Front Side

260 mm

335 mm

AVIOLIX 75
(film-coated tablet)
PM04340275

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

AVIOLIX 75 (film-coated tablet)
Clopidogrel
Contains Sugar (191,375 mg of lactose monohydrate)

Read all of this leaflet carefully before you start taking AVIOLIX 75
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AVIOLIX 75** 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 **AVIOLIX 75** is and what it is used for
2. What you need to know before you take **AVIOLIX 75**
3. How to take **AVIOLIX 75**
4. Possible side effects
5. How to store **AVIOLIX 75**
6. Contents of the pack and other information

1. What AVIOLIX 75 is and what it is used for

AVIOLIX 75 contains the active substance clopidogrel.
AVIOLIX 75 belongs to a group of medicines called antiplatelet medicines. **AVIOLIX 75** is taken to prevent blood clots forming in hardened blood vessels which can lead to events such as stroke, heart attack or death. You have been prescribed **AVIOLIX 75** to help prevent blood clots and reduce the risk of these severe events.

2. What you need to know before you take AVIOLIX 75

Do not take AVIOLIX 75:
- If you are hypersensitive (allergic) to clopidogrel, or any of the other ingredients of **AVIOLIX 75** (listed in **section 6.1**).
- If you have a medical condition that is currently causing bleeding such as an active bleeding stomach ulcer or bleeding within the brain.
- **AVIOLIX 75** should not be taken by children and adolescents below the age of 18.
- If you suffer from severe liver disease.
- If you are pregnant or breastfeeding.
- If you have thrombocytopenia (low count of platelets, which help blood to clot) or dysfunction of the platelets.

Warnings and precautions
AVIOLIX 75 has been reported to cause a blood disorder called thrombotic thrombocytopenic purpura (TTP), which causes blood clots in the small blood vessels throughout the body. If you experience any of the following symptoms contact your doctor or other healthcare provider immediately:
- fever
- bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness
- confusion
- yellowing of the skin or eyes (jaundice)

Inform your doctor before taking **AVIOLIX 75** if any of the situations below apply to you:
- If you have a risk of bleeding such as:
  - A medical condition that puts you at risk of internal bleeding (such as stomach ulcer).
  - A blood disorder that makes you prone to internal bleeding (bleeding inside any tissues, organs or joints of your body).
  - A recent serious injury.
  - A recent surgery (including dental).
  - A planned surgery (including dental) in the next seven days.
- If you have had a clot in artery of your brain (ischaemic stroke) which occurred within the last seven days.
- If you have kidney or liver disease.
- If you are taking medicines that increase your risk of bleeding (see **Taking other medicines**).

Children and adolescents
AVIOLIX 75 should not be taken by children and adolescents below the age of 18.

Other medicines and AVIOLIX 75
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 medicines that may increase your chance of bleeding such as:
  - Aspirin (Acetyl Salicylic Acid), when taken for prolonged periods, except when it has been specifically recommended by your doctor. An occasional dose of aspirin should not cause a problem.
  - Other medicines used to reduce blood clotting such as warfarin and heparin.
  - NSAIDs and COX2-inhibitors (medicines used to treat painful and / or inflammatory conditions of muscles or joints) when taken for prolonged periods.
  - Medicines used to treat depression or anxiety including selective serotonin reuptake inhibitors (including but not restricted to fluoxetine or fluvoxamine).
  - Ticlopidine, prasugrel, abciximab; eptifibatide; and tirofiban (other antiplatelet medicine used to prevent formation of blood clots).
- Tell your doctor if you are taking
  - repaglinide (medicine used to treat diabetes) or paclitaxel (medicine used to treat cancer)
  - omeprazole and esomeprazole (medicines used to treat upset stomach).
  - phenytoin (to treat epilepsy)
  - tolbutamide (for diabetes)
  - tamoxifen (for breast cancer)
  - fluvastatin (used to treat high blood cholesterol).

AVIOLIX 75 with food and drink and alcohol:
AVIOLIX 75 can be taken with or without food.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking **AVIOLIX 75**.
- You must not take **AVIOLIX 75** during pregnancy.
- Do not breastfeed during treatment with **AVIOLIX 75**.

Driving and using machines
Do not drive or operate machines until you know how **AVIOLIX 75** will affect you.

