Front Side

330 mm

VASROV 5/10/20/40 mg TABLETS
(film-coated tablet)
PM03837402

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

VASROV 5 mg TABLETS (film-coated tablets)
VASROV 10 mg TABLETS (film-coated tablets)
VASROV 20 mg TABLETS (film-coated tablets)
VASROV 40 mg TABLETS (film-coated tablets)
Rosuvastatin (as rosuvastatin calcium)
Contains sugar (lactose monohydrate)
VASROV 5 mg TABLETS Contains lactose monohydrate 29,750 mg
VASROV 10 mg TABLETS Contains lactose monohydrate 59,500 mg
VASROV 20 mg TABLETS Contains lactose monohydrate 119,00 mg
VASROV 40 mg TABLETS Contains lactose monohydrate 238,00 mg

Read all of this leaflet carefully before you start taking VASROV:
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **VASROV** 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 **VASROV** is and what it is used for
2. What you need to know before you use **VASROV**
3. How to take **VASROV**
4. Possible side effects
5. How to store **VASROV**
6. Contents of the pack and other information

1. What VASROV is and what it is used for

VASROV contains 5 mg, 10 mg, 20 mg or 40 mg of rosuvastatin, as rosuvastatin calcium, per film-coated tablet and belongs to the pharmacotherapeutic group called HMG-CoA reductase inhibitors.

VASROV is used to reduce the risk of incidents that may cause damage to the heart muscle in patients at risk of developing heart disease as a result of build-up of fats in and on the blood vessels of the heart.
VASROV is used, together with diet, to lower high levels of fats in the blood, which are called lipids, usually when changes to diet and exercise have failed to do this. **VASROV**, in addition to diet, lowers "bad" cholesterol (LDL) and increases "good" cholesterol (HDL) in the blood.
VASROV is also used to reduce total cholesterol and "bad" cholesterol (LDL) in adult patients with very high cholesterol and a family history of high cholesterol, either alone or together with diet and other lipid lowering treatments.

VASROV 40 mg TABLETS should only be considered in patients with severe high cholesterol and high cardiovascular risk who do not achieve their treatment goal on 20 mg of **VASROV** or alternative therapy.
Specialist supervision is recommended when the 40 mg dose is initiated.
VASROV can be used in children and adolescents (10 to 17 years of age) to reduce the total cholesterol, "bad" cholesterol (LDL) and lipids in patients with genetically inherited high cholesterol called heterozygous familial hypercholesterolaemia (HeFH).

2. What you need to know before you take VASROV:

Do not take VASROV:
- if you are hypersensitive (allergic) to rosuvastatin or any of the other ingredients of **VASROV** (listed in section 6)
- if you currently have a liver disease
- if you have severe kidney problems
- if you take a medicine called ciclosporin (used, for example, after organ transplants) (see **Other Medicines and VASROV**)
- if you are pregnant or breastfeeding or if you are a woman of childbearing potential not using appropriate contraceptive measures (see **Pregnancy, breastfeeding and fertility**)

Patients with the following pre-disposing conditions for a muscle disease called myopathy must not take **VASROV 40 mg TABLETS** (the highest dose). The following conditions may increase the risk of muscle disorders:
- if you have moderate kidney problems (if in doubt, please ask your doctor)
- if you have a condition called hypothyroidism (underactive thyroid)
- 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 taking other medicines called fibrates (for high cholesterol)
- if you are of Asian descent

Warnings and precautions
Take special care with VASROV:
Tell your doctor or healthcare professional before taking **VASROV**:
- if you have problems with your kidneys
- if you have unexplained muscle aches and pains, muscle weakness, cramps and especially if you feel unwell or have a fever, tell your doctor immediately
- if your thyroid gland is not working properly (hypothyroidism)
- if you have a personal or family history of hereditary muscular disorders
- if you have a previous history of muscle problems when using cholesterol lowering medicines
- if you regularly consume large amounts of alcohol
- if you are above 70 years of age
- if you are taking fibrates (cholesterol lowering medicine) please see **Other medicine and VASROV**
- 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 **VASROV** can lead to serious muscle problems (rhabdomyolysis), please see **Other medicines and VASROV**
- if you are taking other HMG-CoA reductase inhibitors together with fibric acid derivatives including gemfibrozil, ciclosporin, nicotinic acid, azole antifungals, protease inhibitors (such as lopinavir/ritonavir – medicines used to treat HIV infection) and macrolide antibiotics (see **Other medicine and VASROV**).

VASROV may cause interstitial lung disease, especially with long-term treatment. Tell your doctor if you experience difficulty breathing, develop a non-productive cough and/or deterioration in general health (e.g. fatigue, weight loss and fever) while taking **VASROV**.

In a small number of people, **VASROV** can affect the liver. This is identified by a 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 treatment starts with **VASROV**, and if needed thereafter.

In patients whose high cholesterol is caused by another disease, such as thyroid or kidney problems, the underlying disease should be treated prior to initiating therapy with **VASROV**.

