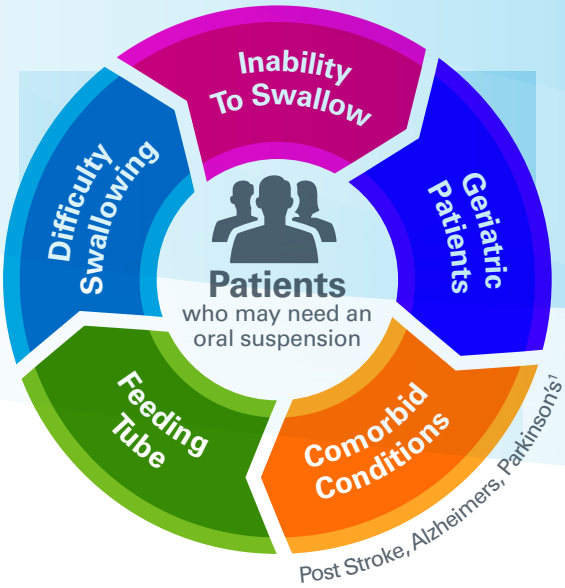
CaroSpir®
Spironolactone
(25mg/5ml Oral Suspension)

The First & Only FDA-approved Spironolactone Oral Suspension

Exclusively from

CMP PHARMA

The Need For
An Oral Suspension of
Spironolactone



– Prior to the approval of CaroSpir, spironolactone had only been available in a tablet dosage form

– Patients who suffer from CHF, edema caused from CHF & Cirrhosis, and hypertension with the symptoms listed in the graph may be appropriate patients

– Previously, these patients had to be prescribed a pharmacy compounded oral liquid form of spironolactone

Challenges of Compounded Formulations

Use of compounded formulations can result in serious risks in addition to being highly inconvenient for patients and caregivers.[2]

Potency

Compounded formulations can exhibit a wide variation in potency due to non-uniformity of compounded materials.[2] The dosing inconsistencies of compounded suspensions have long been a persistent challenge for pharmacists and patients.[2]

FDA Approval and GMP Compliance

Compounded formulations are not approved by FDA, are not manufactured in GMP facilities, and are not tested to assure potency, consistency and sterility/bioburden.[3]

Shelf Life

Compounded spironolactone can have a variable shelf life. The shelf life for compounded spironolactone can be as little as 14 days.[4]

References: 1. Takizawa, C., Gemmell, E., Kenworthy, J. et al. Dysphagia (2016) 31: 434. https://doi.org/10.1007/s00455-016-9695-9 **2.** Kindy K, Sun L, Crites A. Compounding pharmacies have been linked to deaths, illnesses for years. Washington Post. February 7, 2013. http://www.washingtonpost.com. Accessed October 2, 2017. **3.** Food Drug Administration Center for Drug Evaluation & Research (2016). Guidance for Industry: Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act (FDA Maryland). **4.** Food Drug Administration Center for Drug Evaluation & Research (2017). Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities (FDA Maryland). **5.** Data on file, CMP Pharma, Inc.: 2017

CaroSpir®

The Formulation That's Easy

Easy To Swallow

CaroSpir 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.

In clinical studies, other formulations of spironolactone have demonstrated significant mortality benefits and reduced the risk of hospitalization for cardiac causes.

Easy To Prescribe

CaroSpir addresses the complexities and inconsistencies of compounding by providing patients with a convenient and stable FDA-approved oral liquid suspension of spironolactone.

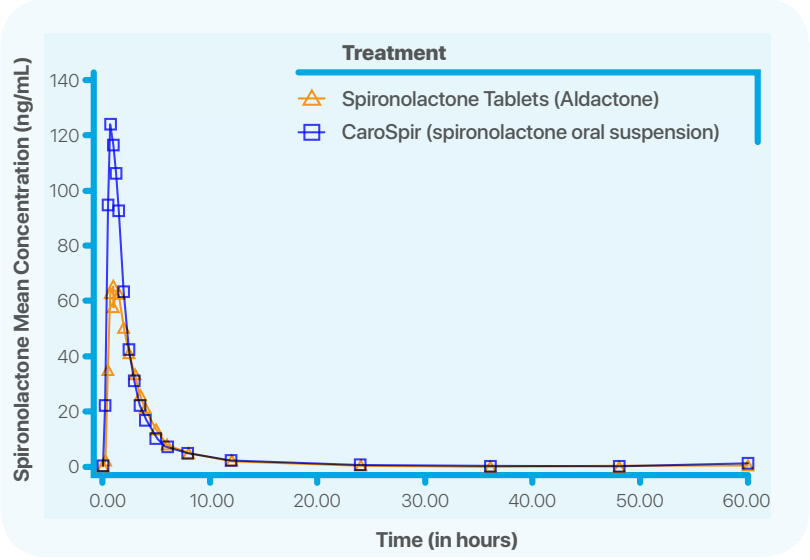
- CaroSpir oral suspension ensures a stable and consistent dose every time.
- CaroSpir is the first and only FDA-approved oral suspension of spironolactone, and is manufactured in CMP Pharma's high-quality GMP facility.
- 118 mL and 473 mL bottles of CaroSpir provide a shelf life of 24 months.