AVIOLIX 75 contains lactose
Tell your doctor if you have galactosaemia (a condition in which the body is unable to use the sugar galactose) or glucose / galactose malabsorption syndrome. **AVIOLIX 75** contains lactose and is unsuitable for patients with these disorders.

3. How to take AVIOLIX 75

Do not share medicines prescribed for you with any other person.
Always take **AVIOLIX 75** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **AVIOLIX 75** is too strong or too weak, talk to your doctor or pharmacist.
- Stay under a healthcare provider's care when taking **AVIOLIX 75**. Do not change your treatment or stop treatment without first talking with your healthcare provider.
- The usual dose of **AVIOLIX 75** is one tablet once a day, taken with or without food.
- **AVIOLIX 75** should not be given to patients less than 18 years of age.

If you take more AVIOLIX 75 than you should
- Seek emergency medical attention if you think you have used too much of **AVIOLIX 75**. A large dose of **AVIOLIX 75** could put you at risk of serious bleeding requiring emergency treatment.

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 AVIOLIX 75
If you forget to take a dose, take it as soon as you remember, and then continue as before. Do not take a double dose to make up for forgotten individual doses.

If you stop taking AVIOLIX 75
Do not stop taking your tablets just because you feel better. It is important that you carry on taking **AVIOLIX 75** for as long as your doctor tells you.

4. Possible side effects

AVIOLIX 75 can have side effects.
Not all side effects reported for **AVIOLIX 75** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking **AVIOLIX 75** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Hives; difficulty breathing; swelling of your face, lips, tongue, or throat.
- Acquired haemophilia A (AHA) which is a potentially life-threatening bleeding disorder occurring in patients without a previous personal or family history of bleeding. Specific symptoms can include nosebleeds, bruising throughout the body, solid swellings of congealed blood, blood in the urine and bleeding from the stomach.
- A severe allergic reaction to the medicine characterised by fever, rash, and multiorgan failure, occurring 1-8 weeks after taking **AVIOLIX 75**.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **AVIOLIX 75**. 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:
- Fever, chills, sore throat, cough, or other signs of infection, or extreme tiredness. These may be due to a decrease in some blood cells.
- Signs of liver problems such as yellowing of the skin and/or the eyes (jaundice), whether or not associated with bleeding which appears under the skin as red pinpoint dots and/or confusion (see **Take special care with AVIOLIX 75**).
- **The most frequent side effect reported with AVIOLIX 75 is bleeding.** Bleeding may occur as bleeding in the stomach or bowels, bruising, haematoma (unusual bleeding or bruising under the skin), nose bleed, blood in the urine. Bleeding in the eye, inside the head, the lung or the joints and bleeding from an operation wound has also been reported.
- Vomiting of blood or coughing up of blood.
- Prolonged bleeding.
- Swelling of the pancreas with symptoms of upper abdominal pain, nausea and vomiting.
- Serum sickness with symptoms of fever, general ill feeling, hives, itching, joint pain, rash, swollen lymph nodes.
- Swelling of the lungs causing coughing, difficulty breathing and wheezing.
- Eosinophilic pneumonia (increase in some white blood cells in the lungs). Symptoms include progressive shortness of breath (dyspnoea), respiratory failure, cough, fatigue, night sweats, fever, and unintended weight loss.
- Itching, inflamed, cracking, blistering of the skin or red skin.
- Confusion or hallucinations.

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:
- Diarrhoea, abdominal pain, indigestion or heartburn
- Bruising
- Bleeding at puncture site

Less frequent side effects:
- Anaemia (being tired and looking pale).
- Headache, dizziness, sensation of tingling and numbness in hands and feet, changes in the way things taste.
- Vertigo.
- Narrowing or blockage of blood vessels, low blood pressure.
- Chest pain caused by reduced blood flow to the heart caused by an allergic reaction or a strong immune reaction to **AVIOLIX 75**.
- Difficulty in breathing, wheezing or coughing.
- Stomach ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines, sore mouth, diarrhoea with blood, mucus, stomach pain and fever (colitis).
- Enlarged breasts in males.
- Abnormal liver functions tests.
- Purplish, itchy, flat-topped bumps on the skin lacy, white patches, sometimes with painful sores in the mouth, itchy, swollen, red skin, eczema.
- Joint pain; muscular pain.
- Kidney disease.
- Fever or other signs of infection, such as a sore throat.
- In addition, your doctor may identify changes in your blood or urine test results.