While you are on **VASROV** 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. **VASROV** should be used with care in patients with Type 2 diabetes and in patients at risk.

Other medicines and VASROV:
Always tell your healthcare professional if you are taking any other medicine.(This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:
Contraindicated combinations
VASROV should not be used together with ciclosporin (used for example, after organ transplants).
The 40 mg dose is contraindicated with concomitant use of a fibrate.

There may be a higher than usual chance of other side effects
Fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe) as these medicines may increase the effect of **VASROV** and the risk of developing serious muscle problems (see **Do not take VASROV** above).

Fusidic acid (an antibiotic) may increase the risk of developing serious muscle problems (see **Take special care with VASROV** above). If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using **VASROV**. Your doctor will tell you when it is safe to restart **VASROV**. Taking **VASROV** with fusidic acid may lead to muscle weakness, tenderness or pain (rhabdomyolysis).

Medicines used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see **Take special care with VASROV** above), as these medicines may increase the effect of **VASROV** and may lead to an increase in the possible side effects of **VASROV**: ritonavir, lopinavir, atazanavir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir, darunavir, tipranavir.

Effect of VASROV may be increased:
- Warfarin or clopidogrel (or any other medicine used for thinning the blood) as **VASROV** may affect the way this medicine works; clopidogrel may increase the effect of **VASROV**.
- Regorafenib (used to treat cancer) as this may increase the effect of **VASROV**.
- Eltrombopag (used to treat low blood platelet counts caused by an autoimmune disorder) as this may increase the effect of **VASROV**.
- Dronedarone (used to treat abnormal heart rhythm) as this may increase the effect of **VASROV**.
- Itraconazole (used to treat fungal infections) as this may increase the effect of **VASROV**.

Effect of VASROV may be decreased:
- Indigestion remedies, such as antacids (used to neutralise acid in your stomach) as these medicines may decrease the effect of **VASROV**.
- Erythromycin (an antibiotic) as this may decrease the effect of **VASROV**.

VASROV may increase the effect of other medicines:
- Oral contraceptives (the pill) as **VASROV** may increase the effect of contraceptives.
- Hormone replacement therapy as **VASROV** may increase the effect of these medicines.

Taking VASROV with food and alcohol
You can take **VASROV** with or without food.
If you regularly drink large amounts of alcohol, it may increase your risk of muscle disorders.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.
Women of child-bearing potential should use appropriate contraceptive measures.
VASROV is contraindicated in pregnancy and lactation.

Driving and using machines
VASROV may cause dizziness, therefore you should not drive or use machines until you know how **VASROV** affects you.

It is not always possible to predict to what extent **VASROV** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **VASROV** affects them.

3. How to take VASROV:

Do not share medicines prescribed for you with any other person.
Always take **VASROV** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Before starting treatment, your doctor should place you on a standard cholesterol-lowering diet that should continue during treatment.
The dosage range for **VASROV** is 5 - 40 mg orally once a day. The recommended start dose is 5 mg once a day.

Your dosage will be individualised according to your cholesterol levels, your risk factors and your response to **VASROV**-therapy. The majority of patients are controlled at the 10 mg dose. However, if necessary, dose adjustment can be made at 2 – 4 week intervals.
A 5 mg starting dose is recommended for patients of Asian ancestry and for patients requiring a smaller reduction in "bad" cholesterol (LDL-C) to achieve treatment target.
For patients with severely high cholesterol (including genetically inherited high cholesterol,), a start dose of 20 mg may be considered.
For patients with genetically inherited high cholesterol, a start dose of 20 mg once a day is recommended.

Children and adolescents 10 - 17 years of age:
In children and adolescents with genetically inherited high cholesterol, the usual dose range is 5 - 20 mg orally once daily.

Special populations:
Use in the elderly:
The usual dose range applies.

Dosage in patients with renal insufficiency:
The starting dose applies in patients with mild to moderate renal impairment.
For patients with severe renal impairment the dose of **VASROV** should not exceed 10 mg once daily.

Dosage in patients with hepatic insufficiency:
The usual starting dose applies in patients with mild to moderate hepatic impairment. Patients with severe hepatic impairment should start therapy with **VASROV** 5 mg, doses above 10 mg should be carefully considered.

Race:
A 5 mg starting dose of **VASROV** should be considered for Asian patients.
Your doctor will tell you how long your treatment with **VASROV** will last. It may take weeks or months of treatment for you to see any improvement in your symptoms and your symptoms might even worsen when **VASROV** is started. Do not stop treatment early.
If you have the impression that the effect of **VASROV** is too strong or too weak, tell your doctor or pharmacist.

