ROSVATOR Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

ROSVATOR 5

ROSVATOR 10

ROSVATOR 20

ROSVATOR 40

Rosuvastatin

This product contains sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking ROSVATOR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ROSVATOR** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **ROSVATOR** is and what it is used for.
2. What you need to know before you take **ROSVATOR**.
3. How to take **ROSVATOR**.
4. Possible side effects.
5. How to store **ROSVATOR**.
6. Contents of the pack and other information.

1. What ROSVATOR is and what it is used for.

ROSVATOR tablets contain rosuvastatin. It belongs to a group of medicines called statins.

Rosuvastatin is used to correct the levels of fatty substances in the blood called lipids, the most common of which is cholesterol. Most of the cholesterol in your blood is made in the liver.

You have been prescribed ROSVATOR because you have a high cholesterol level.

ROSVATOR tablet is used:

- to lower 'bad' cholesterol and triglycerides in the blood, and increase 'good' cholesterol when a low fat diet and other measures (such as exercise, weight loss) have failed.
- to lower the inherited high levels of cholesterol in your blood (homozygous familial hypercholesterolemia), together with dieting and other treatments (e.g. LDL-apheresis), or when such treatments are not adequate.
- to reduce risk of heart attack or stroke.

2. What you need to know before you take ROSVATOR

Do not take ROSVATOR:

- If you are hypersensitive (allergic) to rosuvastatin or any of the other ingredients of **ROSVATOR.**
- If you have active liver disease including persistent elevation of liver enzymes in the blood
- If you have been diagnosed with muscle disease (myopathy; symptoms may include muscle aches and pains)
- If you take a medicine called ciclosporin (used for after organ transplants)
- If you are pregnant or intend to become pregnant.
- If you are breast-feeding currently**.**

Do not take ROSVATOR tablets if any of the above applies to you. If you are not sure, please talk to your doctor or pharmacist before taking these tablets.

Warnings and precautions

Take special care with ROSVATOR:

- If you have problems with your kidneys
- 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
- If you regularly consume large amounts of alcoholic beverages or have a history of liver disease

- If you have an underactive thyroid gland (hypothyroidism) which is treated inadequately
- If you are an elderly person (more than ≥ 65 years old)
- If you take other medicines called fibrates (such as gemfibrozil, niacin) to lower your cholesterol
- If you take medicines used to fight infections (e.g. erythromycin, azithromycin etc.)
- If you take medicines used to fight the HIV infection (e.g. protease inhibitors such as lopinavir/ritonavir)
- If you take medicines used to treat fungal infection (e.g. miconazole, ketoconazole)
- If you are of Asian origin
- If you are diabetic

Myopathy (muscle aches and pains) and muscle breakdown with severe kidney problems have been reported with agents of the same class as ROSVATOR. This can occur at any dose level, but are increased at the highest dose (40 mg). ROSVATOR can cause Myasthenia gravis (muscle weaknes and fatigue) and ocular myasthenia (affects muscles that controls the eye movement).

Serious liver problems may occur. You should notify your medical practitioner right away if you have the following symptoms: unusual fatigue or weakness; loss of appetite; stomach pain; dark-coloured urine; or yellowing of the skin or the whites of the eyes.

Please consult your doctor if these statements were applicable to you any time in the past.

While on treatment

ROSVATOR should be discontinued if markedly elevated creatinine kinase levels occur or muscle breakdown is suspected.

ROSVATOR should not be used in patients developing severe blood infection (sepsis), low blood pressure, severe electrolyte imbalance (abnormalities in the blood levels of e.g. sodium, potassium, and/or calcium), trauma, uncontrolled fits or undergoing major surgery.

An increase in the amount of protein and traces of blood in the urine has been reported in patients taking **ROSVATOR** 40 mg tablet when compared to lower doses. During routine testing if this is observed, your doctor would consider a dose reduction.

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 blood test (liver function test) before and during treatment if necessary with **ROSVATOR** tablets.

