# Information For the User Rosuvastatin 10 mg + Ezetimibe 10 mg tablet

## Rosumore EZ 10 Tablet

Brand Name: Rosumore EZ 10 Tablet

## **Composition:**

Each film-coated tablet contains:

Rosuvastatin Calcium IP equivalent to Rosuvastatin 10 mg

Ezetimibe IP 10 mg

#### **Therapeutic Indication:**

Indicated for the treatment of primary hypercholesterolemia, mixed dyslipidemia, and familial hypercholesterolemia

Helps reduce elevated total cholesterol, LDL-C, apolipoprotein B, and triglycerides Increases HDL-C levels and reduces the risk of cardiovascular events

#### **Mechanism of Action:**

Rosuvastatin is an HMG-CoA reductase inhibitor that inhibits hepatic cholesterol synthesis, leading to upregulation of LDL receptors and increased clearance of LDL-C from plasma Ezetimibe inhibits the absorption of cholesterol at the brush border of the small intestine, reducing cholesterol delivery to the liver

The combination provides complementary lipid-lowering effects for enhanced reduction of LDL-C and other atherogenic lipids

#### **Dosage & Administration:**

Usual adult dose: one tablet once daily or as directed by the physician

Can be taken with or without food

Preferably taken at the same time each day

Dose may be adjusted based on lipid response, renal function, and tolerability

#### **Contraindications:**

Hypersensitivity to Rosuvastatin, Ezetimibe, or any component of the formulation Active liver disease or unexplained persistent elevations of hepatic transaminases Pregnancy and lactation
Severe renal impairment

## **Warnings & Precautions:**

Monitor liver function tests before initiating therapy and periodically thereafter Use with caution in patients with a history of myopathy or risk factors for rhabdomyolysis Discontinue immediately if pregnancy occurs

Avoid concomitant use of other hepatotoxic drugs unless prescribed

#### **Side Effects:**

Common: headache, myalgia, abdominal pain, nausea

Less common: constipation, dizziness, rash

Rare: rhabdomyolysis, elevated liver enzymes, hypersensitivity reactions

## **Storage:**

Store in a cool, dry, and dark place below 25°C Protect from moisture and light Keep out of reach of children

## Packaging:

Rosumore EZ 10 Tablet is available in blister or strip packs

### **Schedule:**

Schedule H Prescription Drug – To be sold by retail on the prescription of a registered medical practitioner only

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

TM: Trademark Applied for