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 **AVIOLIX 75.**

5. How to store AVIOLIX 75

Store at or below 25 °C (room temperature). Protect from light. Keep the containers tightly closed.
Keep the blister in the carton until required for use.
KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What AVIOLIX 75 contains
The active substance is clopidogrel.
Each film-coated tablet contains clopidogrel hydrogen sulphate equivalent to 75 mg of clopidogrel. Contains sugar (191,375 mg of lactose monohydrate).
The other ingredients are: hydroxypropyl cellulose, lactose monohydrate, colloidal anhydrous silica, hydrogenated castor oil, dimethicone.
The coating ingredients contain: hypromellose, Macrogol 400, titanium dioxide (C.I. No: 77891), and iron oxide red (C.I. No.: 77491).

What AVIOLIX 75 looks like and contents of the pack
AVIOLIX 75
Pink coloured, circular, biconvex, film-coated tablet debossed "LII" on one side of the tablet and plain on other surface.

1) Blister Pack:
Tablets are packed in cold form laminate OPA/AL/PVC as the forming material and 25 µ aluminium foil with 6-8 gsm heat seal lacquer as the lidding material.
Pack size: 28's, 30's.

2) HDPE Container Pack:
Tablets are packed in white, round 40 ml HDPE container with 33 mm neck finish closed with 33 mm white closure with wad having induction sealing liner. Each container contains 30 tablets.
Pack size: 30's - One HDPE container contains 30 tablets.
Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration and Manufacturer
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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28 February 2022

Registration number
AVIOLIX 75: 47/8.2/0009

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.

Back Side

260 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S3

AVIOLIX 75 (filmbedekte tablet)
Klopidogrel
Bevat suiker (191,375 mg laktosemonohidraat)

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy begin om AVIOLIX 75 te neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter of jou apteker indien jy verdere vrae het.
- **AVIOLIX 75** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as joune.

Wat in hierdie inligtingstuk is

1. Wat **AVIOLIX 75** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **AVIOLIX 75** neem
3. Hoe om **AVIOLIX 75** te neem
4. Moontlike newe-effekte
5. Hoe om **AVIOLIX 75** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat AVIOLIX 75 is en waarvoor dit gebruik word

AVIOLIX 75 bevat die akiewe bestanddeel klopidogrel.
AVIOLIX 75 behoort aan 'n groep van medisyne wat antiplaatjie-medisyne genoem word. **AVIOLIX 75** word geneem om te verhoed dat bloedklonte in verharde bloedvate vorm wat kan lei tot gebeurtenisse soos beroerte, hartaanval of dood. **AVIOLIX 75** is aan jou voorgeskryf om bloedklonte te help verhoed en die risiko van hierdie ernstige gebeurtenisse te verminder.

2. Wat jy behoort te weet voordat jy AVIOLIX 75 neem

Moet nie AVIOLIX 75 neem nie
- Indien jy hipersensitief (allergies) vir klopidogrel, of enige van die ander bestanddele van **AVIOLIX 75** is (gelys in **afdeling 6.1**).
- Indien jy 'n mediese toestand het wat huidiglik bloeding veroorsaak, soos 'n aktief bloeiende maagseer of bloeding in die brein.
- **AVIOLIX 75** moet nie deur kinders en adolessente jonger as 18 jaar oud geneem word nie.
- Indien jy aan ernstige lewersiekte ly.
- Indien jy swanger is of borsvoed.
- Indien jy trombositopenie het (lae hoeveelheid van plaatjies wat bloed help om te stol) of wanfunksie van die bloedplaatjies.

Waarskuwings en voorsorgmaatreëls
Daar is berig dat **AVIOLIX 75** 'n bloedversteuring naamlik trombotiese trombositopeniese purpura (TTP) veroorsaak, wat bloedklonte in die klein bloedvate regdeur die liggaam veroorsaak. Indien jy enige van die volgende simptome ervaar, kontak jou dokter of ander gesondheidsorgverskaffer onmiddellik:
- koors
- kneusing onder die vel wat kan voorkom as rooi speltpunt kolletjies, met of sonder onverklaarbare uiterste moegheid
- verwarring
- vergeling van die vel of oë (geelsug).

