

CaroSpir® (spironolactone) – New drug approval

- On August 7, 2017, [CMP Pharma announced](#) the FDA approval of [CaroSpir \(spironolactone\)](#) oral suspension, indicated for:
 - The treatment of New York Heart Association Class III - IV heart failure and reduced ejection fraction to increase survival, manage edema, and to reduce the need for hospitalization for heart failure. CaroSpir is usually administered in conjunction with other heart failure therapies.
 - Use as an add-on therapy for the treatment of hypertension, to lower blood pressure in adult patients inadequately controlled on other agents.
 - The management of edema in adult cirrhotic patients when edema is not responsive to fluid and sodium restriction.
- Spironolactone is also generically available as an [oral tablet](#) in 25 mg, 50 mg, and 100 mg strengths and as a [combination product](#) with hydrochlorothiazide (HCTZ).
 - Spironolactone tablets have the same indications as the oral suspension and are also indicated for primary hyperaldosteronism, hypokalemia, and edematous conditions for patients with congestive heart failure and nephrotic syndrome. Consult spironolactone's drug label for specific indication information.
 - Similarly, spironolactone/HCTZ is indicated for essential hypertension and for edematous conditions in patients with congestive heart failure, cirrhosis of the liver, or nephrotic syndrome.
- The safety and efficacy of CaroSpir was based on clinical trials for another formulation of spironolactone.
- For an equivalent dose, CaroSpir results in 15 - 37% higher serum concentration compared to [Aldactone® \(spironolactone\)](#) tablets. Thus, CaroSpir is not therapeutically equivalent to spironolactone 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.
- CaroSpir is contraindicated in patients with hyperkalemia, Addison's disease, and with concomitant use of [eplerenone](#).
- Other warnings and precautions of CaroSpir include hypotension and worsening renal function, electrolyte and metabolic abnormalities, and gynecomastia.
- The most common adverse reaction (> 5%) with CaroSpir use was gynecomastia.
- The recommended dosage of CaroSpir is based on indication. In patients requiring a dose greater than 100 mg, use another formulation.
 - For the treatment of heart failure, doses are generally between 10 mg and 37.5 mg orally once daily based on serum potassium levels and renal function.
 - For the treatment of hypertension, daily doses are between 20 mg and 75 mg administered orally in either single or divided doses. Doses greater than 75 mg/day generally do not provide additional reductions in blood pressure.

- In patients with cirrhosis, initiate therapy in a hospital setting and titrate slowly. The recommended initial daily dose is 75 mg administered orally in either single or divided doses.
 - Consult CaroSpir's drug label for specific recommendations for dosing.
- CMP Pharma plans to launch CaroSpir during the fourth quarter of 2017. CaroSpir will be available as a 25 mg/5 mL oral suspension in 118 mL and 473 mL bottles.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at optum.com.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.