use.
- Acetylsalicylic Acid (ASA): ASA may reduce the efficacy of spironolactone.

Administration

CAROSPIR oral suspension, 25 mg/5 mL, is not therapeutically equivalent to tablet forms of spironolactone. Follow dosing instructions for CAROSPIR. In patients requiring a dose greater than 100 mg, use another formulation of spironolactone. Doses of CAROSPIR suspension greater than 100 mg may result in spironolactone concentrations higher than expected.

Please click link for full Important Safety Information and full Prescribing Information:

<https://carospir.com/prescribing-information/>



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