Stel jou dokter in kennis voordat jy **AVIOLIX 75** neem indien enige van die onderstaande situasies op jou van toepassing is:
- Indien jy. 'n risiko vir bloeding het soos:
  - 'n Mediese toestand wat jou blootstel aan die risiko vir inwendige bloeding (soos 'n maagseer).
  - 'n Bloedafwyking wat jou geneig maak tot inwendige bloeding (bloeding in enige weefsels, organe of gewrigte van jou liggaam).
  - 'n Onlangse ernstige besering.
  - 'n Onlangse operasie (insluitend tandheelkundig).
  - 'n Beplande operasie (insluitend tandheelkundig) in die volgende sewe dae.
- Indien jy 'n klont in die arterie van jou brein gehad het (isgemiese beroerte) wat binne die afgelope sewe dae plaasgevind het.
- Indien jy nier- of lewersiekte het.
- Indien jy medisyne neem wat jou risiko vir bloeding verhoog (sien **Neem ander medisyne**).

Kinders en adolessente
AVIOLIX 75 moet nie deur kinders en adolessente jonger as 18 jaar oud geneem word nie.

Ander medisyne en AVIOLIX 75
Vertel altyd vir jou gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
- Vertel jou dokter indien jy medisyne neem wat jou kans op bloeding kan verhoog soos:
  - Aspirien (asetielsalisielsuur), wanneer dit vir lang tydperke geneem word, behalwe wanneer dit spesifiek deur jou dokter aanbeveel is. 'n Dosis aspirien wat nou en dan geneem word, behoort nie 'n probleem te veroorsaak nie.
  - Ander medisyne wat gebruik word om bloedstolling te verminder soos warfarien en heparien.
  - NSAIM's en COX_2-inhibeerders (medisyne wat gebruik word om pynlike en/of inflammatoriese toestande van spiere of gewrigte te behandel) wanneer dit vir lang tydperke geneem word.
  - Medisyne wat gebruik word om depressie of angs te behandel, insluitend selektiewe serotonien heropname inhibeerders (insluitend, maar nie beperk tot fluoksetien of fluvoksamien nie).
  - Tiklopidien, prasugrel, absiksimab; eptifibatied; en tirofiban (ander antiplaatjie-medisyne wat gebruik word om die vorming van bloedklonte te verhoed).

- Vertel jou dokter indien jy enige van die volgende middels neem:
  - repaglinied (medisyne wat gebruik word om diabetes te behandel) of paklitaksel (medisyne wat gebruik word om kanker te behandel)
  - omeprasool en esomeprasool (medisyne wat gebruik word vir die behandeling van omgekrapte maag).
  - fenitoïen (om epilepsie te behandel)
  - tolbutamied (vir diabetes)
  - tamoksifeen (vir borskanker)
  - fluvastatien (gebruik om hoë bloedcholesterol te behandel).

AVIOLIX 75 met voedsel en drank en alkohol:
AVIOLIX 75 kan met or sonder voedsel geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **AVIOLIX 75** neem.
- Jy moet nie **AVIOLIX 75** neem gedurende swangerskap nie.
- Moet nie borsvoed gedurende behandeling met **AVIOLIX 75** nie.

Bestuur en gebruik van masjinerie
Moet nie bestuur of masjinerie hanteer totdat jy weet hoe **AVIOLIX 75** jou sal beïnvloed nie.

AVIOLIX 75 bevat laktose
Vertel jou dokter indien jy galaktosemie het ('n toestand waarin die liggaam nie die suikergalaktose kan gebruik nie) of glukose/galaktose wanabsorpsie sindroom. **AVIOLIX 75** bevat laktose en is nie geskik vir pasiënte met hierdie afwykings nie.

