



Dosing Information



The First & Only FDA-approved
Spiro nolactone Oral Suspension

Exclusively from



CaroSpir[®]

The Formulation That's Easy To Prescribe

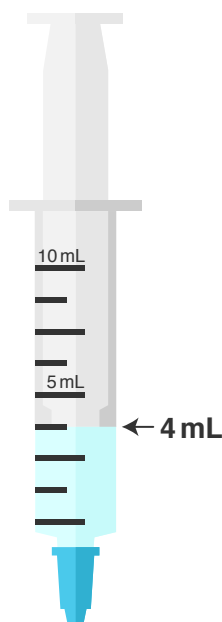
INDICATIONS

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
- The management of edema in adult cirrhotic patients when edema is not responsive to fluid and sodium restrictions

DOSING OVERVIEW

CAROSPIR is not therapeutically equivalent to Aldactone Tablets



HEART FAILURE

- Initiate treatment at 20 mg (4 mL) once daily

ESSENTIAL HYPERTENSION

- Initiate treatment at 20 mg (4 mL) to 75 mg (15 mL) daily in either single or divided doses

EDEMA ASSOCIATED WITH HEPATIC CIRRHOSIS:

- Initiate therapy in a hospital setting and titrate slowly
- The initial recommended daily dose is 75 mg (15 mL) in either single or divided doses

Available as an Oral Suspension,
25 mg/5 mL - Banana Flavor

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The Formulation That's Easy To Swallow



DOSING & ADMINISTRATION

CAROSPIR is not therapeutically equivalent to Aldactone Tablets

TREATMENT OF HEART FAILURE

- In patients with serum potassium ≤ 5.0 mEq/L and eGFR > 50 mL/min/1.73m², initiate treatment at 20 mg (4 mL) once daily.
 - Patients who tolerate 20 mg (4 mL) once daily may have their dosage increased to 37.5 mg (7.5 mL) once daily as clinically indicated.
 - Patients who develop hyperkalemia on 20 mg (4 mL) once daily may have their dosage reduced to 20 mg (4 mL) every other day.
- In patients with an eGFR between 30 and 50 mL/min/1.73m², consider initiating treatment at 10 mg (2 mL) because of the risk of hyperkalemia.

TREATMENT OF ESSENTIAL HYPERTENSION

- The recommended initial daily dose is 20 mg (4 mL) to 75 mg (15 mL) administered in either single or divided doses
- Dosage can be titrated at two-week intervals
- Doses > 75 mg/day generally do not provide additional reductions in blood pressure

TREATMENT OF EDEMA ASSOCIATED WITH HEPATIC CIRRHOSIS

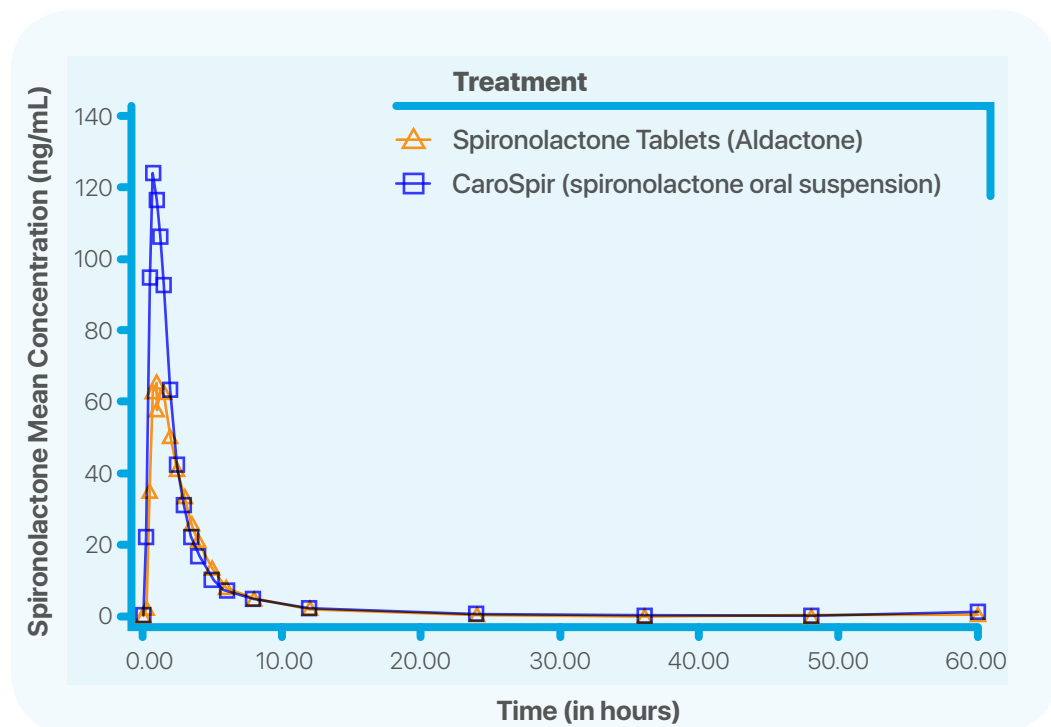
- Initiate therapy in a hospital setting and titrate slowly
- The recommended initial daily dose is 75 mg (15 mL) administered in either single or divided doses
- In patients requiring titration above 100 mg, use another formulation. When given as the sole agent for diuresis, administer for at least five days before increasing dose to obtain desired effect

CaroSpir oral suspension ensures a stable and consistent dose every time. The complexities and inconsistencies of compounding are no longer an issue



Important Pharmacokinetic Differences with CaroSpir

Spirolactone Time vs Mean Concentration Plot Linear Scale¹



An open label, randomized, two treatment, two period, two sequence, crossover, single dose, oral pharmacokinetic and comparative bioavailability study of spironolactone suspension 100 mg (20 mL of 25 mg/5 mL) with Aldactone® (spironolactone) tablets USP, 100 mg healthy adult subjects under the fasting condition.

CAROSPIR results in 15 to 37% higher serum concentration compared to Aldactone tablets. Information about the dose proportionality of spironolactone tablets is limited and, based on the results of studies comparing the suspension to tablets, doses of suspension higher than 100 mg might result in spironolactone concentrations that could be higher than expected. **In patients requiring a dose greater than 100 mg, use another formulation.**

Reference: 1. Data on file, CMP Pharma, Inc.: 2017

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

CAROSPIR is contraindicated for patients with the following conditions:

Hyperkalemia; 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
- Cholestyramine: Hyperkalemic metabolic acidosis has been reported with concomitant use
- Acetylsalicylic Acid (ASA): ASA may reduce the efficacy of spironolactone





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Spiroinolactone

(25mg/5ml Oral Suspension)

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Spiroinolactone Oral Suspension



Dosing Information



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