Creston®

Rosuvastatin Film Coated Tablet

DESCRIPTION

Creston® is a preparation of Rosuvastatin. Rosuvastatin is a selective, potent and competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A to mevalonate, a precursor of cholesterol. Triglycerides (TG) and cholesterol in the liver are incorporated, with apolipoprotein B (ApoB), into very low density lipoprotein (VLDL) and released into the plasma for delivery to peripheral tissues. VLDL particles are TG-rich. Cholesterol-rich low density lipoprotein (LDL) is formed from VLDL and is cleared primarily through the high affinity LDL receptor in the liver. Rosuvastatin produces its lipid-modifying effects in two ways; it increases the number of hepatic LDL receptors on the cell-surface, enhancing uptake and catabolism of LDL and it inhibits the hepatic synthesis of VLDL, thereby reducing the total number of VLDL and LDL particles.

INDICATIONS

Creston® should be used as an adjunct to diet when the response to diet and exercise is inadequate.

Prevention of Major Cardiovascular events

In adult patients without documented history of cardiovascular or cerebrovascular events, but with at least two conventional risk factors for cardiovascular disease, Rosuvastatin is indicated to:

- Reduce the risk of nonfatal myocardial infarction
- Reduce the risk of nonfatal stroke
- Reduce the risk of coronary artery revascularization

Hypercholesterolaemia

Creston® is indicated to:

- Reduce elevated LDL-C, Total Cholesterol, triglycerides and to increase HDLcholesterol in patients with primary hypercholesterolaemia (heterozygous familial and non familial) and mixed dyslipidaemia (Fredrickson Types IIa and IIb). Rosuvastatin also lowers ApoB, nonHDL-C, VLDL-C, VLDL-TG, the LDL-C/HDL-C, total C/HDL-C, nonHDL-C/HDL-C, ApoB/ApoA-I ratios and increases ApoA-I in these populations.
- Treat isolated hypertriglyceridaemia (Fredrickson Type IV hyperlipidaemia).
- Reduce Total Cholesterol and LDL-C in patients with homozygous familial hypercholesterolaemia, as an adjunct to diet and other lipid lowering treatments (eg. LDL apheresis) or alone if such treatments are unavailable.

Prior to initiating therapy with Rosuvastatin, secondary causes of hypercholesterolaemia (e.g. poorly controlled diabetes mellitus, hypothyroidism, nephrotic syndrome, dysproteinaemias, obstructive liver disease, other drug therapy, alcoholism) should be identified and treated.

DOSAGE AND ADMINISTRATION

Creston® may be given at any time of the day, with or without food.

- **Prevention of major cardiovascular events:** A dose of 20 mg once daily has been found to reduce the risk of major cardiovascular events.
- **Hypercholesterolemia:** The usual dose range is 5 - 40 mg orally once a day. The dosage of Rosuvastatin should be individualized according to the goal of therapy and patient response. The majority of patients are controlled at the start dose. However, if necessary, dose adjustment can be made at 2 to 4 week intervals. A dose of 40 mg once a day should only be considered in patients who are still at high cardiovascular risk after their response to a dose of 20 mg once a day is assessed. It is recommended that the 40 mg dose is used only in patients in whom regular follow-up is planned. A dose of 40 mg must not be exceeded in any patient taking Rosuvastatin.
- **Primary hypercholesterolaemia (including heterozygous familial hypercholesterolaemia), mixed dyslipidaemia and isolated hypertriglyceridaemia:** The usual start dose is 5 mg once a day. For patients with severe hypercholesterolaemia (including heterozygous familial hypercholesterolaemia), a start dose of 20 mg may be considered.
- **Homozygous familial hypercholesterolaemia:** For patients with homozygous familial hypercholesterolaemia a start dose of 20 mg once a day is recommended.

CONTRAINDICATIONS

- Patients with hypersensitivity to Rosuvastatin.
- Patients with active liver disease or persistent, unexplained elevations in transaminases.
- During pregnancy, while breast-feeding and in women of child-bearing potential not using appropriate contraceptive measures.
- Patients with pre-disposing factors for myopathy/rhabdomyolysis.

USE IN PREGNANCY AND LACTATION

The safety of Rosuvastatin during pregnancy and whilst breast feeding has not been established. Women of child-bearing potential should use appropriate contraceptive measures.

SIDE EFFECTS

- Headache • Myalgia • Asthenia • Constipation • Dizziness
- Nausea • Abdominal pain

PRECAUTIONS

- Liver function tests should be performed before initiation of treatment and periodically thereafter. Patients who develop increased transaminase levels should be monitored until the abnormalities have resolved. Should an increase in ALT or AST of >3 times ULN persist, reduction of dose or withdrawal of Rosuvastatin is recommended.
- As with other HMG-CoA reductase inhibitors, Creston® should be used with caution in patients who consume excessive quantities of alcohol and/or have a history of liver disease.
- As with other HMG-CoA reductase inhibitors, increases in HbA1c and serum glucose levels have been observed in patients treated with Rosuvastatin. An increased frequency of diabetes has been reported with rosuvastatin in patients with risk factors for diabetes.
- As with other HMG-CoA reductase inhibitors, effects on skeletal muscle eg. uncomplicated myalgia, myopathy and, rarely, rhabdomyolysis, have been reported in patients treated with Rosuvastatin. As with other HMG-CoA reductase inhibitors, the reported rate for rhabdomyolysis in post-marketing use is higher at the highest marketed dose.

PHARMACEUTICAL PRECAUTION

Store in a cool (below 30°C temperature) & dry place, away from light. Keep out of reach of children.

PACKAGING

Creston® 5 Tablet : Box containing 3 strips of 10 tablets each. Each film coated tablet contains Rosuvastatin Calcium INN equivalent to Rosuvastatin 5 mg.

SK+F

Manufactured by

ESKAYEF BANGLADESH LIMITED

GAZIPUR, BANGLADESH