Front Side

320 mm

VASMAK 10/20/40/80
(film-coated tablet)
PM04342089

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

VASMAK 10 MG film-coated tablets
Atorvastatin calcium trihydrate equivalent to 10 mg atorvastatin
Contains 33,31 mg lactose monohydrate
VASMAK 20 MG film-coated tablets
Atorvastatin calcium trihydrate equivalent to 20 mg atorvastatin
Contains 66,62 mg lactose monohydrate
VASMAK 40 MG film-coated tablets
Atorvastatin calcium trihydrate equivalent to 40 mg atorvastatin
Contains 133,24 mg lactose monohydrate
VASMAK 80 MG film-coated tablets
Atorvastatin calcium trihydrate equivalent to 80 mg atorvastatin
Contains 266,48 mg lactose monohydrate
Contains sugar: lactose monohydrate

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

1. What VASMAK is and what it is used for

VASMAK contains a medicine called atorvastatin which belongs to a group of medicines known as lipid or cholesterol (fat) regulating medicines commonly known as statins.
VASMAK lowers cholesterol in your blood. It lowers the LDL-C (bad cholesterol) and triglycerides in your blood. It can raise your HDL-C (good cholesterol) as well. **VASMAK** is for adults and children older than 10 years whose cholesterol does not come down enough with exercise and a low-fat diet alone.
VASMAK can lower risk of heart disease and disorders of the blood vessels of the brain, which are conditions due to reduced blood supply, in patients who have multiple risk factors for heart disease, such as smoking, hypertension, diabetes, low HDL-C, or a family history of early coronary heart disease. **VASMAK** can reduce heart events in patients with heart disease and high cholesterol levels.

2. What you need to know before you take VASMAK

Do not take VASMAK:
- if you are hypersensitive (allergic) to atorvastatin or any of the other ingredients of **VASMAK** (listed in **section 6**).
- if you have or have ever had a disease which affects the liver.
- if you have had any unexplained abnormal blood tests for liver function.
- if you use the combination of glecaprevir/pibrentasvir in the treatment of hepatitis C.
- if you are a woman able to have children and not using reliable contraception.
- if you are pregnant, or trying to become pregnant.
- if you are breastfeeding.
- if you are taking rifampicin, an antibiotic for infection.
- if you take diltiazem, a calcium channel blocker, for angina or high blood pressure.
- if you drink grapefruit juice.

Warnings and precautions
Take special care with VASMAK:
- 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 **VASMAK** can lead to serious muscle problems (rhabdomyolysis).
- if you have had a previous stroke with bleeding into the brain or have small pockets of fluid in the brain from previous strokes.
- if you have kidney problems.
- if you have an under-active thyroid gland (hypothyroidism).
- if you have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems.
- If you have interstitial lung disease (a group of lung disorders in which the lung tissues become inflamed and then damaged).
- if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other 'statins' or 'fibrate' medicines).
- if you regularly drink a large amount of alcohol and/or have a history of liver disease.
- if you are older than 70 years.

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your **VASMAK** treatment to predict your risk of muscle related side effects. The risk of muscle related side effects e.g. rhabdomyolysis is known to increase when certain medicines are taken at the same time (see **section 2 "Other medicines and VASMAK**"). Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.
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.

Children and adolescents.
Do not give **VASMAK** to children below the age of 10 years.

