

# Aldocort

Fludrocortisone Acetate

## Presentation

Aldocort tablet: Each tablet contains Fludrocortisone Acetate USP 0.10 mg.

## Description

Fludrocortisone acetate is a synthetic adrenocortical steroid possessing very potent mineralocorticoid properties and high glucocorticoid activity.

## Indications

Used for oral mineralocorticoid replacement therapy in:

- Primary and secondary adrenocortical insufficiency in Addison's disease
- Salt losing adrenogenital syndrome
- Postural hypotension

## Dosage and Administration

- Primary and secondary Adrenocortical Insufficiency in Addison's disease: Usual dose may range from 0.2 mg 3 times weekly to 0.2 mg daily. If hypertension occurs, reduce dosage to 0.05 mg daily. Administer concomitantly with Cortisone or hydrocortisone.
- Salt-Losing Adrenogenital Syndrome: 0.1 to 0.2 mg/day.
- Postural Hypotension: 0.1-0.4 mg daily to diabetic patients with postural hypotension; 0.05-0.2 mg daily to patients with postural hypotension secondary to Levodopa therapy.

## Adverse Reactions

Most adverse reactions are caused by the drug's mineralocorticoid activity (retention of sodium and water) include erythema, purpura, vertigo, pancreatitis, increased intraocular pressure, muscular weakness, hypertension, edema, cardiac enlargement, congestive heart failure, steroid myopathy, peptic ulcer, osteoporosis, convulsions, menstrual irregularities, potassium loss, hypokalemic alkalosis, allergic and anaphylactic reaction etc.

When Fludrocortisone is used in the small dosages recommended, side effects are not usually a problem; however the above mentioned unwanted effects should be kept in mind, particularly when Fludrocortisone is used over a prolonged period of time or in conjunction with cortisone or a similar glucocorticoid.

## Precautions

Because of its marked effect on sodium retention, the use of Fludrocortisone in the treatment of conditions other than those indicated herein is not advised. Fludrocortisone should be used with caution in patients suffering from different infections (like tuberculosis, measles, chicken pox, herpes zoster or threadworm infestation), congestive cardiac failure, hypertension, renal insufficiency, osteoporosis, drug-induced secondary adrenocortical insufficiency, peptic ulcer, intestinal anastomosis and ulcerative colitis.

## Use in Pregnancy and Lactation

**Pregnancy:** Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. Fludrocortisone is only recommended for use during pregnancy when there are no alternatives and benefit outweighs risk.

**Lactation:** There are no data on the excretion of fludrocortisone into human milk. However, corticosteroids (systemic therapy) are distributed into breast milk and could cause growth suppression and/or other adverse effects in nursing infants. The manufacturer recommends that caution be used when administering Fludrocortisone to nursing women.

## Contraindication

In case of adrenal insufficiency, no absolute contraindications are applicable. In the treatment of non-endocrine diseases where pharmacological dose are more likely to be used, the contraindications to be considered carefully. Relative contraindications include: systemic fungal infection, hypersensitivity to Fludrocortisone, diabetic mellitus, osteoporosis and acute infection.

## Drug Interactions

Interactions can occur with following drugs: Amphotericin B, potassium-depleting diuretics, anticholinesterases, anticoagulants, antidiabetics. Antitubercular drugs, cyclosporine, digitalis glycosides, oral contraceptives and ketoconazole .

## Overdose

Overdose is unlikely; however, treatment of overdose is by supportive and symptomatic therapy.

## Storage

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

## Commercial Pack

Aldocort Tablet: Each box contains 3 blister strips of 10 tablets.