For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

AZILOW

1. Generic Name

Amiloride Hydrochloride Tablets I.P. 5 mg

2. Qualitative and quantitative Composition:

Each uncoated tablet contains:

Amiloride Hydrochloride I.P……. 5 mg
(As Anhydrous)
Excipients…….…. q.s.

The excipients used are Anhydrous Dibasic Calcium Phosphate, Lactose Monohydrate, Magnesium Stearate, Starch, Corn.

3. Dosage form and strength

Dosage form: Tablet

Strength: 5 mg

4. Clinical particulars

4.1. Therapeutic indication

It is indicated for the treatment of edema and hypertension.

4.2. Posology and method of administration

Posology

Adults

Amiloride Hydrochloride alone. The initial dosage is 10 mg (as a single dose or 5mg twice a day). The total daily dose should not exceed 20mg (4 tablets) per day. After diuresis has been achieved, the dosage may be reduced by 5mg increments to the least amount required.

Amiloride Hydrochloride with other diuretic therapy

When Amiloride is used with a diuretic which is given on an intermittent basis, it should be given at the same time as the diuretic.

Hypertension

Usually half Amiloride tablet (2.5mg) given once a day together with the usual antihypertensive dosage of the thiazide concurrently employed. If necessary, increase to 5mg (one Amiloride tablet) given once a day or in divided doses.

Elderly

The elderly are more susceptible to electrolyte imbalance and are more likely to experience hyperkalaemia since renal reserve may be reduced. The dosage should be carefully adjusted according to renal function, blood electrolytes and diuretic response.

Children:

The use of Amiloride in children under 18 years of age is not recommended as safety and efficacy have not been established.

Method of administration

For oral administration only.

4.3. Contraindications

Hypersensitivity to Amiloride or any of the excipients. Hyperkalaemia (plasma potassium over 5.5 mmol/l), other potassium conserving agents or potassium supplements; Addison's disease; anuria, acute renal failure, severe progressive renal disease, diabetic nephropathy; prior sensitivity to this product. Safety for use in children is not established.

4.4. Special warnings and precautions for use

Diabetes Mellitus:

To minimise the risk of hyperkalaemia in known or suspected diabetic patients, the status of renal function should be determined before initiating therapy. Amiloride hydrochloride should be discontinued for at least three days before a glucose tolerance test. In diabetic patients, insulin requirements may change; latent diabetes may become manifest during treatment.

Metabolic or Respiratory Acidosis:

Potassium-conserving therapy should be initiated only with caution in severely ill patients in whom metabolic or respiratory acidosis may occur, e.g. patients with cardiopulmonary disease or decompensated diabetes. Shifts in acid-base balance alter the balance of extracellular-intracellular. potassium and the development of acidosis may be associated with rapid increases in plasma potassium.

Hyperkalaemia:

This has been observed in patients receiving Amiloride Hydrochloride, alone or with other diuretics. These patients should be observed carefully for clinical, laboratory and ECG evidence of hyperkalaemia.

Some deaths have been reported in this group of patients, hyperkalaemia has been noted particularly in the elderly and in hospital patients with hepatic cirrhosis or cardiac oedema who have known renal involvement who were seriously ill or were undergoing vigorous diuretic therapy.

Neither potassium-conserving agents nor a diet rich in potassium should be used with Amiloride except in severe and/or refractory cases of hypokalaemia. If the combination is used, plasma potassium levels must be continuously monitored.

Impaired renal function:

Patients with increases in blood urea over 10 mmol/l, serum creatinine over 150 μmol/l, or with diabetes mellitus, should not receive Amiloride Hydrochloride without careful frequent monitoring of serum electrolytes and blood urea levels. In renal impairment, use of a potassium conserving agent may result in rapid development of hyperkalaemia.

Treatment of Hyperkalaemia

If hyperkalaemia occurs, Amiloride hydrochloride should be discontinued immediately and, if necessary, active measures taken to reduce the plasma potassium level.

Electrolyte imbalance and Reversible blood urea increases:

Hyponatraemia and hypochloraemia may occur when Amiloride Hydrochloride is used with other diuretics. Reversible increases in blood urea levels have been reported accompanying vigorous diuresis, especially when diuretics were used in seriously ill patients, such as those with hepatic cirrhosis with ascites and metabolic alkalosis, or those with resistant oedema.