Other medicines and VASMAK
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

There are some medicines that may change the effect of **VASMAK** or their effect may be changed by **VASMAK**. This type of interaction could make one or both of the medicines less effective. Alternatively, it could increase the risk or severity of side-effects, including the important muscle wasting condition known as rhabdomyolysis described in **section 4 "Possible side effects"**:
- Medicines used to alter the way your immune system works, e.g. ciclosporin.
- Certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampicin, fusidic acid.
- Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol.
- Some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem; medicines to regulate your heart rhythm e.g. digoxin, verapamil, amiodarone.
- Medicines used in the treatment of HIV e.g. atazanavir, indinavir, saquinavir plus ritonavir, lopinavir plus ritonavir, tipranavir plus ritonavir, darunavir plus ritonavir, fosamprenavir and fosamprenavir plus ritonavir
- Some medicines used in the treatment of hepatitis C e.g. telaprevir, boceprevir and the combination of elbasvir/grazoprevir.
- Other medicines known to interact with atorvastatin include:
  - ezetimibe (which lowers cholesterol),
  - warfarin (which reduces blood clotting),
  - oral contraceptives,
  - stiripentol (an anti-convulsant for epilepsy),
  - colchicine (used to treat gout),
  - antacids (indigestion medicines containing aluminium or magnesium) and
  - medicines obtained without a prescription such as St John's Wort.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using **VASMAK**. Your doctor will tell you when it is safe to restart **VASMAK**. Taking **VASMAK** with fusidic acid may lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in **section 4**.

VASMAK with food and drink
You can take **VASMAK** with or without food. Avoid grapefruit juice and large quantities of alcohol.

Pregnancy and breastfeeding
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 **VASMAK**.
Do not take **VASMAK** if you are pregnant, or if you are trying to become pregnant.
Do not take **VASMAK** if you are able to become pregnant unless you use reliable contraceptive measures.
Do not take **VASMAK** if you are breastfeeding.
The safety of **VASMAK** during pregnancy and breastfeeding has not yet been proven.

Driving and using machines
Normally **VASMAK** does not affect your ability to drive or operate machines. However, do not drive if **VASMAK** affects your ability to drive. Do not use any tools or machines if your ability to use them is affected by **VASMAK**.

VASMAK contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **VASMAK**.

3. How to take VASMAK

Do not share medicines prescribed for you with any other person.
Always take **VASMAK** tablets exactly as your doctor has instructed you. Your doctor will decide on the appropriate dose of **VASMAK**, depending on your condition and whether you are taking other medicines.
The usual starting dose is 10 mg once a day. Your doctor may increase the dose, if necessary until you are taking the correct amount required. The maximum dose is 80 mg once a day. **VASMAK** tablets can be taken at any time of the day with or without food. However, try to take your tablet at the same time every day. Remember to continue with your diet and lifestyle changes while you are taking **VASMAK**.
If you have the impression that **VASMAK** is too strong or too weak, talk to your doctor or pharmacist.

If you take more VASMAK than you should
In the event of overdosage or accidental intake, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take VASMAK
If you miss a dose of **VASMAK**, take it as soon as you remember, unless it is time to take the next dose. Do not take 2 doses at the same time to make up for the forgotten dose.

4. Possible side effects

VASMAK can have side effects.

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

If any of the following happens, stop taking **VASMAK** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to **VASMAK**. 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:
- serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever. Skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister,
- muscle weakness, tenderness, pain or rupture, red-brown discolouration of urine and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown. The abnormal muscle breakdown does not always go away, even after you have stopped taking atorvastatin it can be life-threatening and lead to kidney problems,
- if you experience problems with unexpected or unusual bleeding or bruising, this may be suggestive of a liver complaint,
- lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

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

Tell your doctor if you notice any of the following:
Frequent
- inflammation of the nasal passages, pain in the throat, nose bleed,
- allergic reactions,
- increases in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels), increase in blood creatine kinase,
- headache,
- nausea, constipation, wind, indigestion, diarrhoea,
- joint pain, muscle pain and back pain,
- blood test results that show your liver function can become abnormal.