If you take more VASROV than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
If you forget to take VASROV:
Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

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

If any of the following happens, stop taking **VASROV** 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, lips, tongue and/or throat which may cause difficulty in swallowing, severe itching of the skin (with raised lumps).
- Blistering of the skin, mouth and eyes (Steven-Johnson syndrome).
- Jaundice (yellowing of the skin and eyes).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **VASROV**. You may need urgent medical attention or hospitalisation.
Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Any unusual aches and pains in your muscles which go on for longer than you might expect, especially if you develop a fever or feel unwell. Unpleasant muscle effects may become a potentially life threatening muscle damage known as rhabdomyolysis. Muscle symptoms are more frequent in children and adolescents than in adults.
- Tendon disorders sometimes complicated by rupture.
- Serious muscle damage presenting as unexplained muscle aches and pains, feeling unwell and a fever (immune-mediated necrotising myopathy).
- A severe stomach pain (inflamed pancreas).
- Increase in liver enzymes in the blood.
- Hepatitis (an inflamed liver).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects:
- Increased glucose levels, diabetes
- Headache, dizziness
- Constipation, nausea, stomach pain
- Muscle pain
- Feeling weak or a lack of energy.

Less frequent side effects:
- Abnormal bleeding or bruising
- Memory loss
- Numbness, tingling, loss of sensation in the arms and legs, burning feeling in the hands or feet (polyneuropathy)
- Rash, itching or other skin reactions
- Oedema (swelling under the skin)
- Cough, shortness of breath, difficulty breathing
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells)
- Muscle rupture
- Joint pain
- Traces of blood in your urine
- Breast enlargement in men (gynaecomastia).

Side effects with unknown frequency:
- Depression
- Diarrhoea
- An increase in the amount of protein in the urine
- Numbness and tingling in hands or feet (peripheral neuropathy).

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, pharmacist or nurse. 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 this medicine.

5. How to store VASROV

Store at or below 25 °C.
Keep the blisters in the carton until required for use.
Keep the HDPE container tightly closed
Keep all medicines out of the reach and sight of children.
Do not take your **VASROV** after the expiry date on the label or container.
If your doctor decides to stop your treatment, return all unused tablets to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What VASROV contains
VASROV 5 mg TABLETS (film-coated tablets)
Each film-coated tablet contains 5 mg rosuvastatin (as rosuvastatin calcium)
VASROV 10 mg TABLETS (film-coated tablets)
Each film-coated tablet contains 10 mg rosuvastatin (as rosuvastatin calcium)
VASROV 20 mg TABLETS (film-coated tablets)
Each film-coated tablet contains 20 mg rosuvastatin (as rosuvastatin calcium)
VASROV 40 mg TABLETS (film-coated tablets)
Each film-coated tablet contains 40 mg rosuvastatin (as rosuvastatin calcium)

The other ingredients are Microcrystalline Cellulose, Lactose Monohydrate, Anhydrous Dibasic Calcium Phosphate, Hypromellose, crospovidone, Magnesium stearate, Ready to use coating material I [HPMC 2910/Hypromellose (E464), Titanium Dioxide (E171), Triacetin & Iron Oxide Red (E172)] for 10 mg, 20 mg & 40 mg and Ready to use coating material II [HPMC 2910/Hypromellose (E464), Titanium Dioxide, (E171), Triacetin & Iron Oxide Yellow (E172)] for 5 mg.

What VASROV looks like and contents of the pack
VASROV 5 mg TABLETS (film-coated tablet):
Yellow, round, biconvex, film coated tablets debossed with "CL" on one side and "86" on other side.
VASROV 10 mg TABLETS (film-coated tablet):
Pink, round, biconvex, film coated tablets debossed with 'CL 87' on one side and plain on other side.
VASROV 20 mg TABLETS (film-coated tablet):
Pink, round, biconvex, film coated tablets debossed with 'CL 88' on one side and plain on other side.
VASROV 40 mg TABLETS (film-coated tablet):
Pink, oval, biconvex, film coated tablets debossed with 'CL 89' on one side and plain on other side.

Blister Pack: **VASROV 5/10/20/40 mg TABLETS**
Silver coloured cold form foil, OPA/Al/PVC 25/45/60 micron as the forming material and plain, silver coloured, 30 micron aluminium foil/6-8gsm HSL as the lidding material, packed in a pre-printed unit carton.
Pack size include 10's, 14's, 28's, 30's and 100's tablets.

HDPE container pack:
VASROV 5/10/20 mg TABLETS
60 cc round, white, HDPE container with 33 mm neck finish, containing 28 or 30 or 90 tablets and 2 silica gel sachets, closed with a white closure, 33 mm with white printed pulp and heat seal liner and may or may not be packed in a pre-printed unit carton.

