ROSLAREN-AC

Rosuvastatin 10 mg/20 mg, Aspirin 75 mg & Clopidogrel 75 mg Capsules

Background:

The burden of ACS in India is one of the highest in the world.

Acute coronary syndrome (ACS) includes acute myocardial infarction (MI) and unstable angina.

Following an ACS, the chances of recurrent coronary events are higher than that of a stable coronary disease. The major contributing factors relating to ACS are dyslipidemia and atherosclerosis of coronary arteries.

A study called CREATE, involving 20,937 patients, suggested that Indian patients with ACS have a higher rate of STEMI than patients in the developed countries.

Description:
Rosalren-AC is the combination of Rosuvastatin, Aspirin and Clopidogrel used in the primary prevention and secondary prevention of Coronary Artery Diseases. There are two strength available of Roslaren-AC.

Roslaren AC-10/75:
Rosuvastatin 10 mg, Aspirin 75 mg and Clopidogrel 75 mg

Roslaren AC-20/75:
Rosuvastatin 20 mg, Aspirin 75 mg and Clopidogrel 75 mg

Indication:
Roslaren-AC is indicated in primary as well as secondary prevention of atherothrombosis, Acute coronary syndrome, non-ST-elevation myocardial infarction, stroke and angina.

Mechanism of Action:
Rosuvastatin is a lipid lowering agent that competitively inhibits hydroxymethylglutaryl-coenzyme A (HMG-CoA) reductase. HMG-CoA reductase catalyzes the conversion of HMG-CoA to mevalonic acid, the rate-limiting step in cholesterol biosynthesis. Thus Rosuvastatin reduces the formation of cholesterol. Aspirin inhibits cyclooxygenase enzyme, which results in the inhibition of the biosynthesis of prostaglandins. Thus, Aspirin inhibits platelet aggregation and is used in the prevention of arterial and venous thrombosis.
Clopidogrel acts by inhibiting the adenosine diphosphate receptor on platelet cell membranes in order to inhibit platelet activation and aggregation.

Dosage and Administration :
The recommended daily dose of ROSLAREN-AC is one capsule a day or as directed by the physician.

Presentation-
Roslaren-AC 10/75 and Roslaren-AC 20/75 are available as a strip of 10 Capsules.

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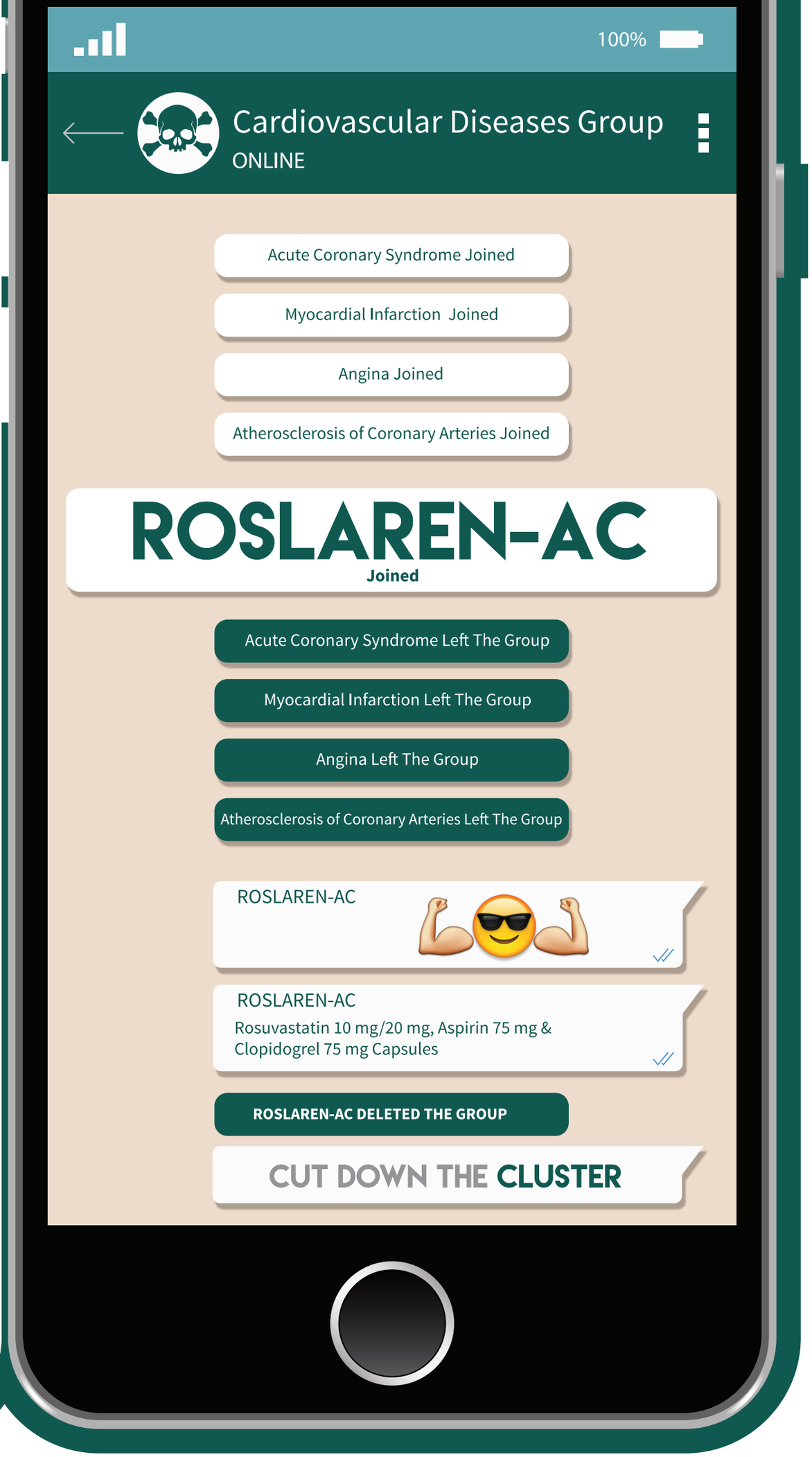

