

# Rozy™

## Drospirenone USP and Estradiol USP

### Composition

**ROZY™** Tablet: Each Tablet contains Drospirenone USP 0.25 mg & Estradiol USP 0.50 mg as Estradiol Hemihydrate.

**ROZY™ DS** Tablet: Each Tablet contains Drospirenone USP 0.50 mg & Estradiol USP 1.00 mg as Estradiol Hemihydrate.

### Pharmacology

Estradiol is the principal intracellular human Estrogen and is substantially more potent than its metabolites, Estrone and Estriol, at the receptor level. The primary source of Estrogen in normally cycling adult women is the ovarian follicle. Estrogens act through binding to nuclear receptors in Estrogen-responsive tissues. Circulating Estrogens modulate the pituitary secretion of the gonadotropins, Luteinizing Hormone (LH), and Follicle Stimulating Hormone (FSH), through a negative feedback mechanism. Estrogens act to reduce the elevated concentrations of these gonadotropins seen in postmenopausal women.

Drospirenone is a synthetic progestin and spironolactone analog with antiminerlocorticoid activity. In animals and in vitro, Drospirenone has antiandrogenic activity, but no glucocorticoid, antigluco-corticoid, Estrogenic, or androgenic activity. Progestins counter Estrogenic effects by decreasing the number of nuclear Estradiol receptors and suppressing epithelial DNA synthesis in endometrial tissue.

### Indication

Moderate to Severe Vasomotor Symptoms due to Menopause in women who have a uterus

Moderate to Severe Symptoms of Vulvar and Vaginal Atrophy due to Menopause in women who have a uterus

### Dosage & Administration

One tablet taken by mouth once daily. Treatment is continuous, which means that the next pack follows immediately without a break. In case a tablet is forgotten, it should be taken as soon as possible. If more than 24 hours have elapsed, the missed tablet should not be taken. Depending upon the improvement of said indication, treatment will continue.

### Contraindication

- Undiagnosed abnormal genital bleeding
- Known, suspected, or history of cancer of the breast
- Known or suspected estrogen-dependent neoplasia
- Active DVT (Deep vein thrombosis), PE (Pulmonary embolism), or a history of these conditions
- Active arterial thromboembolic disease (for example, stroke and MI), or history of these conditions
- Renal impairment
- Known liver impairment or disease
- Adrenal insufficiency
- Known or suspected pregnancy
- Known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders
- Known anaphylactic reaction, angioedema, or hypersensitivity to the ingredients of the product

### Drug interactions:

Inducers and inhibitors of CYP3A4 may affect estrogen drug metabolism and decrease or increase the estrogen plasma concentration  
Serum potassium concentration may increase in women taking drospirenone with other drugs that have the potential to increase potassium

### Warnings and precautions

- Do not use with conditions that predispose to hyperkalemia
- Estrogens increase the risk of gallbladder disease
- Discontinue estrogen if severe hypercalcemia, loss of vision, severe hypertriglyceridemia or cholestatic jaundice occurs
- Monitor thyroid function in women on thyroid replacement therapy

### Adverse reactions

The most common adverse reactions that occurred in at least 1 percent of users in clinical trials are gastrointestinal and abdominal pain, female genital tract bleeding, breast pain and discomfort, and headache.

### Overdose

Overdosage of estrogen plus progestin may cause nausea and vomiting, breast tenderness, abdominal pain, drowsiness and fatigue, and withdrawal bleeding may occur in women.

### Use in pregnancy & Lactation

Should not be used during pregnancy. It should not be used during lactation too.

### Storage

Store below 30°C and keep protected from. Keep out of reach of children.

### How Supplied

**ROZY™** Tablet: Each box contains 30 tablets in Alu-Alu blister pack.

**ROZY™ DS** Tablet: Each box contains 15 tablets in Alu-Alu blister pack

Manufactured by