Other medicines and ROSVATOR:

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor especially if you are taking any of the following:

- ciclosporin (used for example, after organ transplants)
- fibrates such as gemfibrozil, fenofibrate (medicine used to lower cholesterol)
- other cholesterol lowering agents such as niacin, ezetimibe
- itraconazole, ketoconazole (medicines used to treat fungal infection)
- lopinavir/ritonavir (used to fight the HIV infection)
- antibiotics – macrolides such as erythromycin (used to treat infections)
- warfarin (or any other agent used for thinning the blood)
- antacid preparations containing aluminium and magnesium hydroxide used for indigestion (remedies used to neutralise acid in your stomach), cimetidine
- an oral contraceptive (the pill), hormone replacement therapy
- spironolactone (used as water pill)

The effects of these medicines could be changed by ROSVATOR tablets or they could change the effect of ROSVATOR tablets.

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.

Pregnancy

Do not take **ROSVATOR** tablets if you are pregnant. If you become pregnant while taking **ROSVATOR** tablets stop taking it immediately and tell your doctor.

Women should avoid becoming pregnant while taking **ROSVATOR** by using suitable contraception.

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

Breast-feeding

ROSVATOR must not be used during breast-feeding.

Driving and using machinery:

You should be aware of how you react to **ROSVATOR** before you drive or operate machinery. Effect on ability to drive and use machines has not been studied. Some people feel dizzy during treatment with **ROSVATOR** tablets. If you feel dizzy, consult your doctor before attempting to drive or use machines

3. How to take ROSVATOR:

Do not share medicines prescribed for you with any other person.

Always take **ROSVATOR** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Usual Dose in Adults

The usual starting dose of ROSVATOR is 5 mg, even if you have taken a higher dose of a different cholesterol lowering agent (statin) before.

The choice of your start dose will depend upon:

- Your cholesterol level
- 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

In children 10 years of age and above the usual dose range is 5 to 20 mg orally once daily.

Your doctor may decide to give you the lowest dose (5 mg) if you are of Asian origin, over 70 years of age, have kidney problems, or are at risk of muscle aches and pains.

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.

If you take more **ROSVATOR** than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. Take this leaflet or some tablets with you so that your doctor will know what you have taken.

If you forget to take **ROSVATOR**

If you miss a dose of **ROSVATOR**, take them as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for missed doses.

4. Possible side effects

ROSVATOR can have side effects.

Not all side effects reported for **ROSVATOR** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ROSVATOR**, please consult your healthcare professional for advice.

If any of the following happens, stop taking ROSVATOR and tell your doctor immediately or go to the casualty department at your nearest hospital:

Difficulty in breathing, with or without swelling of the face, severe itching, lips, tongue and/or throat, difficulty in swallowing.

Rash or itching.

Yellowing of the skin and eyes, also called jaundice.

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to **ROSVATOR.** You may need urgent medical attention or hospitalisation.

Also stop taking **ROSVATOR** tablets and talk to your doctor immediately

- If you have any unusual aches or pains in your muscles. These have become a potentially life threatening muscle damage known as rhabdomyolysis.
- Severe stomach pain due to inflamed pancreas (pancreatitis)

The following side-effects have been reported frequently:

- Headache
- Rash, ithching
- Dizziness
- Stomach pain
- Constipation
- Feeling sick (nausea)
- Muscle pain
- Feeling weak (asthenia)
- Increased blood glucose levels (diabetes)

Less frequent side-effects:

- Rash, itching or other skin reactions
- Memory loss or impairment, forgetfulness and confusion
- A severe stomach pain (inflamed pancreas)
- Jaundice (yellowing of the skin and eyes)

- Hepatitis (an inflamed liver)
- Increased liver enzymes in the blood
- Joint pain
- Traces of blood in your urine
- Deficiency of platelets in the blood (thrombocytopaenia)
- Inflammation of the pancreas (pancreatitis)
- Swelling of boys' and men's breasts (gynecomastia)

Frequency not known side-effects:

- Depression
- Sleep disturbences, including nightmares and sleeplessness
- Weakness, numbness and pain from nerve damage (peripheral neuropathy)
- Myasthenia gravis (muscle weaknes and fatigue)
- Ocular myasthenia (weakened muscles that controls the eye movement).
- Cough and laboured breathing
- Diarrhoea
- Serious disorder of the skin and mucous membranes (Stevens-Johnson syndrome)
- Swelling (oedema)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **ROSVATOR**

5. How to store ROSVATOR

Store at or below 25 °C in the original pack, protected from light and moisture.

