Rosuvastatin Tablets BP 10 mg

Module 1- Administrative information and prescribing information

1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Enclosed

Rosuvastatin Tablets BP 10 mg

Summary Product Characteristics (SPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Rosuvastatin Tablets BP 10 mg

1.1 Strength

Each film coated tablet contains:
Rosuvastatin calcium BP
Eq. to Rosuvastatin 10 mg
Excipients q.s.
Color: Approved Color Used

1.2 Pharmaceutical form

Film coated Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. No	Ingredients	Spec	Qty/tab (mg)	(%) Over-ages	Input Quantity per tablet (m2:)	Category
Dry Mixing						
1.	Rosuvastatin calcium eq. to Rosuvastatin	BP	10.400	-	10.400	API
2.	Lactose	BP	110.240	-	110.240	Binder
3.	phosphate calcium	BP	[illegible]		[illegible]	Diluent
4.	Micro crystalline cellulose	BP	111.03	-	111.03	Diluent
5.	Cross povidone	BP	12.000	-	12.000	Disintegrant
Wet granulation						
6.	Maize Starch	BP	10.000	-	10.000	Disintegrant
7.	Purified water	BP	Q.S.	-	Q.S.	Solvent
8.	P.V.P.K-30 (Povidone)	BP	3.000	-	3.000	Diluent.
9.	Sodium methyl paraben	BP	0.300	-	0.300	Preservativ
10.	Sodium propyl paraben	BP	0.030	-	0.030	Preservativ.
Blending						
11.	Cross povidone	BP	13.000	-	13.000	Disintegrant
12.	Colloidal Anhydrous Silica (Aerosil)	BP	6.000	-	6.000	Viscosity Agent

ZOBITOR 10 (Rosuvastatin Tablets BP 10 mg)

Sr. No	Ingredients	Spec	Qty/tab (mg)	(%) Over-ages	Input Quantity per tablet (mg)	Category
13.	Purified Talc	BP	6.000	-	6.000	lubricant
Lubrication						
14.	Magnesium Stearate	BP	3.000	-	3.000	lubricant
Total Weight of Uncoated Tablets					**300.0 mg**	
Coating						
15.	Colour Titanium dioxide film coat	In-House	10.000	-	10.000	Film Forming agent
16.	Isopropyl alcohol#	BP	Q.S.	-	Q.S.	solvent
17.	Dichloromethane#	BP	Q.S.	-	Q.S.	Coating agent
Total Weight of coated Tablets					**310.0 mg**	

BP: British Pharmacopeia

Quantity is not calculated in total weight of tablet due to evaporated during process.

3. PHARMACEUTICAL FORM

Brown colour, round shape, Biconvex, film coated Tablet, plain on both side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of hypercholesterolaemia

Adults, adolescents and children aged 6 years or older with primary hypercho- lesterolaemia (type Ila including heterozygous familial hypercholesterolaemia) or mixed dyslipidaemia (type Ilb) as an adjunct to diet when response to diet and other non- pharmacological treatments (e.g. exercise, weight reduction) is inadequate. Adults,
adolescents and children aged 6 years or older with homozygous familial hypercholest- erolaemia as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) or if such treatments are not appropriate.

Prevention of Cardiovascular Events

Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event, as an adjunct to correction ofother risk factors.

4.2 Posology and method of administration

Posology

Before treatment initiation the patient should be placed on a standard cholesterol- lowering diet that should continue during treatment. The dose should be individualized according to the goal oftherapy and patient response, using current consensus guidelines. Rosuvastatin Tablets may be given at any time ofday, with or without food.

Treatment of hypercholesterolaemia

The recommended start dose is 5 or 10 mg orally once daily in both statin naive and patients switched from another HMG CoA reductase inhibitor. The choice of start dose should take into account the individual patient's cholesterol level and future cardiovascular risk as well as the potential risk for adverse reactions. A dose adjustment to the next dose level can be made after 4 weeks, if necessary. In light ofthe increased reporting rate ofadverse reactions with the 40 mg dose compared to lower doses, a final titration to the maximum dose of 40 mg should only be considered in patients with severe hypercholesterolaemia at high cardiovascular risk (in particular those with familial hypercholesterolaemia), who do not achieve their treatment goal on 20 mg, and in whom routine follow-up will be performed. Specialist supervision is recommended when the 40 mg dose is initiated.
Prevention ofcardiovascular events
In the cardiovascular events risk reduction study, the dose used was 20 mg daily. Paediatric population
Paediatric use should only be carried out by specialists.