3. Hoe om AVIOLIX 75 te gebruik

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie
Neem altyd **AVIOLIX 75** presies soos jou dokter jou beveel het. Vra vir jou dokter of apteker indien jy onseker is. Indien jy onder die indruk is dat die effek van **AVIOLIX 75** te sterk of te swak is, praat met jou dokter of apteker.
- Bly onder 'n gesondheidsorgverskaffer se sorg wanneer jy **AVIOLIX 75** neem. Moet nie jou behandeling verander of jou behandeling staak sonder om eers met jou gesondheidsorgverskaffer te praat nie.
- Die gewone dosis van **AVIOLIX 75** is een tablet een keer per dag, geneem met of sonder kos.
- **AVIOLIX 75** moet nie aan pasiënte jonger as 18 jaar oud gegee word nie.

Indien jy meer AVIOLIX 75 geneem het as wat jy behoort te neem
- Soek nood mediese hulp indien jy vermoed dat jy te veel **AVIOLIX 75** geneem het. 'n Groot dosis **AVIOLIX 75** kan jou die risiko van ernstige bloeding laat loop wat noodbehandeling vereis.

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 AVIOLIX 75 te neem
Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy onthou, en gaan dan aan soos voorheen. Moet nie 'n dubbele dosis neem om vir vergete individuele dosisse op te maak nie.

Indien jy ophou om AVIOLIX 75 te neem
Moet nie ophou om jou tablette te neem net omdat jy beter voel nie. Dit is belangrik dat jy aanhou om **AVIOLIX 75** te neem vir so lank as wat jou dokter jou sê om dit te doen.

4. Moontlike newe-effekte

AVIOLIX 75 kan newe-effekte hê.
Nie al die newe-effkte wat vir **AVIOLIX 75** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of indien jy enige ongewenste effekte ervaar terwyl jy hieride medisyne neem, kontak asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, staak die gebruik van **AVIOLIX 75** en vertel onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Galbulte, moeilike asemhaling; swelling van jou gesig, lippe, tong of keel.
- Verworwe hemofilie A (VHA) wat 'n potensieel lewensgevaarlike bloedingsversteuring is wat voorkom in pasiënte sonder 'n vorige persoonlike- of familiegeskiedenis van bloeding. Spesifieke simptome kan neusbloeding, kneusing dwarsdeur die liggaam, soliede swellings van gestolde bloed, bloed in die uriene en bloeding uit die maag insluit.
- 'n Ernstige allergiese reaksie op die medisyne wat gekenmerk word deur koors, uitslag en multi-orgaanversaking, wat 1-8 weke na die inname van **AVIOLIX 75** voorkom.

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie teen **AVIOLIX 75** gehad het. Jy mag dringende mediese aandag of hospitalisasie nodig hê.

Vertel vir jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy enige van die volgende waarneem:
- Koors, koue koors, seer keel, hoes, of ander tekens van infeksie, of uiterste moegheid. Dit kan wees as gevolg van 'n verlaging in hoeveelheid van sommige bloedselle.
- Tekens van lewerprobleme soos vergeling van die vel en/of die oë (geelsug), hetsy geassosieer met bloeding wat verskyn onder die vel as rooi speltpunte en/of verwarring (sien **Wees veral versigtig met AVIOLIX 75**).
- **Die mees algemene newe-effek wat met AVIOLIX 75 aangemeld word, is bloeding**. Bloeding kan voorkom as bloeding in die maag of ingewande, kneusing, hematoom (ongewone bloeding of kneusing onder die vel), neusbloeding, bloed in die uriene. Bloeding in die oog, in die kop, die long of die gewrigte en bloeding vanuit 'n operasiewond is ook aangemeld.
- Braking van bloed of ophoes van bloed.
- Langdurige bloeding.
- Swelling van die pankreas met simptome van boonste buikpyn, naarheid en braking.
- Serumsiekte met simptome van koors, algemene gevoel van sleg voel, galbulte, jeuk, gewrigspyn, uitslag, geswelde limfknope.
- Swelling van die longe wat hoes, moeilike asemhaling en hyg veroorsaak.
- Eosinofiele longontsteking (toename in hoeveelheid van sommige witbloedselle in die longe). Simptome sluit in progressiewe kortasem (dispnee), respiratoriese versaking, hoes, moegheid, nagsweet, koors en onbeplande gewigsverlies.
- Jeukerige, ontsteekte, krakerige, blase op die vel of rooi vel.
- Verwarring of hallusinasies.

