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

The First & Only FDA-Approved Spironolactone Oral Suspension

Why CaroSpir may be right for many of your Long-Term Care patients

As you know, many patients in long-term care facilities are dysphagic or have difficulty swallowing. Dysphagia can lead to a sharp decrease in adherence to treatment. In fact, 69% of older patients report missing or skipping medication doses because of discomfort due to difficulties swallowing.[1]

Dysphagic patients who suffer from chronic heart failure, edema caused by heart or liver failure, and/or hypertension, are often prescribed the potassium-sparing diuretic spironolactone, compounded into a liquid form.

Unfortunately, compounded formulations raise concerns about patient safety and efficacy, and they have come under increasing scrutiny from FDA, which recently released stricter guidance regarding compounding in general.

We're writing today to inform you that CaroSpir®, the first and only FDA-approved oral suspension of spironolactone, is available and should be used instead of compounded spironolactone for patients who may require a liquid dosage form.

CaroSpir provides a stable, ready to use, and consistent liquid treatment option of spironolactone for adult patients who have difficulty swallowing, or who cannot swallow tablets. As a liquid oral suspension, CaroSpir gives you the peace of mind of knowing that your patients are receiving a stable and consistent dose every time.

CaroSpir eliminates the need for additional preparation by either the pharmacist or patient. It comes in 118mL and 473mL bottles, which have a shelf life of 24 months, and is manufactured in CMP Pharma's high-quality GMP facility.

CaroSpir can be prescribed for patients to be picked up at local retail pharmacies and for patients in Long-Term Care facilities and hospitals. You can order CaroSpir through your normal wholesaler or feel free to contact us at (252) 753-7111 with any questions.

CaroSpir®

The Need For
An Oral Suspension Of
Spironolactone

The Challenges of Compounding

Compounded formulations are not FDA-approved, often have a limited shelf life, and frequently require additional preparation by the patient or caregiver. Compounded formulations may also exhibit a wide variation in potency[2], resulting in dosage inconsistencies. A 2006 survey by the FDA found that 12 of the 36 compounded products surveyed failed quality testing, with potency ranging from 68% up to 268% of the labeled dosage.[3]

As you may know, in January of this year the FDA issued stricter guidance about the use of compounded products that are "essentially copies of a commercially available drug product," recommending that drugs not be compounded if an FDA-approved alternative exists.[4] Scott Gottlieb, MD, FDA Commissioner, wrote that "compounded drugs should only be distributed to meet the needs of patients whose medical needs cannot be met by an FDA-approved drug."[5]

Spironolactone tablets appear on the NIOSH list of Hazardous Drugs in Healthcare Settings and requires special safety protocols when compounding. These protocols include double chemotherapy gloves, protective gowns, ventilated engineering control, and—if not compounded in a control device—eye/face and respiratory protection.[6] However, unlike all other spironolactone dosage forms on the market, CaroSpir does not have a black box warning and does not appear on the NIOSH list.

Is Your Facility USP-797 Compliant? Is It Ready For USP-800?

Spironolactone tablets are on the NIOSH List of Hazardous Drugs in Healthcare Settings, and are subject to legally enforceable regulatory guidelines such as USP-797 and the upcoming USP-800.

The pharmacy boards of several states have conducted inspections to ensure compliance with USP-797 standards in hospitals. It is expected that USP-800 will result in pharmacy inspections by both state boards and the FDA.

CaroSpir, a liquid oral suspension of spironolactone, does not appear on the NIOSH list and does not have a black box warning. The guidelines for handling hazardous drugs like spironolactone tablets do not apply to CaroSpir.

For additional safety information, please download the full prescribing information by visiting https://www.carospir.com/prescribing-information/

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	☑	⊗
24-month shelf life	☑	⊗
No black box warning	☑	⊗
Manufactured in GMP-compliant facility	☑	⊗
Has no special handling or storage requirements	☑	⊗
Additional preparation required by pharmacist / patient / caregiver	⊗	☑
On NIOSH List of Hazardous Drugs In Workplace Settings	⊗	☑
Requires special safety protocols when crushed or compounded	⊗	☑

CaroSpir is available to order via all wholesale channels.

For more information, visit CaroSpir.com or contact CMP Pharma at (252) 753-7111

CaroSpir is on a majority of formularies

You can also leverage our copay program, providing $75 off each prescription for appropriate patients.
Order EasyPay Program co-pay cards: (844) 567-9503 or CaroSpir.com/EasyPay

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

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.

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.

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.

1. US Food and Drug Administration. Pharmacy Compounding. 2006 Limited FDA Survey of Compounded Drug Products. 2012. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm204237.htm. Accessed Sept 2012.
2. Kindy K, Sun L, Crites A. Compounding pharmacies have been linked to deaths, illnesses for years. Washington Post. February 7, 2013.
3. US Food and Drug Administration. Pharmacy Compounding. 2006 Limited FDA Survey of Compounded Drug Products. 2012.
4. 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)
5. Food Drug Administration. 2018 Compounding Policy Priorities Plan. https://www.fda.gov/Drugs/ GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm592795.htm
6. NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016-161 (Supersedes 2014-138).