Less frequent
- anorexia (loss of appetite), weight gain, decreases in blood sugar levels (if you have diabetes you should continue careful monitoring of your blood sugar levels),
- having nightmares, insomnia,
- dizziness, numbness or tingling in the fingers and toes, reductions of sensation to pain or touch, change in sense of taste, loss of memory,
- blurred vision,
- ringing in the ears and/or head,
- vomiting, belching, abdominal pain (upper and lower), pancreatitis (inflammation of the pancreas leading to stomach pain),
- hepatitis (liver inflammation),
- rash, skin rash and itching, hives, hair loss,
- neck pain, muscle fatigue
- fatigue, feeling unwell, weakness, chest pain, swelling especially in the ankles (oedema), raised temperature,
- urine tests that are positive for white blood cells,
- visual disturbance,
- unexpected bleeding or bruising,
- cholestasis (yellowing of the skin and whites of the eyes),
- tendon injury,
- an allergic reaction - symptoms may include sudden wheezing and chest pain
- tightness, swelling of the eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse,
- hearing loss,
- gynecomastia (breast enlargement in men).

Frequency not known
- muscle weakness that is constant.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com. By reporting side effects, you can help provide more information on the safety of **VASMAK**.

5. How to store VASMAK

Store at or below 25 °C (room temperature). Protect from light.
Store all medicines out of reach of children.
Store in the original package / container.
Keep the blisters in the carton until required for use.
Keep the HDPE containers tightly closed.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / label / carton / bottle.
Return all unused medicine 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 VASMAK contains
The active substance is atorvastatin calcium trihydrate equivalent to atorvastatin 10 mg, 20 mg, 40 mg and 80 mg
Tablet core excipients:
Calcium carbonate, croscarmellose sodium, hydroxy propyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polysorbate 80.
Film coating containing:
Hypromellose, Polyethylene Glycol 8000, Talc, Titanium Dioxide
Contains lactose

What VASMAK looks like and contents of the pack
VASMAK 10 MG:
White to off-white, oval shaped biconvex film coated tablets debossed with "M35" on one side and plain on other side.
VASMAK 20 MG:
White to off-white, oval shaped biconvex film coated tablets debossed with "M36" on one side and plain on other side.
VASMAK 40 MG:
White to off-white, oval shaped biconvex film coated tablets debossed with "M37" on one side and plain on other side.
VASMAK 80 MG:
White to off-white, oval shaped biconvex film coated tablets debossed with "M38" on one side and plain on other side

1) Blister Pack
Tablets are packed in cold form laminate 25 µ OPA/ 45 µ aluminium foil / 60 µ PVC as the forming material and 25 µ Aluminium plain foil/ 6-8 gsm heat seal lacquered as the lidding material, packed in a pre-printed carton.
Blister pack of 28, 30, 56, 60, 84, 90, 100 and 500 tablets

2) HDPE Container Pack
Container packs of 90 tablets
VASMAK 10 MG Round, white, HDPE container, 60 cc, 33 mm necks finish with a 33 mm child resistant closure and 1 g silica gel sachet
VASMAK 20 MG Round, white, HDPE container, 60 cc, 33 mm neck finish with a 33 mm child resistant closure and 3 g silica gel sachet
VASMAK 40 MG Round, white, HDPE container, 120 cc, 38 mm neck finish with a 38 mm child resistant closure and 3 g silica gel sachet
VASMAK 80 MG Round, white, HDPE container, 200 cc, 38 mm neck finish with a 38 mm child resistant closure and 3 g silica gel sachet

Container packs of 500 tablets
VASMAK 10 MG Round, white, HDPE container, 120 cc, 38 mm neck finish with a 38 mm continuous thread closure and 3 g silica gel sachet
VASMAK 20 MG Round, white, HDPE container, 250 cc, 53 mm neck finish with a 53 mm continuous thread closure and 3 g silica gel sachet
VASMAK 40 MG Round, white, HDPE container, 500 cc, 53 mm neck finish with a 53 mm continuous thread closure and 3 g silica gel sachet
VASMAK 80 MG Round, white, HDPE container, 950 cc, 53 mm neck finish with a 53 mm continuous thread closure and 3 g silica gel sachet
Not all packs and pack sizes are necessarily 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.