Method of Administration
Oral use

4.3 Contraindications

Rosuvastatin Tablets is contraindicated:

- In patients with hypersensitivity to rosuvastatin or to any ofthe excipients.
- In patients with active liver disease including unexplained, persistent elevations ofserum transaminases and any serum transaminase elevation exceeding 3 times the upper limit of normal (ULN).
- In patients with severe renal impairment (creatinine clearance <30 ml/min).
- In patients with myopathy.
- In patients receiving concomitant ciclosporin
- During pregnancy and lactation and in women of childbearing potential not usmg appropriate contraceptive measures.
  The 40 mg dose is contraindicated in patients with pre-disposing factors for myopathy/rhabdomyolysis. Such factors include:
- Moderate renal impairment (creatinine clearance < 60 ml/min)
- Hypothyroidism
- Personal or family history ofhereditary muscular disorders
- Previous history of muscular toxicity with another HMG-CoA reductase inhibitor or fibrate
- Alcohol abuse
- Situations where an increase in plasma levels may occur
- Asian patients
- Concomitant use offibrates.

4.4 Special warnings and precautions for use

Renal Effects

Proteinuria, detected by dipstick testing and mostly tubular in origin, has been observed in patients treated with higher doses ofRosuvastatin Tablets, in particular 40 mg, where it was transient or intermittent in most cases. Proteinuria has not been shown to be predictive of acute or progressive renal disease. The reporting rate for serious renal events in post-marketing use is higher at the 40 mg dose. An assessment of renal function should be considered during routine follow-up ofpatients treated with a dose of40 mg.

Skeletal Muscle Effects

Effects on skeletal muscle e.g. myalgia, myopathy and, rarely, rhabdomyolysis have been reported in Rosuvastatin Tablets -treated patients with all doses and in particular with doses > 20 mg. Very rare cases ofrhabdomyolysis have been reported with the use ofezetimibe in combination with HMG-CoA reductase inhibitors. A pharmacodynamic interaction cannot be excluded and caution should be exercised with their combined use. As with other HMG-CoA reductase inhibitors, the reporting rate for rhabdomyolysis associated with Rosuvastatin Tablets in post-marketing use is higher at the 40 mg dose.

Protease Inhibitors

Increased systemic exposure to rosuvastatin has been observed in subjects receivmg rosuvastatin concomitantly with various protease inhibitors in combination with ritonavir. Consideration should be given both to the benefit oflipid lowering by use ofRosuvastatin Tablets in HIV patients receiving protease inhibitors and the potential for increased rosuvastatin plasma concentrations when initiating and up titrating Rosuvastatin Tablets doses in patients treated with protease inhibitors. The concomitant use with certain protease inhibitors is not recommended unless the dose ofRosuvastatin Tablets is adjusted.

Paediatric Population
The evaluation of linear growth (height), weight, BMI (body mass index), and secondary characteristics ofsexual maturation by Tanner staging in paediatric patients 6 to 17 years of age taking rosuvastatin is limited to a two-year period. After two years of study treatment, no effect on growth, weight, BMI or sexual maturation was detected.

4.5 Interaction with other medicinal products and other forms of interaction

Pharmacodynamic interactions
Effect of co-administered medicinal products on Rosuvastatin.

Transporter protein inhibitors: Rosuvastatin is a substrate for certain transporter proteins including the hepatic uptake transporter OATP1B1 and efflux transporter BCRP. Concomitant administration of Rosuvastatin Tablets with medicinal products that are inhibitors of these transporter proteins may result in increased rosuvastatin plasma concentrations and an increased risk ofmyopathy Ciclosporin.

Protease inhibitors: Although the exact mechanism ofinteraction is unknown, concomitant protease inhibitor use may strongly increase rosuvastatin exposure. For instance, in a pharmacokinetic study, co-administration of 10 mg rosuvastatin and a combination product of two protease inhibitors (300 mg atazanavir/100 mg ritonavir) in healthy volunteers was associated with an approximately three-fold and seven-fold increase in rosuvastatin AUC and Cmax respectively. The concomitant use of Rosuvastatin Tablets and some protease inhibitor combinations may be considered after careful consideration of Rosuvastatin Tablets dose adjustments based on the expected increase in rosuvastatin exposure.
Gemfibrozil and other lipid-lowering products: Concomitant use of Rosuvastatin Tablets and gemfibrozil resulted in a 2-fold increase in rosuvastatin Cmax and AUC.