VASROV 40 mg TABLETS
60 cc / 75 cc round, white, HDPE container with 33 mm / 38 mm neck finish respectively, containing 28 or 30 or 90 tablets and 2 silica gel sachets, closed with a white closure, 33 mm / 38 mm with white printed pulp and heat seal liner and may or may not be packed in a pre-printed unit carton.
Pack size include 28's, 30's & 90's tablets
Not all pack sizes may be marketed

Holder of Certificate of Registration
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

This leaflet was last revised in
26 September 2023

Registration number
VASROV 5 mg TABLETS: 50/7.5/0014
VASROV 10 mg TABLETS : 50/7.5/0015
VASROV 20 mg TABLETS : 50/7.5/0016
VASROV 40 mg TABLETS : 50/7.5/0017

335 mm

Back Side

330 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

VASROV 5 mg TABLETS (filmbedekte tablette)
VASROV 10 mg TABLETS (filmbedekte tablette)
VASROV 20 mg TABLETS (filmbedekte tablette)
VASROV 40 mg TABLETS (filmbedekte tablette)
Rosuvastatien (as rosuvastatienkalsium)
Bevat suiker (laktosemonohidraat)
VASROV 5 mg TABLETS bevat 29,750 mg laktosemonohidraat
VASROV 10 mg TABLETS bevat 59,500 mg laktosemonohidraat
VASROV 20 mg TABLETS bevat 119,00 mg laktosemonohidraat
VASROV 40 mg TABLETS bevat 238,00 mg laktosemonohidraat

Lees hierdie hele inligtingsblad aandagtig deur, voordat jy VASROV begin gebruik:
- Hou hierdie inligtingsblad. Dit mag wees dat jy dit weer wil lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **VASROV** is vir jou persoonlik voorgeskryf en jy behoort nie jou medisyne met ander mense te deel nie. Selfs al het hulle dieselfde simptome as jy, kan dit vir hulle skadelik wees.

Wat is in hierdie inligtingsblad

1. Wat **VASROV** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **VASROV** gebruik
3. Hoe om **VASROV** te neem
4. Moontlike newe-effekte
5. Hoe om **VASROV** te berg
6. Inhoud van die pak en ander inligting

1. Wat VASROV is en waarvoor dit gebruik word

VASROV bevat 5 mg, 10 mg, 20 mg of 40 mg van rosuvastatien, as rosuvastatienkalsium, per filmbedekte tablet en behoort aan die farmakoterapeutiese groep naamlik HMG-CoA reduktase inhibeerders.
VASROV word gebruik om die risiko van voorvalle te verminder, wat skade aan die hartspier kan veroorsaak in pasiënte wat die risiko loop om hartsiektes te ontwikkel as gevolg van die opbou van vette in, en op die bloedvate van die hart.
VASROV word gebruik, tesame met dieet, om hoë vlakke van vette in die bloed, wat lipiede genoem word, te verlaag, gewoonlik wanneer veranderinge in dieet en oefening nie daarin geslaag het om dit te doen nie. **VASROV**, benewens dieet, verlaag "slegte" cholesterol (LDL) en verhoog "goeie" cholesterol (HDL) in die bloed.
VASROV word ook gebruik om die totale cholesterol en "slegte" cholesterol (LDL) te verlaag, in volwasse pasiënte met baie hoë cholesterol en 'n familiegeskiedenis van hoë cholesterol, óf alleen óf saam met dieet en ander lipiedverlagende behandeling.

VASROV 40 mg TABLETS moet slegs oorweeg word in pasiënte met ernstige hoë cholesterol en hoë kardiovaskulêre risiko, wie nie hul behandelingsdoelwit bereik op 20 mg van **VASROV** of alternatiewe behandeling nie.
Spesialis toesig word aanbeveel met die aanvang van die 40 mg dosering.
VASROV kan in kinders en adolessente (10 tot 17 jarige ouderdom) gebruik word om die totale cholesterol, "slegte" cholesterol (LDL) en lipiede te verlaag, in pasiënte met genetiese oorerflike hoë cholesterol, sogenaamde heterosigotiese familiële hipercholesterolemie (HeFH).

2. Wat jy behoort te weet voordat jy VASROV neem:

Moet nie VASROV neem nie:
- indien jy hipersensitief (allergies) vir rosuvastatien, of enige van die ander bestanddele van **VASROV** is (gelys in afdeling 6)
- indien jy tans 'n lewersiekte het
- indien jy ernstige nierprobleme het
- indien jy medisyne neem wat siklosporien genoem word (gebruik, byvoorbeeld, na orgaanoorplantings) (sien **Ander Medisyne en VASROV**)
- indien jy swanger is of borsvoed of indien jy 'n vrou van kinderbarende potensiaal is en nie toepaslike voorbehoedmiddels gebruik nie (sien **Swangerskap, borsvoeding en vrugbaarheid**).

