Roviros Tablets

(Rosuvastatin Tablets USP)

COMPOSITION:
Each film coated tablet contains:
Rosuvastatin Calcium equivalent to Rosuvastatin ... 5mg, 10mg and 20mg.
[USP Specs.]

MECHANISM OF ACTION: 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. High density lipoprotein (HDL), which contains ApoA-1 is involved, amongst other things, in transport of cholesterol from tissues back to the liver (reverse cholesterol transport).

PHARMACOKINETICS: Rosuvastatin is incompletely absorbed from the gastro-intestinal tract, with a bioavailability of about 20%. Peak plasma concentrations are achieved about 5 hours after an oral dose. It is taken up extensively by the liver, its primary site of action, and undergoes limited metabolism, mainly by the cytochrome P450 isoenzyme CYP2C9. It is about 90% bound to plasma proteins. The plasma elimination half life of Rosuvastatin is about 19 hours. Approximately 90% of an oral dose of Rosuvastatin is excreted in the feces, including absorbed and non-absorbed drug, and the remainder is excreted in the urine; about 5% of a dose is excreted unchanged in urine.

INDICATIONS: Hyperlipidemia and Mixed Dyslipidemia: Roviros (Rosuvastatin) is indicated as adjunctive therapy to diet to reduce elevated Total-C, LDL-C, ApoB, nonHDL-C, and triglycerides and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia. Lipid altering agents should be used in addition to a diet restricted in saturated fat and cholesterol when response to diet and non-pharmacological interventions alone has been inadequate.
Hypertriglyceridemia: Roviros (Rosuvastatin) is indicated as adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia.
Homozygous Familial Hypercholesterolemia: Roviros (Rosuvastatin) is indicated as adjunctive therapy to other lipid lowering treatments (e.g., LDL apheresis) or alone if such treatments are unavailable to reduce LDL-C, Total-C, and ApoB in adult patients with homozygous familial hypercholesterolemia.
Slowing of the Progression of Atherosclerosis: Roviros (Rosuvastatin) is indicated as adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels. Prior to initiating therapy with Rosuvastatin, secondary causes of hypercholesterolemia (e.g. poorly controlled diabetes mellitus, hypothyroidism, nephrotic syndrome, dysproteinaemias, obstructive liver disease, other drug therapy) should be identified and treated.

DOSAGE AND ADMINISTRATION:
General Dosing Information: The dose range for **Roviros** is 5 to 40mg orally once daily. **Roviros** can be administered as a single dose at any time of day, with or without food. When initiating **Roviros** therapy or switching from another HMG-CoA reductase inhibitor therapy, the appropriate **Roviros** starting dose should first be utilized, and only then titrated according to the patient's response and individualized goal of therapy. The 40mg dose of **Roviros** should be used only for those patients who have not achieved their LDL-C goal utilizing the 20mg dose.
Hyperlipidemia, Mixed Dyslipidemia, Hypertriglyceridemia and Slowing of the Progression of Atherosclerosis: The recommended starting dose of **Roviros** is 10mg once daily. For patients with marked hyperlipidemia (LDL-C > 190mg/dl) and aggressive lipid targets, a 20mg starting dose may be considered. After initiation or upon titration of **Roviros**, lipid levels should be analyzed within 2 to 4 weeks and the dosage adjusted accordingly.
Homozygous Familial Hypercholesterolemia: The recommended starting dose of **Roviros** is 20mg once daily. Response to therapy should be estimated from pre-apheresis LDL-C levels.
Use in children: Experience is limited to a small number of children (aged 8 years and above) with homozygous familial hypercholesterolemia.
Use in the elderly: The usual dose range applies.
Dosage in patients with renal insufficiency: The usual dose range applies in patients with mild to moderate renal impairment.

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For patients with severe renal impairment the dose of **Roviros** should be started at 5mg once daily and not exceed 10mg once daily.

CONTRA-INDICATION: ROVIROS is contra-indicated in patients with hypersensitivity to any component of this product. Rosuvastatin is contra-indicated in patients with active liver disease or persistent, unexplained elevations in transaminases. **Pregnancy and Lactation: Roviros** is contra-indicated in pregnancy and lactation.