Careful monitoring of serum electrolytes and blood urea levels should therefore be carried out when Amiloride is given with other diuretics to such patients.

Cirrhotic patients:

Oral diuretic therapy is more frequently accompanied by side effects in patients with hepatic cirrhosis with or without ascites because these patients are intolerant of acute shifts in electrolyte balance, and because they often already have hypokalaemia as a result of associated aldosteronism. In patients with pre-existing severe liver disease, hepatic encephalopathy manifested by tremors, confusion, coma, and increased jaundice, has been reported in association with diuretics, including Amiloride hydrochloride.

Paediatric patients:

It has not been established that amiloride can be safely used in children. Its use in children should therefore be discouraged.

Excipients

Lactose: Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5. Drugs interactions

- Lithium should not generally be given with diuretics because they reduce the renal clearance of lithium and add a high risk of lithium toxicity.
- When combined with thiazide diuretics, amiloride can act synergistically with chlorpropamide to increase the risk of hyponatraemia.
- When amiloride is administered concurrently with an angiotensin converting enzyme inhibitor, NSAIDs or ciclosporin the risk of hyperkalaemia may be increased. Therefore, if concomitant use of these agents is indicated because of demonstrated hypokalaemia, they should be used with caution and with frequent monitoring of serum potassium. In patients receiving amiloride with NSAIDs or ciclosporin the risk of nephrotoxicity may also be increased.
- Tacrolimus – risk of increased hyperkalaemia when potassium-sparing diuretics and aldosterone antagonist give with tacrolimus.
- Angiotensin II antagonists (losartan, valsartan) – enhanced hypotensive effects when diuretics given with Angiotensin II receptor antagonists.
- Beta Blockers (Sotalol) – enhanced hypotensive effect when diuretics given with betablockers, hypokalaemia caused by loop diuretics or thiazides and related diuretics increased risk of ventricular arrhythmias with Sotalol.
- Calcium channel blockers (Amlodipine, Diltiazem) – enhanced hypotensive effect when diuretics given with calcium channel blockers.
- Adrenergic neurone blockers – enhanced hypotensive effect when given with adrenergic neuron blockers.
- Alpha blockers (prazosin) enhanced hypotensive effect when diuretics given with Alpha blockers.
- Clonidine enhanced hypotensive effect when diuretics given with clonidine.
- Diazoxide enhanced hypotensive and hyperglycaemic effect when diuretics given with diazoxide.

- Methyldopa enhanced hypotensive effect when diuretics given with methyldopa.
- Moxonidine enhanced hypotensive effect when diuretics given with moxonidine.
- Vasodilator Antihypertensive (Hydralazine, Minoxidil, Sodium nitroprusside) enhanced hypotensive effect when diuretics given with hydralazine, minoxidil, sodium nitroprusside. Diuretics should be discontinued 2-3 days before starting treatment with an ACE inhibitor to reduce the risk of hypotension after the first dose.
- Antidepressants – increased risk of postural hypotension with tricyclics. Enhanced hypotensive effect with monoamine oxidase inhibitors (MAOIs)
- St John's Wort – avoid concomitant use; increased risk of postural hypotension when diuretics given with tricyclics.
- Carbamazepine – increased risk of hyponatremia
- Aldesleukin enhanced hypotensive effect when diuretics given with aldesleukin.
- General Anaesthetic – enhanced hypotensive effect when diuretics given with general anaesthetic.
- Antipsychotics – avoid concomitant use with antipsychotics –hypokalaemia caused by diuretics increases risk of ventricular arrhythmias with Amisulpride, enhanced hypotensive effect when diuretics given with phenothiazines, hypokalaemia caused by diuretics increases risk of ventricular arrhythmias with Pimozide.
- Anxiolytics and hypnotics – enhanced hypotensive effect when given with diuretics.
- Atomoxetine – hypokalaemia caused by diuretics increases risk of ventricular arrhythmias with Atomoxetine.
- Corticosteroids increased risk of hypokalaemia when diuretics and related diuretics given with corticosteroids.
- Levodopa enhanced hypotensive effect when diuretics given with levodopa.
- Moxisylyte enhanced hypotensive effect when diuretics given with moxisylyte
- Muscle relaxants enhanced hypotensive effect when diuretics given with baclofen or tizanidine.
- Nitrates enhanced hypotensive effect when diuretics given with nitrates.
- Oestrogen – diuretics effect of diuretics antagonised by oestrogen.
- Drospirenone – risk of hyperkalaemia when potassium sparing diuretics are given with drospirenone (monitor serum potassium during first cycle)
- Alprostadil enhanced hypotensive effect when diuretics given with alprostadil
- Potassium salts – increased risk of hyperkalaemia when potassium sparing diuretics given with potassium salts.
- Alcohol – enhanced hypotensive effect when diuretics given with alcohol.
- Trilostane – increased risk of hyperkalaemia
- Prostaglandin synthetase inhibitors - In some patients, administration of a prostaglandin synthetase inhibitor may reduce the diuretic, natriuretic and antihypertensive effect of diuretics. Concomitant administration of prostaglandin synthetase inhibitors and potassium-sparing agents, including amiloride HCl, may cause hyperkalaemia and renal