Do not remove the blisters from the carton until required for use.

Keep out of the reach and sight of children.

Do not take ROSVATOR tablets after expiry date on the labelling.

If you doctor tells you to stop taking the tablets, please take them back to the pharmacist..

6. Contents of the pack and other information

What ROSVATOR contains

The active substance is rosuvastatin.

The other ingredients are:

Crospovidone, lactose monohydrate, microcrystalline cellulose, magnesium stearate, opadry yellow or opadry pink and sodium citrate.

What ROSVATOR looks like and contents of the pack

ROSVATOR 5

Each film-coated tablet contains Rosuvastatin calcium equivalent to Rosuvastatin 5 mg.

Contains sugar: Lactose monohydrate 42,952 mg per film-coated tablet.

ROSVATOR 10

Each film-coated tablet contains Rosuvastatin calcium equivalent to Rosuvastatin 10 mg.

Contains sugar: Lactose monohydrate 85,905 mg per film-coated tablet.

ROSVATOR 20

Each film-coated tablet contains Rosuvastatin calcium equivalent to Rosuvastatin 20 mg.

Contains sugar: Lactose monohydrate 171,810 mg per film-coated tablet.

ROSVATOR 40

Each film-coated tablet contains Rosuvastatin calcium equivalent to Rosuvastatin

40 mg.

Contains sugar: Lactose monohydrate 343,619 mg per film-coated tablet.

Cartons contain 28 or 30 tablets packed in silver cold form blister packs or desiccant embedded silver cold form blister packs, each blister strip of silver cold form blister pack and desiccant embedded silver cold form blister pack contains 7 or 10 tablets.

The carton contains 4 blister strips of 7 tablets each for the 28’s pack and 3 blister strips of 10 tablets each for the 30’s pack.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road, Stomill, Ext 1

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website

ROSVATOR Pasiëntinligtingstuk

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS:

S4

ROSVATOR 5

ROSVATOR 10

ROSVATOR 20

ROSVATOR 40

Rosuvastatien

Hierdie produk bevat suiker (laktosemonohidraat)

Lees hierdie hele inligtingstuk noukeurig deur voordat jy begin om ROSVATOR te neem

- Hou hierdie inligtingstuk. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief jou dokter of apteker as jy verdere vrae het.
- **ROSVATOR** is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met enige ander persoon deel nie. Dit kan skadelik vir hulle wees, selfs as hulle simptome dieselfde as joune is.

Wat is in hierdie inligtingstuk

1. Wat **ROSVATOR** is en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy **ROSVATOR** neem.
3. Hoe om **ROSVATOR** te neem.
4. Moontlike newe-effekte.

5. Hoe om **ROSVATOR** te bewaar.

6. Inhoud van die verpakking en ander inligting.

1. Wat ROSVATOR is en waarvoor dit gebruik word.

ROSVATOR tablette bevat rosuvastatien. Dit behoort aan ‘n groep medisyne wat statiene genoem word. Rosuvastatien word gebruik om die vlakke van vetterige stowwe in die bloed, wat lipiede genoem word, waarvan die mees algemene een cholesterol is, reg te stel. Die meeste van die cholesterol in jou bloed word in die lewer vervaardig.

ROSVATOR is vir jou voorgeskryf omdat jy ‘n hoë cholesterolvlak het.