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Registration numbers
VASMAK 10 MG: 52/7.5/0321
VASMAK 20 MG: 52/7.5/0322
VASMAK 40 MG: 52/7.5/0323
VASMAK 80 MG: 52/7.5/0324

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodssaproducts.co.za or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

335 mm

Back Side

320 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

VASMAK 10 MG filmbedekte tablette
Atorvastatienkalsiumtrihidraat gelykwaardig aan 10 mg atorvastatien
Bevat 33,31 mg laktosemonohidraat
VASMAK 20 MG filmbedekte tablette
Atorvastatienkalsiumtrihidraat gelykwaardig aan 20 mg atorvastatien
Bevat 66,62 mg laktosemonohidraat
VASMAK 40 MG filmbedekte tablette
Atorvastatienkalsiumtrihidraat gelykwaardig aan 40 mg atorvastatien
Bevat 133,24 mg laktosemonohidraat
VASMAK 80 MG filmbedekte tablette
Atorvastatienkalsiumtrihidraat gelykwaardig aan 80 mg atorvastatien
Bevat 266,48 mg laktosemonohidraat
Bevat suiker: laktosemonohidraat

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy VASMAK begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het.
- **VASMAK** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat in hierdie inligtingstuk is

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

1. Wat VASMAK is en waarvoor dit gebruik word

VASMAK bevat 'n medisyne naamlik atorvastatien wat aan 'n groep van medisyne behoort bekend as lipied of cholesterol (vet) regulerende medisyne, algemeen bekend as statiene.
VASMAK verlaag die cholesterol in jou bloed. Dit verlaag die LDL-C (slegte cholesterol) en trigliseriede in jou bloed. Dit kan jou HDL-C (goeie cholesterol) ook verhoog. **VASMAK** is vir volwassenes en kinders ouer as 10 jaar oud wie se cholesterol nie genoeg verlaag met oefening en 'n lae vet dieet alleen nie.
VASMAK kan die risiko van hartsiektes en versteurings van die bloedvate van die brein verlaag, wat toestande is as gevolg van verminderde bloedtoevoer, in pasiënte wat verskeie risiko faktore vir hartsiektes het, soos rook, hipertensie, diabetes, lae HDL-C, of 'n familiegeskiedenis van vroeë koronêre hartsiekte. **VASMAK** kan hartgevalle in pasiënte met hartsiektes en hoë cholesterolvlakke verminder.

2. Wat jy behoort te weet voordat jy VASMAK gebruik

Moet nie VASMAK neem nie:
- indien jy hipersensitief (allergies) vir atorvastatien of enige van die ander bestanddele van **VASMAK** is (gelys in **afdeling 6**).
- indien jy 'n siekte het of al ooit gehad het wat die lewer aantas.
- indien jy enige onverklaarbare abnormale bloedtoetse vir lewerfunksie gehad het.
- indien jy die kombinasie van glekaprevir/pibrentasvir gebruik in die behandeling van hepatitis C.
- indien jy 'n vrou is wat kinders kan hê en nie betroubare voorbehoedmiddels gebruik nie.
- indien jy swanger is, of probeer om swanger te raak.
- indien jy borsvoed.
- indien jy rifampisien, 'n antibiotika vir infeksie neem.
- indien jy diltiasem, 'n kalsiumkanaalblokker neem vir angina of hoë bloeddruk.
- indien jy pomelosap drink.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met VASMAK:
- indien jy 'n medisyne genaamd fusidiensuur ('n medisyne vir bakteriële infeksie) mondelings of deur inspuiting neem of in die laaste 7 dae geneem het. Die kombinasie van fusidiensuur en **VASMAK** kan lei tot ernstige spierprobleme (rabdomiolise).
- indien jy 'n vorige beroerte gehad het met bloeding in die brein of klein sakkies met vloeistof in die brein het van vorige beroertes.
- indien jy nierprobleme het.
- indien jy 'n onderaktiewe skildklier het (hipotireose).
- indien jy herhaalde of onverklaarbare spierpyne of skete gehad het, 'n persoonlike geskiedenis of familiegeskiedenis van spierprobleme.
- indien jy interstisiële longsiekte het ('n groep longafwykings waarin die longweefsel ontsteek en dan beskadig word).
- indien jy vorige spierprobleme gehad het tydens behandeling met ander lipiedverlagende medisyne (bv. ander 'statiene' of 'fibraat' medisyne).
- indien jy gereeld 'n groot hoeveelheid alkohol drink en/of 'n geskiedenis van lewersiekte het.
- indien jy ouer as 70 jaar oud is.