failure, especially in elderly patients. Therefore, when amiloride HCl and prostaglandin synthetase inhibitors are used simultaneously, renal function and serum potassium should be carefully monitored.

4.6. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy

Because clinical experience is limited, Amiloride is not recommended for use during pregnancy. The potential benefits of the drug must be weighed against possible hazards to a foetus if it is administered to women of childbearing age. It has been found that the routine use of diuretics in otherwise healthy pregnant women with or without mild oedema is not indicated because they may be associated with hypovolaemia, increased blood viscosity, and decreased placental perfusion. Foetal and neonatal jaundice, foetal bone marrow depression and thrombocytopenia have also been described.

Breast-feeding

It is not known whether Amiloride is excreted in human milk. Because many drugs are excreted by this route and because there is a risk that it might take this route of excretion and that it might then cause serious side effects in the breast feeding infant, the mother should either stop breast feeding or stop taking the drug. The decision depends on the importance of the drug to the mother.

4.7. Effects on ability to drive and use machines

Reduced mental alertness may impair ability to drive or operate dangerous machinery.

4.8. Undesirable effects

The following adverse reactions may occur during the use of Amiloride. The side effects are listed below by system/organ class and frequency. Frequencies are defined as follows:

Very common (≥1/10 patients)

Common (≥1/100, <1/10 patients)

Uncommon (≥1/1,000, <1/100 patients)

Rare (≥1/10,000, <1/1,000 patients)

Very rarely (<1/10,000 patients)

Not known (cannot be determined with available data).

Amiloride Hydrochloride is normally well tolerated, although minor side effects are reported relatively frequently. Except for hyperkalaemia, significant side effects are infrequent. Nausea, anorexia, abdominal pain, flatulence and mild skin rashes have been reported and are probably related to Amiloride: but other side effects are generally associated with diuresis, or with the underlying disease being treated.

Blood and lymphatic system disorders

Not known: Aplastic anaemia, neutropenia.

Nervous system disorders

Not known: Tremors, encephalopathy.

Eye disorders

Not known: Increased eye pressure.

Balance organ and ear disorders

Not known: Tinnitus.

Cardiac disorders[1]

Not known: Palpitations.

Respiratory, thoracic, and mediastinal disorders

Not known: Coughing.

Gastrointestinal disorders

Not known: Activation of probably pre-existing peptic ulcer, dyspepsia, dry mouth.

Liver and bile disorders

Not known: Hepatic function abnormalities, jaundice.

Skin and subcutaneous tissue disorders

Not known: Hair loss

Kidney and urinary tract disorders

Not known: Polyuria, pollakiuria, bladder spasms.

Reproductive system and breast disorders

Not known: Decreased libido.

General disorders and administration site disorders

Not known: Pain in neck and shoulder, pain in extremities.

Description of selected side effects

[1] *Cardiac disorder*: One patient with partial heart block suffered total heart block.