Hierdie is alles ernstige newe-effekte. Jy mag dalk dringende mediese hulp benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereelde newe-effekte:
- Diaree, abdominale pyn, swak spysvertering of sooibrand.
- Kneusing
- Bloeding by punktuur posisie.

Minder gereelde newe-effekte:
- Bloedarmoede (voel moeg en lyk bleek)
- Hoofpyn, duiseligheid, sensasie van tinteling en gevoelloosheid in hande en voete, verandering in die manier wat dinge proe.
- Vertigo.
- Vernouing of blokkasie van bloedvate, lae bloeddruk.
- Borskaspyn wat veroorsaak word deur verminderde bloedvloei na die hart wat veroorsaak word deur 'n allergiese reaksie of 'n sterk immuunreaksie op **AVIOLIX 75**.
- Moeilike asemhaling, asemgefluit of hoes.
- Maagseer, braking, naarheid, hardlywigheid, oormatige gas in maag of ingewande, seer mond, bloed in die stoelgang, slym, maagpyn en koors (kolitis).
- Vergrote borste in mans.
- Abnormale lewerfunksietoetse.
- Perserige, jeukerige, plat knoppe op die vel, wit kolle, soms met pynlike sere in die mond, jeukerige, geswelde, rooi vel, ekseem.
- Gewrigspyn; spierpyn.
- Niersiekte.
- Koors of ander tekens van infeksie, soos 'n seer keel.
- Daarbenewens kan jou dokter veranderinge in jou bloed- of urientoets resultate identifiseer.

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

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer 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 beskikbaar te stel aangaande die veiligheid van **AVIOLIX 75**.

5. Hoe om AVIOLIX 75 te bewaar

Bewaar by of benede 25°C (kamertemperatuur). Beskerm teen lig. Hou die houers dig toe.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
HOU ALLE MEDISYNE BUITE BEREIK EN SIG VAN KINDERS.
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 AVIOLIX 75 bevat
Die aktiewe bestanddeel is klopidogrel.
Elke filmbedekte tablet bevat klopidogrel hidrogeensulfaat ekwivalent aan 75 mg van klopidogrel. Bevat suiker (191,375 mg van laktosemonohidraat).
Die ander bestanddele is: hidroksipropielsellulose, laktosemonohidraat, kolloïdale anhidriese silika, gehidrogeneerde kasterolie, dimetikoon.
Die bedekkings bestanddele bevat: hipromellose, Makrogol 400, titaandioksied (C.I. No: 77891), en rooi ysteroksied (C.I. No.: 77491).

Hoe AVIOLIX 75 lyk en inhoud van die pak
AVIOLIX 75
Pienk gekleurde, sirkelvormige, bikonvekse, filmbedekte tablet met "LII" gedruk op die een kant van die tablet en glad aan die ander kant.

1) Stulpstrook verpakking:
Tablette word verpak in koue vorm gelamineerde OPA/AL/PVC as die vormingsmateriaal en 25 µ aluminiumfoelie met 6-8 gsm hitteseëllak as dekmateriaal.
Verpakkingsgrootte: 28's, 30's.

2) HDPE houer verpakking:
Tablette word verpak in wit, ronde 40 ml HDPE houer met 33 mm nekafwerking gesluit met 33 mm wit sluiting met induksie-seëlvoering. Elke houer bevat 30 tablette.
Verpakkingsgrootte: 30's – Elke HDPE houer bevat 30 tablette.
Nie alle verpakkings en verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat en Vervaardiger
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
28 Februarie 2022.

Registrasienommer
AVIOLIX 75: 47/8.2/0009

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

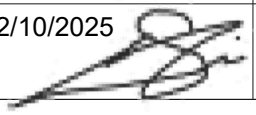
PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: AVIOLIX 75 (Clopidogrel Tablets 75 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 260 (W) mm**
9. Design / Style: Booklet type	**10. Item code No.: PM04340275**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40587 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: NA**
15. Revision no: 00	**16. A/W File name: Z:\South Africa\Clopidogrel Tablets 75 mg\SA Private Market\Daman\Clopidogrel Tablets 75 mg PIL - PM04340275.cdr**
Approved By:	**17. Location: Daman**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	22/10/2025 				

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.

Format No: FRM/SOP/CO/CQA/021/03-003

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa - Private Market	PM04340275		