Brand Name: Rozva-20

Generic Name: Rosuvastatin

Dosage Forms: Oral Tablet

Strength of Rozva-20:

1. **Rosuvastatin 20 mg Tab**

Rosuvastatin in Rozva-20 is a statin medication primarily used to lower cholesterol levels in the blood, particularly to reduce the risk of cardiovascular diseases such as heart attacks and strokes.

Mechanism of Action (MOA): Rozva-20

1. **HMG-CoA Reductase Inhibition:**
    - **Rosuvastatin works by inhibiting the enzyme HMG-CoA reductase (3-hydroxy-3-methyl-glutaryl-CoA reductase).**
    - **This enzyme is a key catalyst in the cholesterol biosynthesis pathway in the liver. It converts HMG-CoA to mevalonate, which is a precursor for cholesterol production.**
2. **Reduced Cholesterol Synthesis:**
    - **By inhibiting HMG-CoA reductase, rosuvastatin reduces the liver's ability to produce cholesterol.**
    - **As a result, the liver upregulates LDL (low-density lipoprotein) receptors on its surface, which leads to increased clearance of LDL cholesterol from the bloodstream.**
3. **Increase in LDL Receptor Activity:**
    - **The increase in LDL receptors enhances the liver's ability to remove circulating LDL cholesterol (often referred to as "bad" cholesterol).**
    - **This results in a decrease in total cholesterol, LDL cholesterol, and triglyceride levels.**
4. **Increase in HDL Cholesterol:**
    - **Rosuvastatin may also lead to a modest increase in HDL cholesterol (high-density lipoprotein, or "good" cholesterol), which helps to remove cholesterol from the bloodstream.**

Overall Effect: Rozva-20

By lowering LDL cholesterol and total cholesterol levels while increasing HDL cholesterol, rosuvastatin helps to reduce the risk of atherosclerosis, heart attacks, and stroke. It is effective in managing hyperlipidemia (high cholesterol) and preventing cardiovascular diseases.

1. Indications of Rozva-20:

Rosuvastatin is prescribed for the following conditions:

- **Hyperlipidemia**: To reduce elevated total cholesterol, low-density lipoprotein cholesterol (LDL-C), and triglycerides in adults and children ≥10 years of age.
- **Primary Hypercholesterolemia**: For the treatment of primary hypercholesterolemia (type IIa) and mixed dyslipidemia (type IIb).
- **Prevention of Cardiovascular Events**: To reduce the risk of cardiovascular events, including heart attacks, strokes, and the need for revascularization procedures in patients with a history of cardiovascular disease or at risk of developing cardiovascular disease.
- **Familial Hypercholesterolemia**: For the treatment of adults and children ≥10 years old with heterozygous familial hypercholesterolemia.
- **Hypertriglyceridemia**: To reduce elevated triglyceride levels.

2. Dosage and Administration of Rozva-20:

- **Initial Dose**:
    - For most patients, the recommended starting dose is **10 mg** once daily, which can be adjusted based on therapeutic goals.
    - For patients with significant risk factors for cardiovascular disease, starting at **20 mg** daily may be considered.
- **Dosing Range**:
    - **10 mg** to **40 mg** once daily, based on individual patient needs and goals.
    - The maximum recommended dose is **40 mg** once daily.
- **Administration**:
    - Rosuvastatin should be taken **once daily** with or without food.
    - Doses can be adjusted every 2 to 4 weeks based on lipid response and tolerance.
- **Renal Impairment**:
    - For patients with mild-to-moderate renal impairment, a starting dose of **5 mg** may be considered, and the maximum dose should not exceed **20 mg** daily.
- **Liver Impairment**:
    - Use caution in patients with liver disease. For patients with hepatic impairment, avoid starting therapy with high doses.

3. Contraindications

- **Hypersensitivity**: Contraindicated in patients with a known hypersensitivity to Rosuvastatin or any component of the formulation.
- **Active Liver Disease**: Contraindicated in patients with active liver disease or unexplained persistent elevations in liver transaminases.
- **Pregnancy**: Rosuvastatin is contraindicated during pregnancy due to the potential risk to the fetus. Women who are pregnant or planning to become pregnant should not take Rosuvastatin.

- **Breastfeeding**: Contraindicated for use during breastfeeding because of the risk to the infant.
- **Severe Renal Impairment**: Contraindicated in patients with severe renal impairment (creatinine clearance < 30 mL/min).
- **Concomitant Use with Strong CYP3A4 Inhibitors**: Use caution with drugs that strongly inhibit CYP3A4 (e.g., certain antifungals, antibiotics, and antivirals).