Effect of rosuvastatin on co-administered medicinal products
Vitamin K antagonists: As with other HMG-CoA reductase inhibitors, the initiation of treatment or dosage up-titration of Rosuvastatin Tablets in patients treated concomitantly with vitamin K antagonists (e.g. warfarin or another coumarin anticoagulant) may result in an increase in International Normalised Ratio (INR). Discontinuation or down- titration of Rosuvastatin Tablets may result in a decrease in INR. In such situations, appropriate monitoring ofINR is desirable.
Oral contraceptive/hormone replacement therapy (HRT): Concomitant use of Rosuvastatin Tablets and an oral contraceptive resulted in an increase in ethinyl estradiol and norgestrel AUC of 26% and 34%, respectively. These increased plasma levels should be considered when selecting oral contraceptive doses. There are no pharmacokinetic data available in subjects taking concomitant Rosuvastatin Tablets and HRT, therefore, a similar effect cannot be excluded.

4.6 Fertility, pregnancy and lactation

Rosuvastatin Tablets is contraindicated in pregnancy and lactation.

Women ofchild bearing potential should use appropriate contraceptive measures.

Since cholesterol and other products of cholesterol biosynthesis are essential for the development of the foetus, the potential risk from inhibition of HMG-CoA reductase outweighs the advantage of treatment during pregnancy. Animal studies provide limited evidence of reproductive toxicity. If a patient becomes pregnant during use of this product, treatment should be discontinued immediately.

Rosuvastatin is excreted in the milk of rats. There are no data with respect to excretion in milk in humans.

4.7 Effects on ability to drive and use machines

Rosuvastatin Tablets on the ability to drive and use machines have not been conducted. However, based on its pharmacodynamic properties, Rosuvastatin Tablets is unlikely to affect this ability. When driving vehicles or operating machines, it should be taken into account that dizziness may occur during treatment.

4.8 Undesirable effects

Adverse reactions are as below:

Blood and lymphatic system disorders: Thrombocytopenia Immune system disorders: Hypersensitivity reactions Endocrine disorders: Diabetes mellitus
Psychiatric disorders: Depression

Nervous system disorders: Headache, Dizziness, Peripheral neuropathy Respiratory, thoracic and mediastinal disorders: Cough, Dyspnoea Gastro-intestinal disorders: Constipation, Nausea, Abdominal pain

Hepatobiliary disorders: Increased hepatic transaminases

Skin and subcutaneous tissue disorders: Pruritus, Rash, Urticaria

Musculo-skeletal and connective tissue disorders: Myopathy Rhabdomyolysis, Lupus-like syndrome, Muscle rupture

Renal and urinary disorders: Haematuria

4.9 Overdose

There is no specific treatment in the event of overdose. In the event of overdose, the patient should be treated symptomatically and supportive measures instituted as required. Liver function and CK levels should be monitored. Haemodialysis is unlikely to be ofbenefit.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: HMG-CoA reductase inhibitors

ATC-code: CIOA A07

Mode of action:

Rosuvastatin is a selective and competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A to mevalonate, a precursor for cholesterol. The primary site of action of rosuvastatin is the liver, the target organ for cholesterol lowering.

Rosuvastatin 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 ofVLDL and LDL particles.

5.2 Pharmacokinetic properties

Absorption: Maximum rosuvastatin plasma concentrations are achieved approximately 5 hours after oral administration. The absolute bioavailability is approximately 20%.

Distribution: Rosuvastatin is taken up extensively by the liver which is the primary site of cholesterol synthesis and LDL-C clearance. The volume of distribution of rosuvastatin is approximately 134 L. Approximately 90% of rosuvastatin is bound to plasma proteins, mainly to albumin.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Lactose	BP
Calcium phosphate	BP
Microcrystalline Cellulose	BP
Crospovidone	BP
Maize starch	BP
Purified Water	BP
Povidone	BP
Sodium Methyl Paraben	BP
Sodium Proovl Paraben	BP
Colloidal Anhydrous Silica	BP
Purified Talc	BP
Magnesium Stearate	BP
Titanium dioxide film coat	In-House
Isopropyl Alcohol	BP
Dichloromethane	BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C in dry place.

Protected From light and moisture.