Pasiënte met die volgende voorafbepalende toestande vir 'n spiersiekte genoem miopatie, moet nie **VASROV 40 mg TABLETS** (die hoogste dosering) neem nie. Die volgende toestande kan die risiko vir spierafwykings verhoog:
- indien jy matige nierprobleme het (indien jy twyfel, vra asseblief jou dokter)
- indien jy 'n toestand genaamd hipotiroïedisme het (onderaktiewe skildklier)
- indien jy voorheen enige herhaalde of onverklaarbare spierpyne of pyne, 'n persoonlike of familiegeskiedenis van spierprobleme, of 'n vorige geskiedenis van spierprobleme tydens die neem van ander cholesterolverlagende medisyne gehad het
- indien jy gereeld groot hoeveelhede van alkohol inneem
- indien jy ander medisyne neem wat fibrate genoem word (vir hoë cholesterol)
- indien jy van Asiatiese afkoms is

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met VASROV:
Vertel jou dokter of gesondheidsorgwerker voordat jy **VASROV** neem:
- indien jy probleme met jou niere het
- indien jy onverklaarbare spierpyne en pyne, spierswakheid en krampe het en veral indien jy siek voel of 'n koors het, moet jy onmiddellik jou dokter vertel
- indien jou tiroïedklier nie behoorlik werk nie (hipotiroïedisme)
- indien jy 'n persoonlike of familiegeskiedenis van oorerflike spierversteurings het
- indien jy 'n vorige geskiedenis van spierprobleme het wanneer cholesterolverlagende medisyne geneem word
- indien jy gereeld groot hoeveelhede alkohol verbruik
- indien jy ouer as 70 jarige ouderdom is
- indien jy fibrate neem (cholesterolverlagende medisyne) sien asseblief **Ander Medisyne en VASROV**
- indien jy 'n geneesmiddel, naamlik fusidiensuur ('n middel vir bakteriële infeksie), mondelings of deur inspuiting neem, of geneem het binne die laaste 7 dae. Die kombinasie van fusidiensuur en **VASROV** kan lei tot ernstige spierprobleme (rabdomiolise), sien asseblief **Ander Medisyne en VASROV**
- indien jy ander HMG-CoA reduktase inhibeerders saam met fibriensuurderivate, insluitend gemfibrosiel, siklosporien, nikotiensuur, asool swambestrydende middels, protease inhibeerders (soos lopinavir/ritonavir – medisyne wat gebruik word om MIV infeksie te behandel) en makrolied antibiotika (sien **Ander Medisyne en VASROV**).

VASROV kan interstisiële longsiekte veroorsaak, veral met langtermynbehandeling. Vertel jou dokter indien jy asemhalingsprobleme ondervind, 'n nie-produktiewe hoes ontwikkel en/of 'n agteruitgang in algemene gesondheid (bv. moegheid, gewigsverlies en koors) terwyl **VASROV** geneem word.

In 'n klein hoeveelheid van mense kan **VASROV** die lewer affekteer. Dit word geïdentifiseer deur 'n toets wat kyk na verhoogde vlakke van lewerensieme in die bloed. Om hierdie rede sal jou dokter gewoonlik hierdie bloedtoets uitvoer (lewerfunksietoets) voordat behandeling met **VASROV** begin, en indien nodig daarna.

In pasiënte wie se hoë cholesterol veroorsaak word deur 'n ander siekte, soos skildklier- of nierprobleme, moet die onderliggende siekte behandel word voordat behandeling met **VASROV** begin word.

Terwyl jy op **VASROV** is, sal jou dokter jou deeglik monitor indien jy diabetes het of 'n risiko loop om diabetes te ontwikkel. Dit is waarskynlik dat jy die risiko loop om diabetes te ontwikkel indien jy hoë vlakke van suikers en vette in jou bloed het, oorgewig is en hoë bloeddruk het. **VASROV** moet met versigtigheid gebruik word in pasiënte met Tipe 2 diabetes en in pasiënte met 'n risiko.

Ander medisyne en VASROV:
Vertel altyd jou gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in).

Vertel jou dokter indien jy enige van die volgende medisyne neem:
Teenaangeduide kombinasies
VASROV moet nie saam met siklosporien (gebruik byvoorbeeld na orgaanoorplantings) gebruik word nie.
Die 40 mg dosering is teenaangedui met gelyktydige gebruik van 'n fibraat.

Daar kan 'n groter as normale kans wees op ander newe-effekte
Fibrate (soos gemfibrosiel, fenofibraat) of enige ander medisyne wat gebruik word om cholesterol te verlaag (soos esetimibe), aangesien hierdie medisyne die effek van **VASROV** en die risiko om ernstige spierprobleme te ontwikkel, kan verhoog (sien hierbo **Moet nie VASROV neem nie**).

Fusidiensuur ('n antibiotikum) kan die risiko om ernstige spierprobleme te ontwikkel, verhoog (sien hierbo **Wees veral versigtig met VASROV**). Indien jy nodig het om fusidiensuur mondelings te moet inneem om 'n bakteriële infeksie te behandel, sal dit nodig wees dat jy tydelik moet stop met die gebruik van **VASROV**. Jou dokter sal jou vertel wanneer dit veilig is om weer met **VASROV** te begin. Om **VASROV** saam met fusidiensuur te neem, kan lei tot spierswakheid, -teerheid of -pyn (rabdomiolise).