Indien enige van hierdie op jou van toepassing is, sal jou dokter 'n bloedtoets wil uitvoer voor en moontlik tydens jou behandeling met **VASMAK** om jou risiko van spierverwante newe-effekte te bepaal. Die risiko van spierverwante newe-effekte bv. rabdomiolise is bekend om toe te neem wanneer sekere medisyne gelyktydig geneem word (sien **afdeling 2 "Ander medisyne en VASMAK**"). Vertel ook jou dokter of apteker indien jy 'n spierswakheid het wat konstant is. Bykomende toetse en medisyne mag nodig wees om dit te diagnoseer en te behandel.
Terwyl jy hierdie medisyne gebruik, sal jou dokter jou noukeurig monitor as jy diabetes het of die risiko loop om diabetes te ontwikkel. Jy loop waarskynlik die risiko om diabetes te ontwikkel as jy hoë vlakke van suikers en vette in jou bloed het, oorgewig is en hoë bloeddruk het.

Kinders en adolessente
Moet nie **VASMAK** aan kinders onder die ouderdom van 10 jaar oud gee nie.
Ander medisyne en VASMAK
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Daar is sommige medisyne wat die effek van **VASMAK** kan verander of hul effek kan deur **VASMAK** verander word. Hierdie tipe interaksie kan een of albei van die medisyne minder doeltreffend maak. Alternatiewelik kan dit die risiko of erns van newe-effekte verhoog, insluitend die belangrike spiervermorsingstoestand bekend as rabdomiolise wat in **afdeling 4 "Moontlike newe-effekte"** beskryf word:
- Medisyne wat gebruik word om die manier waarop jou immuunstelsel werk te verander, bv. siklosporien.
- Sekere antibiotika of swambestrydende medisyne, bv. eritromisien, klaritromisien, telitromisien, ketokonasool, itrakonasool, vorikonasool, flukonasool, posakonasool, rifampisien, fusidiensuur.
- Ander medisyne om lipiedvlakke te reguleer, bv. gemfibrosil, ander fibrate, kolestipol.
- Sommige kalsiumkanaalblokkeerders wat gebruik word vir angina of hoë bloeddruk, bv. amlodipien, diltiasem; medisyne om jou hartritme te reguleer bv. digoksien, verapamil, amiodaroon.
- Medisyne wat gebruik word in die behandeling van MIV bv. atasanavir, indinavir, sakwinavir plus ritonavir, lopinavir plus ritonavir, tipranavir plus ritonavir, darunavir plus ritonavir, fosamprenavir en fosamprenavir plus ritonavir.
- Sommige medisyne wat gebruik word in die behandeling van hepatitis C bv. telaprevir, boseprevir en die kombinasie van elbasvir/grasoprevir.
- Ander medisyne wat bekend is daarvoor dat hulle met atorvastatien interaksie het, sluit in:
  - esetimieb (wat cholesterol verlaag),
  - warfarien (wat bloedstolling verminder),
  - orale voorbehoedmiddels,
  - stiripentol ('n anti-konvulsiemiddel vir epilepsie),
  - kolgisien (gebruik om jig te behandel),
  - teensuurmiddels (medisyne vir swak spysvertering wat aluminium of magnesium bevat) en
  - medisyne wat sonder 'n voorskrif verkry word, soos St Johannes kruid.

