



<b>Brand Name</b> : AGOLACTONE-25	2021
<b>Generic Name</b> : Spironolactone-25 Tablets BP	
<b>Module 1</b> Administrative Information and Product Information	<b>Confidential</b>
<b>1.5</b> Product Information	

## 1.5 PRODUCT INFORMATION

### 1.5.1 Prescribing information (Summary of products characteristics)

#### SUMMARY PRODUCT CHARACTERISTICS

#### 1. Name of drug product:

AGOLACTONE-25 (Spironolactone-25 Tablets BP)

#### 2. Qualitative and Quantitative Composition:

Each uncoated tablet contains: Spironolactone-25 Tablets BP

#### 3. Pharmaceutical form: White, circular, flat uncoated tablets having breakline on one side and other side is plain of each tablet.

#### 4. Clinical particulars:

##### 4.1 Therapeutic Indications:

Spironolactone is used to treat high blood pressure and heart failure. Lowering high blood pressure helps prevent strokes, heart attacks, and kidney problems. It is also used to treat swelling (edema) caused by certain conditions (such as heart failure, liver disease) by removing excess fluid and improving symptoms such as breathing problems.

Spironolactone is also used to treat low potassium levels and conditions in which the body is making too much of a natural chemical (aldosterone).

Spironolactone is known as a "water pill" (potassium-sparing diuretic).

Spironolactone has also been used to treat excessive hair growth (hirsutism) in women with polycystic ovary disease.

Spironolactone is available under the following different brand names: Aldactone.



## 4.2 Posology and Method of Administration:

### Adult and Pediatric Dosage Forms and Strengths

#### Tablet

- 25 mg
- 50 mg
- 100 mg

#### Primary Hyperaldosteronism

As a diagnostic agent

Long test: 400 mg orally once/day for 3-4 weeks

Short test: 400 mg orally once/day for 4 days

Short-term perioperative treatment for adrenalectomy

- Initial: 100-400 mg orally once/day in preparation for surgery
- Maintenance: Lowest effective\_dose individualized for patient

Geriatric, Initial: 400 mg/day orally, THEN 100-300 mg/day

#### Edematous Conditions

- Cirrhosis of the liver with edema and/or ascites; nephrotic syndrome
- Initial: 100 mg once/day or divided every 12 hours for 5 days; if no clinical response,
- add second diuretic with more specific mechanism of action
- Range: 25-200 mg orally once/day or divided every 12 hours
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#### Edema, Pediatric (Off-label)

- CHF, cirrhosis, ascites, and nephrotic syndrome
- 1-3.3 mg/kg/day orally or divided every 12 hours; not to exceed 3.3 mg/kg/day or up to 100 mg/day

#### Essential Hypertension

- Adult, Initial: 25-100 mg orally once/day or divided every 12 hours for more than 2 weeks; adjust to patient response



- Pediatric: Among therapeutic options recommended by the National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents
- 1-3.3 mg/kg/day orally or divided every 12 hours; not to exceed 3.3 mg/kg/day or up to 100 mg/day

Congestive Heart Failure

Adult and Geriatric

- Indicated for NYHA class II/IV heart failure (provided CrCl greater than 30 mL/min and serum K less than 5 mEq/dL)
- Initial: 25 mg orally once/day
- Range: 12.5-25 mg/day orally; may increase to 50 mg/day if needed; if 25 mg/day not tolerated, reduce to 25 mg every other day
- ACC/AHA guidelines recommend aldosterone antagonist to be added to an ACEI or ARB, plus a beta-blocker; patient conditions may also require additional medications (e.g., loop diuretics, hydralazine, nitrates, digoxin)

#### **4.3 Contraindications:**

- Hypersensitivity
- Anuria
- Severe renal impairment, acute renal insufficiency
- Addison's disease or other conditions associated with hyperkalemia
- Co-administration with eplerenone

#### **4.4 Special Warnings and Precautions for Use :**

Spironolactone has been shown to be tumorigenic in chronic toxicity studies in rats; use only for specified indications.

This medication contains spironolactone. Do not take Aldactone if you are allergic to spironolactone or any ingredients contained in this drug.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately.



#### **4.5 Pregnancy and Lactation:**

- Use spironolactone with caution during pregnancy if benefits outweigh risks. Animal studies show risk and human studies are not available or neither animal nor human studies done.
- Metabolites of spironolactone are excreted into breast milk; discontinue breastfeeding or do not use spironolactone.

#### **6. Pharmaceutical particulars:**

##### **6.1 List of Excipients:**

Lactose	BP
Microcrystalline cellulose	BP
Maize starch	BP
Iso Propyl alcohol	BP
Poly vinyl pyrrolidone K-30	BP
Purified talc	BP
Magnesium stearate	BP
Sodium Starch Glycolate	BP
Cross Carmellose sodium	BP
Colloidal silicon dioxide	BP

##### **6.2 Incompatibilities:**

None Reported

##### **6.3 Shelf-Life:**

36 months from the date of manufacture.

##### **6.4 Special Precautions for Storage:**

Store in a cool, dry and dark place. Protect from light.

##### **6.5 Nature and Contents of Container:**

10 tablets packed in one blister. Such 10 blister packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.

##### **6.6 Special precautions for disposal:**

None reported.

#### **7. Registrant:**

**AGOG PHARMA LTD.**

Plot No. 33, Sector II,  
The Vasai Taluka Industrial  
Co-Op. Estate Ltd., Gauraipada,  
Vasai (E), Dist. Thane, India.

#### **8. Manufacturer:**



**AGOG Pharma Ltd.**



(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.  
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

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**9. Date of revision of the text :**