SPIRONOLACTONE- spironolactone tablet, film coated
Direct Rx

SPIRONOLACTONE

1.1 Heart Failure

Spironolactone tablets are indicated for treatment of NYHA Class III–IV heart failure and reduced ejection fraction to increase survival, manage edema, and reduce the need for hospitalization for heart failure.

Spironolactone tablets are usually administered in conjunction with other heart failure therapies.

1.2 Hypertension

Spironolactone tablets are indicated as add-on therapy for the treatment of hypertension, to lower blood pressure in patients who are not adequately controlled on other agents. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes.

Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals. For specific advice on goals and management, see published guidelines, such as those of the National High Blood Pressure Education Program's Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC).

Numerous antihypertensive drugs, from a variety of pharmacologic classes and with different mechanisms of action, have been shown in randomized controlled trials to reduce cardiovascular morbidity and mortality, and it can be concluded that it is blood pressure reduction, and not some other pharmacologic property of the drugs, that is largely responsible for those benefits. The largest and most consistent cardiovascular outcome benefit has been a reduction in the risk of stroke, but reductions in myocardial infarction and cardiovascular mortality also have been seen regularly.

Elevated systolic or diastolic pressure causes increased cardiovascular risk, and the absolute risk increase per mmHg is greater at higher blood pressures, so that even modest reductions of severe hypertension can provide substantial benefit. Relative risk reduction from blood pressure reduction is similar across populations with varying absolute risk, so the absolute benefit is greater in patients who are at higher risk independent of their hypertension (for example, patients with diabetes or hyperlipidemia), and such patients would be expected to benefit from more aggressive treatment to a lower blood pressure goal.

Some antihypertensive drugs have smaller blood pressure effects (as monotherapy) in black patients, and many antihypertensive drugs have additional approved indications and effects (e.g., on angina, heart failure, or diabetic kidney disease). These considerations may guide selection of therapy.

1.3 Edema Associated with Hepatic Cirrhosis or Nephrotic Syndrome

Spironolactone tablets are indicated for the management of edema in the following settings:

Cirrhosis of the liver when edema is not responsive to fluid and sodium restriction.
Nephrotic syndrome when treatment of the underlying disease, restriction of fluid and sodium intake, and the use of other diuretics produce an inadequate response.

Because it increases serum potassium, spironolactone tablets may be useful for treating edema when administration of other diuretics has caused hypokalemia.

1.4 Primary Hyperaldosteronism

Spironolactone tablets are indicated in the following settings:

Short-term preoperative treatment of patients with primary hyperaldosteronism.
Long-term maintenance therapy for patients with discrete aldosterone-producing adrenal adenomas who are not candidates for surgery.
Long-term maintenance therapy for patients with bilateral micro or macronodular adrenal hyperplasia (idiopathic hyperaldosteronism).

Spironolactone tablets USP 25 mg are light yellow to yellow colored, round, biconvex, film coated tablets with inscription “AD” on one side and plain on the other side having faint odour of peppermint.

Spironolactone tablets USP 50 mg are light orange to orange colored, oval, biconvex, film coated tablets with inscription “AE” on one side and breakline on the other side having faint odour of peppermint.

Spironolactone tablets USP 100 mg are light peach to peach colored, round, biconvex, film coated tablets with inscription “AF” on one side and breakline on the other side having faint odour of peppermint.

Spironolactone tablets are contraindicated in the patients with:

Hyperkalemia
Addison's disease
Concomitant use of eplerenone

Spironolactone oral tablets USP, for oral administration contain 25 mg, 50 mg, or 100 mg of the aldosterone antagonist spironolactone, 17-hydroxy-7α-mercapto-3-oxo-17α-pregn-4-ene-21-carboxylic acid γ-lactone acetate, which has the following structural formula:

Chemical Structure
Spironolactone is practically insoluble in water, soluble in alcohol, and freely soluble in benzene and in chloroform.

Inactive ingredients include lactose monohydrate, dibasic calcium phosphate, povidone, peppermint oil, purified talc, pregelatinised starch, colloidal anhydrous silica, magnesium stearate, hypromellose, polyethylene glycol 400, titanium dioxide and iron oxide yellow. In addition iron oxide red (50 mg and 100 mg tablets) is included in the film coating of specific strengths.

Spironolactone tablets USP 25 mg tablets are Light yellow to yellow colored, round,

biconvex, film coated tablets with inscription “AD” on one side and plain on the other side having faint odour of peppermint, supplied as:
NDC Number Size
16729-225-01 bottle of 100 with a child-resistant closure
16729-225-16 bottle of 500
16729-225-17 bottle of 1,000
16729-225-19 bottle of 2,500
Spironolactone tablets USP 50 mg tablets are Light orange to orange colored, oval, biconvex, film coated tablets with inscription “AE” on one side and breakline on the other side having faint odour of peppermint, supplied as:
NDC Number Size
16729-226-01 bottle of 100 with a child-resistant closure
16729-226-16 bottle of 500
Spironolactone tablets USP 100 mg tablets are Light peach to peach colored, round, biconvex, film coated tablets with inscription “AF” on one side and breakline on the other side having faint odour of peppermint, supplied as:
NDC Number Size
16729-227-01 bottle of 100 with a child-resistant closure
16729-227-16 bottle of 500
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature] Protect from light. Dispense in tight, Light-resistant containers.

SPIRONOLACTONE

spironolactone tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72189-329(NDC:16729-227)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SPIRONOLACTONE (UNII: 27O7W4T232) (SPIRONOLACTONE - UNII:27O7W4T232)	SPIRONOLACTONE	100 mg

Inactive Ingredients

Ingredient Name	Strength
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K25 (UNII: K0KQV10C35)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	orange ((Light peach to peach))	**Score**	2 pieces
Shape	ROUND	**Size**	11mm
Flavor	PEPPERMINT	**Imprint Code**	AF
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-329-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/28/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203512	02/28/2022	

Labeler - Direct Rx (079254320)

Registrant - Direct Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Direct Rx		079254320	repack(72189-329)