CaroSpir is not therapeutically equivalent to tablet formulations of spironolactone. For an equivalent dose, CaroSpir results in a 15 to 37% higher serum concentration compared to Aldactone (spironolactone) tablets.

Important Pharmacokinetic Differences with CaroSpir

Spironolactone Time vs Mean Concentration Plot Linear Scale[5]

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.

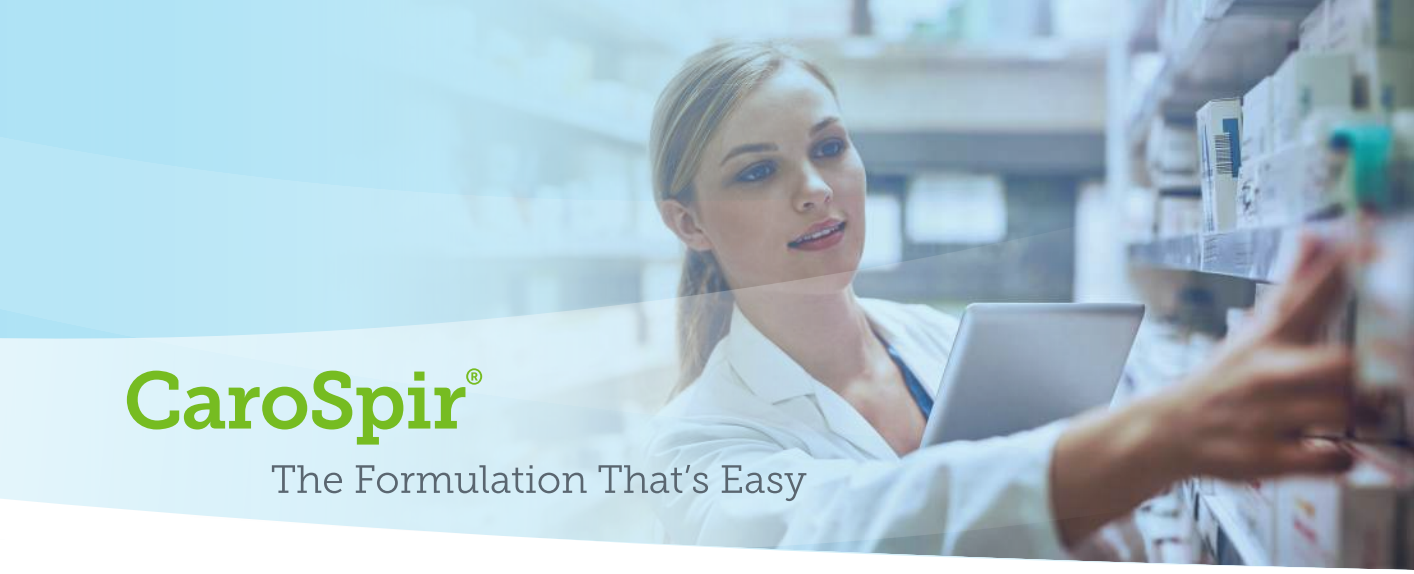


IMPORTANT SAFETY INFORMATION

Contraindications

CAROSPIR is contraindicated for patients with the following conditions:

- Hyperkalemia
- Addison's disease
- Concomitant use of eplerenone



CaroSpir®

The Formulation That's Easy

Easy To Fill

- CaroSpir oral suspension eliminates the need for additional preparation by the pharmacist or patient.
- 118 mL and 473 mL bottles of CaroSpir have a 24-month shelf life.
- Unlike all other spironolactone dosage forms on the market, CaroSpir does not have a black box warning.
- There are no special handling and storage requirements with CaroSpir.

Easy To Afford

We want every patient who needs CaroSpir to have access to it. That's why we've created the EasyPay Program so your patients can lower their out-of-pocket costs associated with a CaroSpir prescription.

EasyPay PROGRAM

Order your EasyPay Program co-pay cards for your patients by calling (844) 567-9503 or by visiting CaroSpir.com/EasyPay.

IMPORTANT SAFETY INFORMATION

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.

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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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.
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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.

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The First & Only FDA-approved Spironolactone Oral Suspension

- CaroSpir® is the first and only FDA-approved oral suspension of spironolactone.
- CaroSpir provides a stable, ready to use and consistent liquid treatment option for adult patients, including those who have difficulty swallowing, or who cannot swallow tablets.
- CaroSpir provides consistent bioavailability as demonstrated in studies.
- 118 mL and 473 mL bottles of CaroSpir provide a shelf life of 24 months
- CaroSpir does NOT carry a black box warning.

IMPORTANT SAFETY INFORMATION

Indications And Usage

CAROSPIR is an antagonist of aldosterone indicated for:

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