4. Warnings and Precautions

- **Muscle Pain and Weakness**: Statins, including Rosuvastatin, have been associated with muscle pain, tenderness, and weakness (myopathy). Rarely, this can lead to rhabdomyolysis, a serious condition that can cause kidney damage.
- **Liver Function**: Monitor liver function tests periodically. If significant liver enzyme elevation occurs, discontinuation of Rosuvastatin should be considered.
- **Renal Function**: Use Rosuvastatin with caution in patients with renal impairment. The dose should be adjusted based on renal function, especially in those with moderate renal impairment.
- **Diabetes Risk**: Statins may increase the risk of developing type 2 diabetes in some patients. Risk factors for diabetes should be considered when prescribing Rosuvastatin.
- **Cognitive Impairment**: Some patients may experience memory loss, forgetfulness, and confusion. If such symptoms occur, consideration of discontinuing the medication should be made.
- **Interactions with Other Medications**: Careful monitoring is needed when used with other drugs that affect the CYP450 enzyme system or alter renal function.

5. Adverse Reactions

- **Common Side Effects**:
    - Headache
    - Muscle pain (myalgia)
    - Abdominal pain
    - Nausea
    - Weakness
    - Constipation
- **Serious Side Effects**:
    - **Rhabdomyolysis** (muscle breakdown that can lead to kidney damage)
    - **Liver toxicity** (increased liver enzymes)
    - **Severe allergic reactions**, such as anaphylaxis or angioedema
    - **Kidney impairment** (particularly with high doses or in patients with pre-existing renal disease)

6. Drug Interactions

- **CYP450 Inhibitors**: Drugs that inhibit the CYP3A4 enzyme (e.g., ketoconazole, ritonavir, cyclosporine) may increase Rosuvastatin plasma concentrations, leading to an increased risk of muscle-related side effects.
- **Antacids**: Antacids containing aluminium or magnesium can reduce the absorption of Rosuvastatin, so they should be taken at least 2 hours apart.
- **Warfarin**: Use with caution when Coad ministering with warfarin, as Rosuvastatin may increase the anticoagulant effect.
- **Fibrates**: The use of fibrates with Rosuvastatin may increase the risk of myopathy and rhabdomyolysis, especially in patients with renal impairment.
- **Other Lipid-Lowering Agents**: Concomitant use of Rosuvastatin with other lipid-lowering agents such as ezetimibe may require dose adjustments to minimize the risk of side effects.

7. Use in Specific Populations

- **Pregnancy**: Rosuvastatin is **contraindicated** during pregnancy. Statins can cause serious birth defects. If a woman becomes pregnant while taking Rosuvastatin, the medication should be discontinued immediately.
- **Lactation**: Rosuvastatin is **contraindicated** during breastfeeding. It is unknown if Rosuvastatin is excreted in human milk, but because of the potential for serious adverse reactions in infants, breastfeeding should be avoided.
- **Pediatrics**: The safety and effectiveness of Rosuvastatin in children under 10 years of age have not been established. For children ≥10 years, the dosing regimen is adjusted based on lipid levels and individual health conditions.
- **Geriatrics**: In elderly patients, Rosuvastatin should be used with caution. Renal and liver function should be monitored regularly. Lower starting doses may be appropriate.

8. Overdose

- **Symptoms of Overdose**: Overdose may cause symptoms such as muscle pain, weakness, or tenderness, and gastrointestinal issues like nausea or abdominal pain.
- **Management of Overdose**: There is no specific antidote for Rosuvastatin overdose. Treatment should be supportive, and the patient should be monitored for symptoms of rhabdomyolysis, liver dysfunction, or kidney damage.

9. Pharmacology

- **Mechanism of Action**: Rosuvastatin is an **HMG-CoA reductase inhibitor** (statin) that reduces cholesterol synthesis in the liver by inhibiting the enzyme HMG-CoA reductase. This leads to a decrease in LDL-C levels and an increase in HDL-C levels, thereby lowering overall cardiovascular risk.
- **Absorption**: Rosuvastatin is rapidly absorbed after oral administration, with peak plasma concentrations occurring within 3 to 5 hours.
- **Metabolism**: It is primarily metabolized in the liver by the CYP2C9 enzyme, with minimal involvement of CYP3A4.

- **Half-Life**: The half-life of Rosuvastatin is approximately 19 hours, allowing for once-daily dosing.

10. Storage

- Store at room temperature (15°C to 30°C) in a dry place.
- Keep out of the reach of children.

Packaging:

- Each Alu-Alu strip of Rozva-20 contains 10 tablets.
- Each box of Rozva-20 contains 10 strips.

Note: This summary provides general prescribing information.