Vertel jou dokter of apteker indien jy enige ander medisyne gebruik, onlangs gebruik het of dalk kan gebruik.
- Indien jy orale fusidiensuur moet neem om 'n bakteriële infeksie te behandel, sal jy tydelik moet ophou om **VASMAK** te gebruik. Jou dokter sal vir jou sê wanneer dit veilig is om weer met **VASMAK** te begin. Die neem van **VASMAK** saam met fusidiensuur kan lei tot spierswakheid, teerheid of pyn (rabdomiolise). Sien meer inligting oor rabdomiolise in **afdeling 4**.

VASMAK met voedsel en drank
Jy kan **VASMAK** met of sonder kos neem. Vermy pomelosap en groot hoeveelhede alkohol.

Swangerskap en borsvoeding
Indien jy swanger is of borsvoed, vermoed dat jy moontlik swanger kan wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy **VASMAK** neem.
Moet nie **VASMAK** neem indien jy swanger is, of as jy probeer om swanger te raak nie.
Moet nie **VASMAK** neem as jy swanger kan raak nie, tensy jy betroubare voorbehoedmaatreëls gebruik.
Moet nie **VASMAK** neem indien jy borsvoed nie.
Die veiligheid van **VASMAK** gedurende swangerskap en borsvoeding is nog nie bewys nie.

Bestuur en gebruik van masjinerie
Normaalweg beïnvloed **VASMAK** nie jou vermoë om te bestuur of masjinerie te hanteer nie. Moet egter nie bestuur indien **VASMAK** jou vermoë om te bestuur beïnvloed nie. Moet nie enige gereedskap of masjiene gebruik indien jou vermoë om dit te gebruik deur **VASMAK** beïnvloed word nie.

VASMAK bevat laktose
Raadpleeg jou dokter voordat jy **VASMAK** neem, indien jou dokter vir jou gesê het dat jy 'n onverdraagsaamheid teenoor sommige suikers het.

3. Hoe om VASMAK te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **VASMAK** tablette presies soos jou dokter jou beveel het. Jou dokter sal besluit oor die toepaslike dosis van **VASMAK**, afhangend van jou toestand en of jy ander medisyne neem. Die gewone aanvangsdosis is 10 mg een keer per dag. Jou dokter kan die dosis verhoog, indien nodig, totdat jy die regte hoeveelheid wat benodig word neem. Die maksimum dosis is 80 mg een keer per dag. **VASMAK** tablette kan enige tyd van die dag met of sonder kos geneem word. Probeer egter om jou tablet elke dag op dieselfde tyd te neem. Onthou om voort te gaan met jou dieet en lewenstylveranderinge terwyl jy **VASMAK** gebruik.
Indien jy onder die indruk is dat **VASMAK** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer VASMAK neem as wat jy behoort te neem
In die geval van 'n oordosering of toevallige inname, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om VASMAK te neem
Indien jy 'n dosis van **VASMAK** oorslaan, neem dit so gou as wat jy daarvan onthou, tensy dit tyd is om die volgende dosis te neem. Moet nie 2 dosisse gelyktydig neem om vir die vergete dosis op te maak nie.

4. Moontlike newe-effekte

VASMAK kan newe-effekte hê.

Nie alle newe-effekte wat vir **VASMAK** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of indien jy enige ongewenste effekte ervaar terwyl jy **VASMAK** gebruik, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om **VASMAK** te neem en vertel onmiddellik jou dokter daarvan of gaan na die ongevalle afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal.
- uitslag of jeuk.

Al hierdie newe-effekte is baie ernstig. Indien jy dit ervaar, het jy moontlik 'n ernstige reaksie op **VASMAK** gehad. Jy mag dringende mediese aandag of hospitalisasie benodig.