ROSVATOR tablette word gebruik om:

- die ‘slegte’ cholesterol en trigliseriede in die bloed te verlaag, en ‘goeie’ cholesterol te verhoog wanneer ‘n lae vetdieet en ander maatreëls (soos oefening, gewigsverlies) onsuksesvol was.
- om die oorgeërfde hoë vlakke van cholesterol in jou bloed (homosigotiese familiële hipercholesterolemie) te verlaag, tesame met dieet en ander behandelings (bv. LDL-aferese), of wanneer sulke behandelings nie voldoende is nie.
- om die risiko van ‘n hartaanval of beroerte te verminder.

2. Wat jy moet weet voordat jy ROSVATOR neem

Moenie ROSVATOR neem nie:

- As jy hipersensitief (allergies) is vir rosuvastatien of vir enige van die ander bestanddele van **ROSVATOR**
- As jy ‘n aktiewe lewersiekte het, insluitend volgehoue verhoogde vlakke van lewerensieme in die bloed
- As jy gediagnoseer is met ‘n spiersiekte (miopatie; simptome kan spierpyne en ander pyne insluit)
- As jy ‘n middel wat siklosporien genoem word, neem (gebruik ná orgaanoorplantings)

- As jy swanger is of beplan om swanger te raak.
- As jy huidiglik borsvoed**.**

Moenie ROSVATOR tablette neem as enige van die bogenoemde op jou van toepassing is nie. Praat asseblief met jou dokter of apteker voordat jy hierdie tablette neem as jy nie seker is nie.

Waarskuwings en voorsorgmaatreëls

Tref spesiale voorsorg met ROSVATOR:

- As jy probleme met jou niere het
- As jy herhaaldelik of onverklaarbare spierpyne of ander pyne ervaar, ‘n persoonlike of familiegeskiedenis het van spierprobleme, of ‘n vorige geskiedenis van spierprobleme wanneer jy ander cholesterol-verlagende medisyne gebruik het. Lig jou dokter dadelik in as jy onverklaarbare spierpyne of ander pyne het veral as jy nie goed voel nie of ‘n koors het
- As jy gereeld groot hoeveelhede alkoholiese drankies inneem of ‘n geskiedenis van lewersiekte het
- As jy ‘n onderaktiewe skildklier het (hipotiroïdisme) wat ontoereikend behandel is
- As jy ‘n bejaarde persoon is (ouer as ≥ 65 jaar oud)
- As jy ander medisyne gebruik wat fibrate genoem word (soos gemfibrosiel, niasien) om jou cholesterol te verlaag
- As jy medisyne gebruik om infeksies te beveg (bv. eritromisien, asitromisien ens.)
- As jy medisyne gebruik om MIV-infeksie te beveg (bv. protease-inhibeerders soos lopinavir/ritonavir)
- As jy medisyne gebruik om fungusinfeksies te behandel (bv. mikonasool, ketokonasool)
- As jy van Asiatiese oorsprong is

- As jy diabeties is

Miopatie (spierpyne en ander pyne) en spierafbraak met ernstige nierprobleme is aangemeld met middels van dieselfde klas as ROSVATOR. Dit kan by enige dosisvlak voorkom, maar is verhoog by die hoogste dosis (40 mg). ROSVATOR kan myasthenia gravis (spierswakheid en -moegheid) en okulêre miastenie (spiere wat oogbeweging beheer word geaffekteer) veroorsaak.

Ernstige lewerprobleme kan voorkom. Jy moet jou dokter dadelik in kennis stel as jy die volgende simptome het: ongewone moegheid of swakheid; verlies aan aptyt; maagpyn; donkergekleurde urine; of vergeling van die vel of die wit van die oë.

Raadpleeg asseblief jou dokter as hierdie stellings op enige tydstip in die verlede op jou van toepassing was.

Terwyl jy op behandeling is

ROSVATOR moet gestaak word as ‘n merkbare verhoging in kreatinienkinase-vlakke voorkom of spierafbraak vermoed word.

ROSVATOR moet nie gebruik word by pasiënte wat ernstige bloedinfeksie (sepsis) ontwikkel, lae bloeddruk het, ernstige elektrolietwanbalans (abnormaliteite in die bloedvlakke van bv. natrium, kalium en/of kalsium) het, trauma ervaar, ongekontrolleerde toevalle ervaar of as groot chirurgie ondergaan word.