6.5 Nature and contents of container

3 X 10 Alu- Alu Blister Pack

6.6 Special precautions for disposal and other handling

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

7. APPLICANT/MANUFACTURER

NAME AND ADDRESS OF APPLICANT

Company name - Eliora Chemicals and Pharmaceuticals Limited

Company Address- No 4, Moferere Street, Ado-Ekiti, Ekiti State, Nigeria

Email id : eliopharmalimited@gmail.com

NAME AND ADDRESS OF MANUFACTURER

SHUKRA PHARMACEUTICALS LTD

Plot No. 795, Rakanpur Sola-Santej Road,

Ta. Kalol, Dist. Gandhinagar

Gujarat, India

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Rosuvastatin Tablets BP 10 mg

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. WHAT ROSUVASTATIN TABLETS BP 10 MG IS AND WHAT IT IS USED FOR.

Rosuvastatin belongs to a group of medicines called statins.

You have been prescribed Rosuvastatin because

you have a high cholesterol level. This means you are at risk from a heart attack or stroke. Rosuvastatin is used in adults, adolescents and children 6 years or older to treat high cholesterol you have been advised to take a statin, because changing your diet and doing more exercise were not enough to correct your cholesterol levels. You should continue with your cholesterol-lowering diet and exercise while you are taking Rosuvastatin.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ROSUVASTATIN TABLETS BP 10 MG. DO NOT TAKE ROSUVASTATIN TABLETS BP 10 MG IF YOU

Do not take Rosuvastatin
if you are allergic to rosuvastatin or any of the other ingredients of this medicine.

if you are pregnant or breast-feeding. If you become pregnant while taking Rosuvastatin stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking Rosuvastatin by using suitable contraception.
if you have liver disease
if you have severe kidney problems
if you have repeated or unexplained muscle aches or pains
if you take a drug combination of sofosbuvir/velpatasvir/voxilaprevir (used for viral infection of the liver called hepatitis C)
if you take a drug called ciclosporin (used, for example, after organ transplants)
if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Rosuvastatin or other related medicines.
If any of the above applies to you (or you are in doubt), please go back and see your doctor.

In addition, do not take Rosuvastatin 40 mg (the highest dose)
if you have moderate kidney problems (if in doubt, please ask your doctor)
if your thyroid gland is not working properly
if you have had any repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol lowering medicines.
if you regularly drink large amounts of alcohol
if you are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian) - if you take other medicines called fibrates to lower your cholesterol.
If any of the above applies to you (or you are in doubt), please go back and see your doctor.

Warnings and precautions
Talk to your doctor or pharmacist before taking Rosuvastatin.

if you have problems with your kidneys
if you have problems with your liver
if you have had repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol lowering medicines. Tell your doctor immediately if you have unexplained muscle aches or pains, especially if you feel unwell or have a fever.
Tell your doctor or pharmacist if you have a muscle weakness that is constant.
if you regularly drink large amounts of alcohol
if your thyroid gland is not working properly
if you take other medicines called fibrates to lower your cholesterol. Please read this leaflet carefully, even if you have taken other medicines for high cholesterol before.
if you take medicines used to treat the HIV infection e.g. ritonavir with lopinavir and/or atazanavir, please see "Other medicines and Rosuvastatin ".

if you are taking or have taken in the last 7 days a medicine called fusidic acid (a medicine for bacterial infection), orally or by injection. The combination of fusidic acid and Rosuvastatin can lead to serious muscle problems (rhabdomyolysis), please see "Other medicines and Rosuvastatin".
if you are over 70 (as your doctor needs to choose the right start dose of Rosuvastatin to suit you)
If you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia (see section 4).
if you have severe respiratory failure
if you are of Asian origin – that is Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the right start dose of Rosuvastatin to suit you.
If any of the above applies to you (or if you are not sure):

Do not take Rosuvastatin 40 mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of Rosuvastatin.
In a small number of people, statins can affect the liver. This is identified by a simple test which looks for increased levels of liver enzymes in the blood. For this reason, your doctor will usually carry out this blood test (liver function test) before and during treatment with Rosuvastatin.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Rosuvastatin treatment. Stop using Rosuvastatin and seek medical attention immediately if you notice any of the symptoms described in section 4.

Children and adolescents
if the patient is under 6 years old: Rosuvastatin should not be given to children younger than 6 years
if the patient is below 18 years of age: The Rosuvastatin 40 mg capsule is not suitable for use in children and adolescents below 18 years of age.
Other medicines and Rosuvastatin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking any of the following

ciclosporin (used for example, after organ transplants)
warfarin, ticagrelor or clopidogrel (or any other drug used for thinning the blood)
fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe)
indigestion remedies (used to neutralise acid in your stomach)
erythromycin (an antibiotic), fusidic acid (an antibiotic – please see below and Warnings and precautions)
an oral contraceptive (the pill)
regorafenib (used to treat cancer)
darolutamide (used to treat cancer)
hormone replacement therapy
any of the following drugs used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see Warnings and precautions): ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.
The effects of these medicines could be changed by Rosuvastatin or they could change the effect of Rosuvastatin.