Vertel onmiddellik jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy enige van die volgende waarneem**:**
- ernstige siekte met erge afskilfering en swelling van die vel, blase van die vel, mond, oë, geslagsdele en koors. Veluitslag met pienk-rooi vlekke veral op handpalms of voetsole wat blase kan vorm,
- spierswakheid, teerheid, pyn of skeuring, rooibruin verkleuring van uriene en veral, as jy terselfdertyd onwel voel of 'n hoë temperatuur het, kan dit veroorsaak word deur 'n abnormale spierafbreking. Die abnormale spierafbreking gaan nie altyd weg nie, selfs nadat jy opgehou het om atorvastatien te neem kan dit lewensgevaarlik wees en tot nierprobleme lei,
- indien jy probleme ervaar met onverwagte of ongewone bloeding of kneusing, kan dit dui op 'n lewerklag,
- lupusagtige siektesindroom (insluitend uitslag, gewrigsafwykings en uitwerking op bloedselle).

Al hierdie newe-effekte is ernstig. Jy mag dringende mediese aandag benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereeld
- ontsteking van die neusgange, pyn in die keel, neusbloeding,
- allergiese reaksies,
- stygings in bloedsuikervlakke (indien jy diabetes het, gaan voort om jou bloedsuikervlakke noukeurig te monitor), toename in bloedkreatienkinase,
- hoofpyn,
- naarheid, hardlywigheid, winde, swak spysvertering, diaree,
- gewrigspyn, spierpyn en rugpyn,
- bloedtoetsresultate wat wys dat jou lewerfunksie abnormaal kan word.

Minder gereeld
- anoreksie (verlies aan eetlus), gewigstoename, afname in bloedsuikervlakke (indien jy diabetes het, moet jy voortgaan om jou bloedsuikervlakke noukeurig te monitor),
- kry nagmerries, slapeloosheid,
- duiseligheid, gevoelloosheid of tinteling in die vingers en tone, vermindering in sensasie van pyn of aanraking, verandering in smaaksintuig, geheueverlies,
- dowwe visie,
- gesuis in die ore en/of kop,
- braking, winde opbreek, boonste en onderste abdominale pyn, pankreatitis (ontsteking van die pankreas wat lei tot maagpyn),
- hepatitis (lewerontsteking),
- uitslag, veluitslag en jeuk, galbulte, haarverlies,
- nekpyn, spiervermoeidheid
- vermoeidheid, voel onwel, swakheid, borskaspyn, swelling veral in die enkels (edeem), verhoogde temperatuur,
- urientoetse wat positief is vir witbloedselle,
- visuele versteuring,
- onverwagte bloeding of kneusing,
- cholestase (vergeling van die vel en wit van die oë),
- seningbesering,
- 'n allergiese reaksie - simptome kan skielike asemgefluit en borskaspyn insluit
- styfheid, swelling van die ooglede, gesig, lippe, mond, tong of keel, moeilike asemhaling, ineenstorting,
- gehoorverlies,
- ginekomastie (borsvergroting by mans).

Onbekende frekwensie
- spierswakheid wat konstant is.

Indien jy enige newe-effekte waarneem wat nie in hierdie inligtingstuk genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA se webwerf gevind word of aan Macleods Pharmaceuticals SA (Edms) Bpk. by safety@macleodspharma.com. Deur newe-effekte aan te meld, kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **VASMAK**.

5. Hoe om VASMAK te bewaar

Bewaar by of benede 25 °C (kamertemperatuur). Beskerm teen lig.
Bewaar alle medisyne buite bereik van kinders.
Bewaar in die oorspronklike verpakking/houer.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Hou die HDPE houers dig toe.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat op die stulpstrook/etiket/karton/bottel aangebring is nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat VASMAK bevat
Die aktiewe bestanddeel is atorvastatienkalsiumtrihidraat gelykwaardig aan 10 mg, 20 mg, 40 mg en 80 mg atorvastatien.
Tabletkern:
Kalsiumkarbonaat, natriumkroskarmellose, hidroksipropielsellulose, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, polisorbaat 80.
Filmbedekking bevat:
Hipromellose, poliëtileenglikol 8 000, talk, titaniumdioksied
Bevat laktose