‘n Toename in die hoeveelheid proteïen en spore van bloed in die urine is aangemeld by pasiënte wat die 40 mg **ROSVATOR** tablet neem, vergeleke met laer dosisse. As dit waargeneem word tydens roetine toetse, sal jou dokter ‘n dosisverlaging oorweeg.

Statiene kan die lewer affekteer in ‘n klein aantal persone. Dit is waargeneem deur ‘n eenvoudige toets wat uitgevoer word om verhoogde vlakke van lewerensieme in die bloed vas te stel. Om hierdie rede sal jou dokter, indien nodig, gewoonlik ‘n bloedtoets (lewerfunksie-toets) uitvoer vóór en tydens behandeling met **ROSVATOR** tablette.

Ander medisyne en ROSVATOR:

Lig jou gesondheidsorgverskaffer altyd in as jy ander medisyne gebruik. (Dit sluit aanvullende of tradisionele medisyne in.)

Lig jou dokter veral in as jy die volgende gebruik:

- siklosporien (byvoorbeeld gebruik ná orgaanoorplantings)
- fibrate soos gemfibrosiel, fenofibraat (medisyne wat gebruik word om cholesterol te verlaag)
- ander cholesterol-verlagende middels soos niasien, esetimieb
- itrakonasool, ketokonasool (medisyne wat gebruik word om fungusinfeksies te behandel)
- lopinavir/ritonavir (gebruik om MIV-infeksie te beveg)
- antibiotika – makroliede soos eritromisien (gebruik om infeksies te behandel)
- warfarien (of ander middels wat gebruik word om bloed te verdun)
- teensuurpreparate wat aluminium- en magnesiumhidroksied bevat wat gebruik word om slegte spysvertering te behandel (middels wat gebruik word om suur in jou maag te neutraliseer), simetidien
- ‘n orale voorbehoedmiddel (die pil), hormoonvervangingsterapie
- spironolaktoon (gebruik as waterpil)

Die effekte van hierdie medisyne kan verander word deur ROSVATOR-tablette of hulle kan die effek van ROSVATOR-tablette verander.

Swangerskap, borsvoeding en vrugbaarheid

As jy swanger is of borsvoed, dink dat jy swanger is of van plan is om 'n baba te kry, raadpleeg asseblief jou dokter, apteker vir advies voordat jy hierdie medisyne gebruik.

Swangerskap

Moenie **ROSVATOR-**tablette neem as jy swanger is nie. As jy swanger raak terwyl jy **ROSVATOR-**tablette neem, staak die gebruik onmiddellik en lig jou dokter in.

Vroue moet verhoed dat hulle swanger raak terwyl hulle **ROSVATOR** neem deur geskikte voorbehoeding te gebruik.

Vra jou dokter of apteker vir advies voordat jy enige medisyne gebruik.

Borsvoeding

ROSVATOR moet nie tydens borsvoeding gebruik word nie.

Bestuur en gebruik van masjinerie:

Jy moet bewus wees van hoe jy teenoor **ROSVATOR** reageer voordat jy bestuur of masjinerie hanteer. Die effek van die vermoë om te bestuur en masjinerie te gebruik is nie bestudeer nie. Sommige persone kan duiselig voel tydens behandeling met **ROSVATOR**-tablette. As jy duiselig voel, raadpleeg jou dokter voordat jy ‘n poging aanwend om te bestuur of masjinerie te hanteer.

3. Hoe om ROSVATOR te neem:

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem **ROSVATOR** altyd presies soos wat jou dokter of apteker dit aan jou voorgeskryf het.

As jy nie seker is nie, moet jy dit met jou dokter of apteker bespreek.

Normale dosis vir volwassenes

Die normale aanvangsdosis van ROSVATOR is 5 mg, selfs as jy voorheen ‘n hoër dosis van ‘n ander cholesterol-verlagende middel (statien) gebruik het.