If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart Rosuvastatin. Taking Rosuvastatin with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis.

Rosuvastatin with food and drink
You can take Rosuvastatin with or without food.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Rosuvastatin if you are pregnant or breast-feeding. If you become pregnant while taking Rosuvastatin stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking Rosuvastatin by using suitable contraception.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Most people can drive a car and operate machinery while using Rosuvastatin – it will not affect their ability. However, some people feel dizzy during treatment with Rosuvastatin. If you feel dizzy, consult your doctor before attempting to drive or use machines.

For a full list of ingredients, please see Contents of the pack and other information.

Rosuvastatin contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per hard capsule, that is to say essentially 'sodium-free'.

3. HOW TO TAKE ROSUVASTATIN TABLETS BP 10 MG

Always take this medicine as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Usual doses in adults
If you are taking Rosuvastatin for high cholesterol

Starting dose

Your treatment with Rosuvastatin must start with the 5 mg or the 10 mg dose, even if you have taken a higher dose of a different statin before. The choice of your start dose will depend upon: - your cholesterol levels

- the level of risk you have of experiencing a heart attack or stroke
- whether you have a factor that may make you more sensitive to possible side effects.

Please check with your doctor or pharmacist which start dose of Rosuvastatin will best suit you.

Your doctor may decide to give you the lowest dose (5 mg) if:

- you are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian)
- you are over 70 years of age
- you have moderate kidney problems
- you are at risk of muscle aches and pains (myopathy).

Increasing the dose and maximum daily dose

Your doctor may decide to increase your dose. This is so that you are taking the amount of Rosuvastatin that is right for you. If you started with a 5 mg dose, your doctor may decide to double this to 10 mg, then 20 mg and then 40 mg if necessary. If you started on 10 mg, your doctor may decide to double this to 20 mg and then 40 mg if necessary. There will be a gap of four weeks between every dose adjustment.

The maximum daily dose of Rosuvastatin is 40 mg. It is only for patients with high cholesterol levels and a high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 10 mg.

If you are taking Rosuvastatin to reduce your risk of having a heart attack, stroke or related health problems

The recommended dose is 10 mg daily. However, your doctor may decide to use a lower dose if you have any of the factors mentioned above.

Use in children and adolescents aged 6-17 years
The dose range in children and adolescents aged 6 to 17 years is 5 to 20 mg once daily. The usual start dose is 5 mg per day, and your doctor may gradually increase your dose to find the right amount of Rosuvastatin for you. The maximum daily dose of Rosuvastatin is 10 or 20 mg for children aged 6 to 17 years depending on your underlying condition being treated. Take your dose once a day. Rosuvastatin 40 mg capsule should not be used by children.

Taking your capsules
Swallow each capsule whole with a drink of water.
Take Rosuvastatin once daily. You can take it at any time of the day with or without food.
Try to take your capsule at the same time every day to help you to remember it.

Method of Administration
Taking Rosuvastatin with soft food (applesauce or chocolate/vanilla flavoured pudding).

For people who have difficulty in swallowing capsules, Rosuvastatin may be given with soft food (applesauce or chocolate/vanilla flavored pudding) as follows:

1. Carefully open the Rosuvastatin capsule.
2. Sprinkle the granules filled in the capsules on 1 teaspoonful of soft food (such as applesauce or chocolate/vanilla flavoured pudding).
3. Swallow the drug/food mixture within 60 minutes with drinking of at least 240 ml water (after ingestion of the sprinkled drug). Do not chew the granules.
4. Do not save the drug/food mixture for later use. Throw away any remaining drug/food mixture.

Giving Rosuvastatin through a nasogastric tube (NG tube) 8 French or larger, as prescribed by your doctor.

For people who have a nasogastric tube in place, Rosuvastatin may be given as follows:

1. The appropriate volume of syringe should be selected based on the dose of Rosuvastatin capsule to be administered.
2. The plunger should be removed from the syringe.
3. The Rosuvastatin capsule should be carefully opened and the granules should be emptied into the syringe barrel.
4. Water should be added to the granules in the syringe barrel. Do not use other liquids.