Hoe VASMAK lyk en inhoud van die pak
VASMAK 10 MG:
Wit tot naaswit, ovaalvormige bikonvekse filmbedekte tablette, met "M35" ingeprent op die een kant en glad op die ander kant.
VASMAK 20 MG:
Wit tot naaswit, ovaalvormige bikonvekse filmbedekte tablette, met "M36" ingeprent op die een kant en glad op die ander kant.
VASMAK 40 MG:
Wit tot naaswit, ovaalvormige bikonvekse filmbedekte tablette, met "M37" ingeprent op die een kant en glad op die ander kant.
VASMAK 80 MG:
Wit tot naaswit, ovaalvormige bikonvekse filmbedekte tablette, met "M38" ingeprent op die een kant en glad op die ander kant.

1) Stulpverpakking
Tablette word verpak in koue vorm laminaat 25 µ OPA/45 µ aluminiumfoelie/60 µ PVC as die vormingsmateriaal en 25 µm aluminiumfoelie/6-8 gsm hitteseëllak as die dekmateriaal, verpak in 'n voorafgedrukte karton.
Stulpverpakking van 28, 30, 56, 60, 84, 90, 100 en 500 tablette.

2) HDPE Houer verpakking
Houer verpakkings van 90 tablette
VASMAK 10 MG Rond, wit, HDPE houer, 60 cc, 33 mm nekafwerking met 'n 33 mm kinderbestande sluiting en 1 g silikagel sakkie
VASMAK 20 MG Rond, wit, HDPE houer, 60 cc, 33 mm nekafwerking met 'n 33 mm kinderbestande sluiting en 3 g silikagel sakkie
VASMAK 40 MG Rond, wit, HDPE houer, 120 cc, 38 mm nekafwerking met 'n 38 mm kinderbestande sluiting en 3 g silikagel sakkie
VASMAK 80 MG Rond, wit, HDPE houer, 200 cc, 38 mm nekafwerking met 'n 38 mm kinderbestande sluiting en 3 g silikagel sakkie

Houer verpakkings van 500 tablette
VASMAK 10 MG Rond, wit, HDPE houer, 120 cc, 38 mm nekafwerking met 'n 38 mm deurlopende draadsluiting en 3 g silikagel sakkie
VASMAK 20 MG Rond, wit, HDPE houer, 250 cc, 53 mm nekafwerking met 'n 53 mm deurlopende draadsluiting en 3 g silikagel sakkie
VASMAK 40 MG Rond, wit, HDPE houer, 500 cc, 53 mm nekafwerking met 'n 53 mm deurlopende draadsluiting en 3 g silikagel sakkie
VASMAK 80 MG Rond, wit, HDPE houer, 950 cc, 53 mm nekafwerking met 'n 53 mm deurlopende draadsluiting sluiting en 3 g silikagel sakkie
Nie alle verpakkings en verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid Afrika

Hierdie inligtingstuk was hersien in
14 Junie 2022

Registrasienommer
VASMAK 10 MG: 52/7.5/0321
VASMAK 20 MG: 52/7.5/0322
VASMAK 40 MG: 52/7.5/0323
VASMAK 80 MG: 52/7.5/0324

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodssaproducts.co.za of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Exclusion of PI from text matter as per commercial requirement, change in type of closure for 80 mg strength and change in dimensions of leaflet.

1. Product: VASMAK 10/20/40/80 MG (Atorvastatin Tablets 10/20/40/80 mg)	
2. Country: South Africa - Private Market	**3. Packaging component: Patient Information Leaflet**
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 320 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM04342089**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 41064 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: PM03845401**
15. Revision No: 01	**16. A/W File name: G:\Regulated_Artwork\SOUTH AFRICA\Atorvastatin Calcium\SA Private Market\02\Vasmak PIL -PM04342089.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	12/03/2026 				

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 Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa- Private Market	**PM03845401**	**06/09/22**	**22/07/24**
2) Exclusion of PI from text matter as per commercial requirement, change in type of closure for 80 mg strength and change in dimensions of leaflet.	**PM04342089**		