Introduction:-

- Cardiovascular diseases (CVD) are considered as major cause of death and disability in both developed as well as developing countries.
- The highest rate of CVD includes acute coronary syndrome (ACS), myocardial infarction (MI), angina and stroke.
- The major contributing factors relating to ACS are dyslipidemia and atherosclerosis of coronary arteries. Various factors characterizing dyslipidemias are diabetes mellitus, chronic renal or liver insufficiency or failure, hypothyroidism and use of other drugs (ex. glucocorticoids, β-blockers, etc).
- Atherosclerosis is a complex inflammatory-fibroprotective response with early lesions of sub-endothelial accumulation of cholesterol engorged macrophages.
- This deposition results in plaque formation that narrows artery, leading to reduction in thickness of fibrous cap of lesion that decreases blood flow and other proteolytic enzymes.
- Further it may cause an irreversible muscle injury leading to heart attack or MI, where sudden stoppage of blood supply and thrombus formation or complete occlusion of arteries occurs.
- If the blockage is only partial and the blood flow to the heart is decreased, it causes angina. It may not cause lasting damage to the heart muscle, but it is a warning sign that a person could develop a major heart attack.
- The main cause of angina is improper contractivity of the heart muscle and coronary artery disease, due to atherosclerosis of the arteries which feed the heart. A stroke results when the blood supply to the brain is suddenly cut off due to block or burst of blood vessel in the brain or neck.

Rationale of Rosuvastatin, Aspirin & Clopidogrel Combination therapy:-

- The standard therapy considered for patients undergoing percutaneous coronary intervention or ACS is dual antiplatelet therapy with aspirin and clopidogrel.
- Both interfere with platelet activation in complementary via distinct pathways. Both possess potent protective effect against adverse vascular events and as a combination they exhibit even stronger antiplatelet activity translating into superior antithrombotic protection in coronary, cerebral or peripheral arterial disease.
- Various studies have shown that co-administration of aspirin with statins has a synergistic action in the secondary prevention of atherothrombosis.
- Moreover, the scientific community and results from various studies have proven that lipophilic statins such as Rosuvastatin does not interfere with the antiplatelet effect of clopidogrel in patients with cardiovascular disease.

Clinical outcomes of combined use of Clopidogrel and Statin vs. Clopidogrel alone in the presence of aspirin in a range of ACS patients

Total 15,693 patients across 14 countries admitted with non-ST-segment elevation MI or unstable angina

Four groups

- **Group 1:** Aspirin alone (n= 3342)
- **Group 2:** Aspirin + Clopidogrel (n = 866)
- **Group 3:** Aspirin + Statin (n=3071)
- **Group 4:** Aspirin + Clopidogrel + Statin (n=1728)

Post discharge to 6 months outcomes -

Outcome	Group 1	Group 2	Group 3	Group 4
	(n=3342)	(n=866)	(n=3071)	(n=1728)
Rehospitalization (%)	17	21	19	22
Stroke (%)	1.3	1.0	1.0	0.7
Revascularization (%)	9.5	13	13	15
Death (%)	5.8	4.4	3.6	2.1

- Among the Clopidogrel administered patients (2nd and 4th group), 2nd group patients were comparatively older with less probabilities of prior MI or revascularization.
- In-hospital, cardiac catheterization and revascularization rates were alike among 2nd and 4th group.
- Kaplan–Meier analysis showed significant decrease in 6 months mortality rate in 4th group which remained lower compared to 2nd group.
- The study shows a significantly lower mortality rate among patients who were discharged on aspirin, clopidogrel, and a statin when compared with those receiving aspirin and clopidogrel even when the differences in baseline variables and the bias in treatment allocation were accounted for. In fact, the use of triple therapy (aspirin, clopidogrel, and statins) was associated with the lowest mortality among the four groups of patients.
- The study confirmed that when Clopidogrel and statin is used along with aspirin, no significant drug interaction was encountered.

“ The combination of Clopidogrel with a statin has synergistic effects on the clinical outcomes in patients with non-ST-segment elevation ACS. ”

Reference: Eur Heart J. 2005 Jun;26(11):1063-9. Epub 2005 Feb 16