INTERACTIONS: The most serious consequence of drug interactions with statins is the development of myopathy or rhabdomyolysis. Drugs that can cause myopathy when given alone increase the risk of myopathy with all statins; these drugs include fibric acid derivatives (fibrates or gemfibrozil), and nicotinic acid. The risk of myopathy is also increased by drugs that increase the plasma levels of statins by inhibiting their metabolism. Rosuvastatin under goes limited metabolism, principally by the cytochrome P450 isoenzyme CYP2C9, and may not have the same interactions with enzyme inhibitors as simvastatin. However, increased Rosuvastatin plasma concentrations have been reported with cyclosporine and, to a lesser extent, with gemfibrozil, and such combinations should be avoided. If they must be given together, lower doses of Rosuvastatin should be used. Statins may also have effects on other drugs. Bleeding and increases in prothrombin time have been reported in patients taking with coumarin anticoagulants.

WARNINGS AND PRECAUTIONS: Statins should not be given to patients with active liver disease or unexplained persistently raised serum aminotransferase concentrations. They should be avoided during pregnancy since there is a possibility that they could interfere with fetal sterol synthesis; there have been a few reports of congenital abnormalities associated with statins. They should be discontinued if marked or persistent increases in serum aminotransferase or creatine phosphokinase concentrations occur, or if myopathy is diagnosed. Rosuvastatin should be used with caution in patients with servere renal impairment.

ADVERSE EFFECTS: The commonest adverse effects of therapy with statins are gastrointestinal disturbances. Other adverse effects reported include headache, skin rashes, dizziness, blurred vision, insomnia, and dysgeusia. Reversible increases in serum aminotransferase concentrations may occur and liver function should be assessed before treatment is initiated and then monitored periodically until one year after the last elevation in dose. Hepatitis and pancreatitis have been reported. Hypersensitivity reactions including anaphylaxis and angioedema have also occurred. Myopathy, characterized by myalgia and muscle weakness and associated with increased creatine phosphokinase concentrations, has been reported, especially in patients taking statins concurrently with cyclosporin, fibric acid derivatives, or nicotinic acid, Rarely, rhabdomyolysis with acute renal failure may develop.

INSTRUCTIONS: Store below 30°C. Protect from light & moisture. Keep out of the reach of children.

PRESENTATION:
Roviros (Rosuvastatin) 5mg tablets is available in a Alu Alu blister pack of 10'sx1.
Roviros (Rosuvastatin) 10mg tablets is available in a Alu Alu blister pack of 10'sx1.
Roviros (Rosuvastatin) 20mg tablets is available in a Alu Alu blister pack of 10'sx1.

روّیروز گولیاں

(روزیوواسٹیٹن)

اجزائے ترکیب: ہر فلم کوٹڈ گولی میں روزیوواسٹیٹن کیلشیم بطور عامل روزیوواسٹیٹن ۵ ملی گرام، ۱۰ ملی گرام اور ۲۰ ملی گرام موجود ہے۔

علامات: یہ دوا مختلف اقسام کے کولیسٹرول کو کم کرنے کے لیے استعمال کی جاتی ہے۔

خوراک: مختلف اقسام کے کولیسٹرول کو کم کرنے کے لیے روزیوواسٹیٹن ۵ ملی گرام سے ۴۰ ملی گرام تجویز کی جاتی ہے۔

روّیروز دن میں ایک مرتبہ کسی بھی وقت کھانے کے ساتھ یا کھانے کے بغیر لی جاسکتی ہے۔ حاملہ خواتین اور دودھ پلانے والی مائیں روّیروز کا استعمال نہ کریں۔

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

طریقہ فراہمی: روّیروز ۵ ملی گرام گولیاں 1 x 10's کے ایلو ایلو بلسٹر پیک میں دستیاب ہیں۔
روّیروز ۱۰ ملی گرام گولیاں 1 x 10's کے ایلو ایلو بلسٹر پیک میں دستیاب ہیں۔
روّیروز ۲۰ ملی گرام گولیاں 1 x 10's کے ایلو ایلو بلسٹر پیک میں دستیاب ہیں۔

Manufactured by:
NABIQASIM INDUSTRIES (PVT) LTD.
17/24, Korangi Industrial Area, Karachi-Pakistan.
PHARMA
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