Geneesmiddels wat gebruik word om virale infeksies te behandel, insluitend MIV, of hepatitis C infeksie, alleen of in kombinasie (sien asseblief hierbo **Wees veral versigtig met VASROV**), aangesien hierdie medisyne die effek van **VASROV** kan verhoog en kan lei tot 'n toename in die moontlike newe-effekte van **VASROV**: ritonavir, lopinavir, atasanavir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grasoprevir, elbasvir, glesaprevir, pibrentasvir, darunavir, tipranavir.

Effek van VASROV mag verhoog word:
- Warfarien of klopidogrel (of enige ander medisyne wat gebruik word om bloed te verdun) aangesien **VASROV** die werking van hierdie medisyne kan beïnvloed; klopidogrel kan die effek van **VASROV** verhoog.
- Regorafenib (gebruik om kanker te behandel), aangesien dit die effek van **VASROV** kan verhoog.
- Eltrombopag (wat gebruik word vir die behandeling van lae bloedplaatjie tellings, wat veroorsaak word deur 'n outoïmmuun afwyking), aangesien dit die effek van **VASROV** kan verhoog.
- Dronedaroon (gebruik vir behandeling van abnormale hartritme), aangesien dit die effek van **VASROV** kan verhoog.
- Itrakonasool (gebruik vir behandeling van swaminfeksies), aangesien dit die effek van **VASROV** kan verhoog.

Effek van VASROV kan verlaag word:
- Swak spysverterings middels, soos teensuurmiddels (gebruik om suur in jou maag te neutraliseer), aangesien hierdie medisyne die effek van **VASROV** kan verminder.
- Eritromisien ('n antibiotikum), aangesien dit die effek van **VASROV** kan verminder.

VASROV kan die effek van ander medisyne verhoog:
- Orale voorbehoedmiddels (die pil) aangesien **VASROV** die effek van voorbehoedmiddels kan verhoog.
- Hormoonvervangingsterapie aangesien **VASROV** die effek van hierdie medisyne kan verhoog.

Neem van VASROV met voedsel en alkohol
Jy kan **VASROV** met of sonder voedsel neem.
Indien jy gereeld groot hoeveelhede van alkohol drink, kan dit jou risiko vir spierafwykings verhoog.

Swangerskap, borsvoeding en vrugbaarheid
Indien jy swanger is of jou baba borsvoed, dink dat jy swanger kan wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne neem.
Vrouens met kinderbarende potensiaal behoort gepaste voorbehoedmiddels te gebruik.
VASROV is teenaangedui in swangerskap en borsvoeding.

Bestuur en gebruik van masjinerie
VASROV kan duiseligheid veroorsaak, daarom moet jy nie bestuur of masjiene gebruik totdat jy weet hoe **VASROV** jou affekteer nie.

Dit is nie altyd moontlik om te voorspel tot watter mate **VASROV** met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie aan die bogenoemde aktiwiteite deelneem, totdat hulle bewus is van die mate waarin **VASROV** hulle affekteer nie.

3. Hoe om VASROV te neem:

Moet nie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie.
Neem altyd **VASROV** presies soos jou dokter jou opdrag gegee het. Jy behoort dit met jou dokter of apteker te bevestig, indien jy onseker is.

Voordat jy met die behandeling begin, moet jou dokter jou op 'n standaard cholesterolverlagende dieet plaas wat gedurende die behandeling moet voortgaan.
Die dosisreeks vir **VASROV** is 5 - 40 mg oraal, een keer per dag. Die aanbevole aanvangsdosis is 5 mg een keer per dag.

Jou dosering sal individueel aangepas word volgens jou cholesterolvlakke, jou risikofaktore en jou reaksie op behandeling met **VASROV**. Die meerderheid van pasiënte word gekontrolleer met die 10 mg dosering. Indien nodig, kan die dosis egter aangepas word met 2 - 4 weke intervalle.
'n Aanvangsdosis van 5 mg word aanbeveel vir pasiënte van Asiatiese afkoms en vir pasiënte wat 'n kleiner verlaging in "slegte" cholesterol (LDL-C) benodig, om die behandelingsdoelwit te bereik.
Vir pasiënte met ernstige hoë cholesterol (insluitend geneties oorerflike hoë cholesterol), kan 'n aanvangsdosis van 20 mg oorweeg word.
Vir pasiënte met geneties oorerflike hoë cholesterol word 'n aanvangsdosis van 20 mg een keer per dag aanbeveel.

Kinders en adolessente 10 - 17 jarige ouderdom:
In kinders en adolessente met geneties oorerflike hoë cholesterol, is die gewone dosisreeks 5 - 20 mg oraal, een keer per dag.

Spesiale populasies:
Gebruik in bejaardes:
Die gewone dosisreeks is van toepassing.

Dosis in pasiënte met nierinkorting:
Die aanvangsdosis is van toepassing op pasiënte met ligte tot matige nierinkorting.
Vir pasiënte met erge nierinkorting moet die dosering van **VASROV** nie 10 mg een keer per dag oorskry nie.