Die keuse van jou aanvangsdosis hang af van:

- Jou cholesterolvlak
- Die risikovlak wat jy het om ‘n hartaanval of beroerte te ervaar
- Of jy ‘n faktor besit wat jou meer sensitief vir moontlike newe-effekte maak

By kinders van 10-jarige ouderdom en ouer, is die gewone dosisreeks 5 tot 20 mg een keer per dag, mondeliks geneem.

Jou dokter kan besluit om die laagste dosis (5 mg) voor te skryf as jy van Asiatiese oorsprong is, bo die ouderdom van 70 jaar is, nierprobleme het of ‘n risiko het om spierpyne en ander pyne te ontwikkel.

Dit is belangrik om terug te gaan na jou dokter toe vir gereelde opvolg van die cholesterolvlak om seker te maak dat jou cholesterol die korrekte vlak bereik het en daarop bly.

As jy meer **ROSVATOR** geneem het as wat jy behoort te neem

Raadpleeg jou dokter of apteker in die geval van oordosering. Indien nie een van hulle beskikbaar is nie, kry hulp by jou naaste hospitaal of gifbeheersentrum. Neem hierdie inligtingstuk of sommige van die tablette saam met jou sodat jou dokter kan weet wat jy geneem het.

As jy vergeet het om **ROSVATOR** te neem

As jy ‘n dosis van **ROSVATOR** oorgeslaan het, neem dit so gou as wat jy onthou. As dit egter amper tyd is vir jou volgende dosis, slaan die dosis oor wat jy vergeet het en gaan terug na jou normale dosisskedule. Moenie ‘n dubbele dosis neem om te vergoed vir die dosis wat jy oorgeslaan het nie.

4. Moontlike newe-effekte

ROSVATOR kan newe-effekte hê.

Nie alle newe-effekte wat vir **ROSVATOR** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Raadpleeg asseblief jou gesondheidsorgdeskundige vir advies indien jou algemene gesondheid versleg of as jy enige ongewenste effete ervaar terwyl jy neem.

Indien enige van die volgende gebeur, staak die gebruik van ROSVATOR en lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal:

Probleme met asemhaling, met of sonder swelling van die gesig, lippe, tong en/of keel, ernstige gejeuk, probleme met sluk.

Uitslag of gejeuk.

Vergeling van die vel en oë, ook geelsug genoem.

Hierdie is almal baie ernstige newe-effekte. As jy dit het, kon jy ‘n ernstige allergiese reaksie teenoor **ROSVATOR** gehad het**.** Jy mag dringende mediese aandag of hospitalisasie benodig.

Staak die gebruik van **ROSVATOR-**tablette en praat dadelik met jou dokter:

- As jy enige ongewone pyn of pyn in jou spiere het. Hierdie kan moontlik lewensbedreigende spierskade, bekend as rabdomiolise, word.
- Ernstige maagpyn as gevolg van ‘n ontsteekte pankreas (pankreatitis)

Die volgende newe-effekte word dikwels aangemeld:

- Hoofpyn
- Uitslag, gejeuk
- Duiseligheid
- Maagpyn
- Hardlywigheid
- Mislike gevoel (naarheid)
- Spierpyn
- Swak gevoel (astenie)
- Verhoogde bloedglukosevlakke (diabetes)

Minder dikwelse newe-effekte:

- Uitslag, gejeuk of ander veltoestande
- Geheueverlies of benadeling, vergeetagtigheid en verwarring
- ‘n Ernstige maagpyn (ontsteekte pankreas)
- Geelsug (vergeling van die vel en oë)
- Hepatitis (‘n ontsteekte lewer)
- Verhoogde lewerensieme in die bloed
- Gewrigspyn

- Spore van bloed in jou urine
- Tekort aan plaatjies in die bloed (trombositopenie)
- Inflammasie van die pankreas (pankreatitis)
- Swelling van seuns en manne se borste (ginekomastie)

Onbekende voorkoms van newe-effekte:

- Depressie
- Slaapversteurings, insluitend nagmerries en slapeloosheid
- Swakheid, dooie gevoel en pyn as gevolg van senuweeskade (perifere neuropatie)
- Myasthenia gravis (spierswakheid en moegheid)
- Okulêre miastenie (verswakte spiere wat oogbeweging beheer).
- Hoes en swaar asemhaling
- Diarree
- Ernstige versteuring van die vel en slymvliesmembrane (Stevens-Johnson-sindroom)
- Swelling (edeem)

As jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, moet jy jou dokter of apteker daarvan in kennis stel.