Reactions in which no causal relationship could be established were activation of probable pre-existing peptic ulcer, aplastic anaemia, neutropenia, and abnormal liver function tests. In a few cirrhotic patients, jaundice associated with the underlying disease had deepened, but the drug relationship is uncertain.

Reporting of adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Report suspected adverse reactions via any point of contact available at www.torrentpharma.com.

4.9. Overdose

No data are available; and it is not known whether the drug is dialysable. The most likely signs and symptoms are dehydration and electrolyte imbalance which should be treated by established procedures. Therapy should be discontinued, and the patient observed closely. No specific antidote is available. If ingestion is recent, emesis should be induced, or gastric lavage should be performed.

Treatment is symptomatic and supportive. If hyperkalaemia occurs, active measures should be taken to reduce plasma potassium levels.

The plasma half-life of amiloride is about six hours.

5. Pharmacological properties

5.1. Mechanism of Action

Amiloride interferes with transport of electrolytes in the nephron. As electrogenic sodium transport is interrupted the electrical potential across the tubular epithelium fails. The reduction of elimination of this potential, which is one of the driving forces of secretion of potassium, is probably the basis of the potassium-sparing effect.

5.2. Pharmacodynamic properties

Amiloride prevents, in the distal tubule and in the transition to the cortical collecting duct, the reabsorption of sodium and, especially as a result, the secretion of potassium and hydrogen ions to the urine.

The potassium-retaining action of amiloride occurs within the first 2 hours after administration and reaches a maximum about 6-10 hours after oral administration. The effective efficacy of the drug persists for at least 12 hours and the antikaliuretic action is noticeable for 24 hours.

5.3. Pharmacokinetic properties

Absorption

Amiloride is absorbed from the gastrointestinal tract by approximately 50% after oral administration. Concomitant food intake reduces absorption by approximately 30%.

Distribution

Peak serum concentrations are achieved about 3-4 hours after administration by mouth.

Metabolism

Amiloride does not bind to proteins and the volume of distribution is approximately 5 l/kg.

Elimination

Amiloride is not metabolised and is excreted by ± 50% in the urine and by ± 40% in the faeces. The plasma half-life is approximately 6-9 hours.

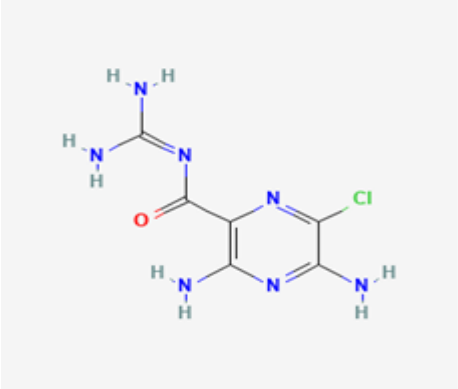
6. Nonclinical properties

6.1. Animal Toxicology or Pharmacology

None stated.

7. Description

Amiloride is 3,5-diamino-6-chloro-N-(diaminomethylidene)pyrazine-2-carboxamide. The empiric formula of $C_6H_8ClN_7O$ and its molecular weight is 229.63 g/mol. Its structural formula is:



AZILOW is yellow coloured, round shape, plain on both side uncoated tablets. The excipients used are Anhydrous Dibasic Calcium Phosphate, Lactose Monohydrate, Magnesium Stearate, Starch, Corn.

8. Pharmaceutical particulars

8.1. Incompatibilities

Not applicable

8.2. Shelf-life

Do not use later than date of expiry.

8.3. Packaging information

AZILOW is packed in 10 Tablets.

8.4. Storage and handing instructions

Store in a cool, dry place, protected from light.

Keep all medicine out of reach of children.

9. Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies
- Have kidney or liver problems
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illness
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

10. Details of manufacturer

Lucent Biotech Limited (Unit-II)

K-165/3, Nalhera Anantpur

Puhana-Iqbalpur Road, Roorkee,

Distt. Haridwar Uttarakhand, INDIA.

11. Details of permission or licence number with date

Mfg Lic No. 43/UA/2016 issued on 17.10.2025.

12. Date of revision

NA

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/AZILOW 5 mg/JAN-2026/01/PI