5. The plunger should be replaced and the syringe should be shaken vigorously for 15 seconds.
6. The tipped syringe should be attached to a nasogastric tube (≥8-French) depending on the patient age.
7. The mixture should be administered right away through the nasogastric tube into the stomach. ,

Regular cholesterol checks
It is important to go back to your doctor for regular cholesterol checks, to make sure your cholesterol has reached and is staying at the correct level.

Your doctor may decide to increase your dose so that you are taking the amount of Rosuvastatin that is right for you.

If you take more Rosuvastatin than you should
Contact your doctor or nearest hospital for advice.
If you go into hospital or receive treatment for another condition, tell the medical staff that you are taking Rosuvastatin.

If you forget to take Rosuvastatin
Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Rosuvastatin
Talk to your doctor if you want to stop taking Rosuvastatin. Your cholesterol levels might increase again if you stop taking Rosuvastatin.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDEEFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. It is important that you are aware of what these side effects may be. They are usually mild and disappear after a short time.

Stop taking Rosuvastatin and seek medical help immediately if you have any of the following allergic reaction

- difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat
- swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing - severe itching of the skin (with raised lumps)
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome)

- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

Also, stop taking Rosuvastatin and talk to your doctor immediately

- if you have any unusual aches or pains in your muscles which go on for longer than you might expect. Muscle symptoms are more common in children and adolescents than in adults. As with other statins, a very small number of people have experienced unpleasant muscle effects and rarely these have gone on to become a potentially life threatening muscle damage known as rhabdomyolysis
- if you experience muscle rupture
- if you have lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

Common possible side effects (these may affect between 1 in 10 and 1 in 100 patients)

- headache, stomach pain, constipation, feeling sick, muscle pain, feeling weak, dizziness
- an increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your Rosuvastatin capsules (only Rosuvastatin 40 mg)
- diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

Uncommon possible side effects (these may affect between 1 in 100 and 1 in 1,000 patients) - rash, itching or other skin reactions

- an increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your Rosuvastatin hard capsules (only Rosuvastatin 5 mg, 10 mg and 20 mg).

Rare possible side effects (these may affect between 1 in 1,000 and 1 in 10,000 patients)

- severe allergic reaction – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, a severe itching of the skin (with raised lumps). If you think you are having an allergic reaction, then stop taking Rosuvastatin and seek medical help immediately.
- muscle damage in adults – as a precaution, stop taking Rosuvastatin and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than expected.
- a severe stomach pain (inflamed pancreas)
- increase in liver enzymes in the blood
- bleeding or bruising more easily than normal due to low level of blood platelets - lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

5. HOW TO STORE ROSUVASTATIN TABLETS BP 10 MG

Keep this medicine out of the sight and reach of children.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of the month.

Blisters: Store below 30°C. Store in original pack in order to protect from light and moisture.

Containers: Store below 30°C. Store in original pack in order to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What ROSUVASTATIN TABLETS BP 10 MG contain

The active substance in Rosuvastatin is rosuvastatin calcium.

Rosuvastatin capsules contain Rosuvastatin Calcium BP Eq. to Rosuvastatin 10 mg

The other ingredients are:

Lactose, Tri basic calcium phosphate, Micro crystalline cellulose, Cross povidone, Maize Starch, Purified water, P.V.P.K-30 (Povidone), Sodium methyl paraben, Sodium propyl paraben, Colloidal Anhydrous Silica (Aerosil), Purified Talc, Magnesium Stearate, Titanium dioxide film coat, Isopropyl alcohol, Dichloromethane

What ROSUVASTATIN TABLETS BP 10 MG look like and contents of the pack White colour, round shape, biconvex, film coated tablet, plain on both size.

Packs: 3 X 10 Alu-Alu Blister Pack

Manufacturer:

SHUKRA PHARMACEUTICALS LTD

Plot No. 795, Rakanpur Sola-Santej Road, Ta. Kalol,

Dist. Gandhinagar (Gujarat), India.

Phone No.: +91 (2764) 286317

Email: info@shukrapharmaceuticals.com

For any information about this medicinal product, please contact the

Eliora Chemicals and Pharmaceuticals Limited

No 4, Moferere Street, Ado-Ekiti, Ekiti State, Nigeria.

This is a Medicament

– Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

– Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

– The doctor and the pharmacist are the experts in medicines, their benefits and risks.

– Do not by yourself interrupt the period of treatment prescribed for you.

– Keep out of the reach and sight of children