Dosis in pasiënte met lewerinkorting:
Die gewone aanvangsdosis is van toepassing op pasiënte met ligte tot matige lewerinkorting. Pasiënte met erge lewerinkorting moet behandeling met 5 mg **VASROV** begin, doserings hoër as 10 mg moet met omsigtigheid oorweeg word.

Ras:
'n Aanvangsdosis van 5 mg **VASROV** moet vir Asiatiese pasiënte oorweeg word.
Jou dokter sal jou vertel hoe lank jou behandeling met **VASROV** sal aanhou. Dit kan weke of maande van behandeling neem voordat jy 'n verbetering in jou simptome sal sien, en jou simptome kan selfs vererger wanneer met **VASROV** begin word. Moet nie vroeg met behandeling stop nie.
Vertel jou dokter of apteker indien jy die indruk kry dat die effek van **VASROV** te sterk of te swak is.

Indien jy meer VASROV neem as wat jy moet:
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om VASROV te neem:
Moet nie 'n dubbele dosis neem om vir die vergete individuele dosisse op te maak nie.

4. Moontlike newe-effekte

VASROV kan newe-effekte hê.
Nie alle newe-effekte wat vir **VASROV** aangemeld is, is in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid versleg of indien jy enige ongunstige effekte ervaar terwyl **VASROV** geneem word, kontak asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om **VASROV** te neem, en vertel onmiddellik jou dokter, of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Asemhalingsprobleme, met of sonder swelling van die gesig, lippe, tong en/of keel, wat dit moeilik kan maak om te sluk, erge jeuk van die vel (met verhoogde knobbels).
- Blaasvorming van die vel, mond en oë (Steven Johnson sindroom).
- Geelsug (vergeling van die vel en oë).

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, het jy moontlik 'n ernstige allergiese reaksie op **VASROV** gehad. Jy kan moontlik dringende mediese aandag of hospitalisasie nodig hê.
Vertel jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal, indien jy enige van die volgende opmerk**:**
- Enige ongewone aanhoudende pyn, en pyne in jou spiere wat langer aanhou as wat jy sou verwag, veral as jy 'n koors ontwikkel of sleg voel. Onaangename spiereffekte kan 'n potensieel lewensbedreigende spierskade, bekend as rabdomiolise, word. Spiersimptome kom meer gereeld in kinders en adolessente voor, as in volwassenes.
- Tendonversteurings soms gekompliseerd deur 'n skeur.
- Ernstige spierskade wat presenteer as onverklaarbare aanhoudende spierpyne en pyne, gevoel van ongesteldheid en 'n koors, (immuunbemiddelde nekrotiserende miopatie).
- 'n Erge maagpyn (ontsteekte pankreas).
- Verhoging in lewerensieme in die bloed.
- Hepatitis ('n ontsteekte lewer).

Hierdie is almal ernstige newe-effekte. Jy kan moontlik dringende mediese aandag nodig hê.

Vertel jou dokter indien jy enige van die volgende opmerk:
Algemene newe-effekte:
- Verhoogde glukose vlakke, diabetes
- Hoofpyn, duiseligheid
- Harlywigheid, naarheid, maagpyn
- Spierpyn
- Swak gevoel, of 'n tekort aan energie

Minder algemene newe-effekte:
- Abnormale bloeding of kneusing
- Geheueverlies
- Gevoelloosheid, tinteling, verlies van gevoel in die arms en bene, brandgevoel in die hande of voete (polineuropatie)
- Uitslag, jeuk of ander velreaksies
- Edeem (swelling onder die vel)
- Hoes, kortasem¸ asemhalingsprobleme
- Lupus-agtige siekte sindroom (insluitend uitslag, gewrigsversteurings en effekte op bloedselle)
- Skeur van spier
- Gewrigspyn
- Spore van bloed in jou uriene
- Vergroting van borste in mans (ginekomastie)

Newe-effekte met onbekende frekwensie:
- Depressie
- Diaree
- 'n Verhoging in die hoeveelheid van proteïene in die uriene.
- Gevoelloosheid en tinteling in hande of voete (perifere neuropatie)

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

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aanmeld by SAHPRA via die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van hieride medisyne te verskaf.