Aanmelding van newe-effekte

As jy newe-effekte ervaar, moet jy jou dokter of apteker inlig. Jy kan ook newe-effekte by SAHPRA *via* die Med Safety toepassing (Medsafety X SAHPRA) en eReporting-platform (who-umc.org) aanmeld wat op SAHPRA se webtuiste beskikbaar is. Vermoedelike ongunstige reaksies kan ook direk by die Houer van die Registrasiesertifikaat aangemeld word *via* epos: pharmacovigilance.africasme@sunpharma.com of tel: +27(0) 12 643 2000. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van **ROSVATOR** te verskaf.

5. Hoe om ROSVATOR te bewaar

Bewaar by of onder 25 °C in die oorspronklike verpakking, beskerm teen lig en vog.

Moenie die stulpstroke uit die karton verwyder voor benodig vir gebruik nie.

Hou buite die bereik en sig van kinders.

Moenie ROSVATOR-tablette ná die vervaldatum soos op die etikette aangedui, gebruik nie.

As jou dokter jou inlig om op te hou om die tablette te gebruik, neem dit asseblief terug na jou apteker toe.

6. Inhoud van die verpakking en ander inligting

Wat ROSVATOR bevat

Die aktiewe bestanddeel is rosuvastatien.

Die ander bestanddele is:

krospovidoon, laktosemonohidraat, mikrokristallyne sellulose, magnesiumstearaat, geel Opadry of pienk Opadry en natriumsitraat.

Hoe ROSVATOR lyk en inhoud van die verpakking

ROSVATOR 5

Elke filmbedekte tablet bevat Rosuvastatienkalsium gelykstaande aan Rosuvastatien 5 mg.

Bevat suiker: Laktosemonohidraat 42,952 mg per filmbedekte tablet.

ROSVATOR 10

Elke filmbedekte tablet bevat Rosuvastatienkalsium gelykstaande aan Rosuvastatien 10 mg.

Bevat suiker: Laktosemonohidraat 85,905 mg per filmbedekte tablet.

ROSVATOR 20

Elke filmbedekte tablet bevat Rosuvastatienkalsium gelykstaande aan Rosuvastatien 20 mg.

Bevat suiker: Laktosemonohidraat 171,810 mg per filmbedekte tablet.

ROSVATOR 40

Elke filmbedekte tablet bevat Rosuvastatienkalsium gelykstaande aan Rosuvastatien 40 mg.

Bevat suiker: Laktosemonohidraat 343,619 mg per filmbedekte tablet.

Kartonne bevat 28 of 30 tablette verpak in ‘n silwer kouevorm-stulpverpakking of in ‘n droogmiddel-ingebedde silwer kouevorm-stulpverpakking, elke stulpstrook van silwer kouevorm-stulpverpakking en droogmiddel-ingebedde silwer kouevorm-stulpverpakking bevat 7 of 10 tablette.

Die karton bevat 4 stulpstroke van 7 tablette elk vir die 28’s-verpakking en 3 stulpstroke van 10 tablette elk vir die 30’s-verpakking.

Houer van die Registrasiesertifikaat

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14, Stormill, Uitbreiding 1

Roodepoort, 1724

Hierdie inligtingstuk was laas hersien op

22 Januarie 2024

Registrasienommers

ROSVATOR 5: 45/7.5/0955/59

ROSVATOR 10: 45/7.5/0956/60

ROSVATOR 20: 45/7.5/0957/61

ROSVATOR 40: 45/7.5/0958/62

Toegang tot die ooreenstemmende Professionele Inligting

Kan vanaf die SAHPRA-webtuiste verkry word