5. Hoe om VASROV te bewaar

Bewaar by of benede 25 °C.
Hou die stulpstrook in die karton, totdat dit benodig word vir gebruik.
Hou die HDPE verpakking dig gesluit.
Bewaar alle medisyne buite bereik en sig van kinders.
Moet nie **VASROV** na die vervaldatum op die etiket of verpakking, gebruik nie.
Neem alle ongebruikte tablette terug na jou apteker, indien jou dokter besluit om jou behandeling te staak.
Moet nie ongebruikte medisyne in die riool of rioolstelsel (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat VASROV bevat
VASROV 5 mg TABLETS (filmbedekte tablette)
Elke filmbedekte tablet bevat 5 mg rosuvastatien (as rosuvastatienkalsium)
VASROV 10 mg TABLETS (filmbedekte tablette)
Elke filmbedekte tablet bevat 10 mg rosuvastatien (as rosuvastatienkalsium)
VASROV 20 mg TABLETS(filmbedekte tablette)
Elke filmbedekte tablet bevat 20 mg rosuvastatien (as rosuvastatienkalsium)
VASROV 40 mg TABLETS (filmbedekte tablette)
Elke filmbedekte tablet bevat 40 mg rosuvastatien (as rosuvastatienkalsium)

Die ander bestanddele is Mikrokristallyne Sellulose, Laktosemonohidraat, Anhidriese dibasiese kalsiumfosfaat, Hipromellose, Krospovidoon, Magnesiumstearaat, Gereed om te gebruik bedekkingsmateriaal I [HPMC 2910/Hipromellose (E464), Titaniumdioksied (E171), Triasetien & Rooi Ysteroksied (E172)] vir 10 mg, 20 mg & 40 mg en Gereed om te gebruik bedekkingsmateriaal II [HPMC 2910/Hipromellose (E464), Titaniumdioksied (E171), Triasetien & Geel Ysteroksied (E172)] vir 5 mg.

Hoe VASROV lyk en die inhoud van die pak
VASROV 5 mg TABLETS (filmbedekte tablet):
Geel, ronde, bikonvekse filmbedekte tablette, met "CL" op die een kant en "86" op die ander kant gedruk.
VASROV 10 mg TABLETS (filmbedekte tablet):
Pienk, ronde, bikonvekse filmbedekte tablette, met "CL 87" op die een kant gedruk en glad aan die ander kant.
VASROV 20 mg TABLETS (filmbedekte tablet):
Pienk, ronde, bikonvekse filmbedekte tablette, met "CL 88" op die een kant gedruk en glad aan die ander kant.
VASROV 40 mg TABLETS (filmbedekte tablet):
Pienk, ovaal, bikonvekse filmbedekte tablette, met "CL 89" op die een kant gedruk en glad aan die ander kant.

Stulpverpakking:
VASROV 5/10/20/40 mg TABLETS
Silwerkleurige koue vormfoelie, OPA/Al/PVC 25/45/60 mikron as die vormingsmateriaal en gewone, silwerkleurige, 30 mikron aluminiumfoelie/6-8 gsm HSL as die dekmateriaal, verpak in 'n voorafgedrukte eenheidskarton .
Verpakkingsgroottes sluit 10's, 14's, 28's, 30's en 100's tablette in.

HDPE verpakking:
VASROV 5/10/20 mg TABLETS
60 cc ronde, wit HDPE houer met 33 mm nekafwerking, wat 28 of 30 of 90 tablette en 2 sakkies met silikagel bevat, gesluit met 'n wit sluiting, 33 mm met wit gedrukte pulp en hitte seëlvoering en mag of mag nie wees nie verpak in 'n voorafgedrukte eenheidskarton.

VASROV 40 mg TABLETS
60 cc / 75 cc ronde, wit HDPE houer met 33 mm / 38 mm nekafwerking onderskeidelik, wat 28 of 30 of 90 tablette en 2 sakkies met silikagel bevat, gesluit met 'n wit sluiting, 33 mm / 38 mm met wit gedrukte pulp en hitte seëlvoering en mag of mag nie verpak in 'n voorafgedrukte eenheidskarton wees nie.
Verpakkingsgroottes sluit 28's, 30's en 90's tablette in.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die Sertifikaat van Registrasie
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Rylaan 1, Bassonia Rock, Uitbreiding 12,
Alberton, Suid Afrika

Hierdie inligtingsblad is laas hersien in
26 September 2023

Registrasienommer:
VASROV 5 mg TABLETS : 50/7.5/0014
VASROV 10 mg TABLETS : 50/7.5/0015
VASROV 20 mg TABLETS : 50/7.5/0016
VASROV 40 mg TABLETS : 50/7.5/0017

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Removal of English PI, Inclusion of URL, change in dimension and same wordings used for CR and CT closure.

1. Product: VASROV 5/10/20/40 mg TABLETS (Rosuvastatin Tablets 5/10/20/40 mg)	
2. Country: South Africa (Private Market)	**3. Packaging component: Patient Information**
4. No. of Colours: 1 Colour	**5. Pantone Shade No.: Black**
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	**8. Dimensions: 335 (L) x 330 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM03837402**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 33941 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: PM03837401**
15. Revision no: 01	**16. A/W File name: Z:\Rosuvastatin\SA Private Market\01\VASROV 5-10-20-40 PI & PIL - PM03837402.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	30/09/2024				

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM03837401	03/09/22	28/10/22
2) Removal of English PI, Inclusion of URL, change in dimension and same wordings used for CR and CT closure.	PM03837402		