Front Side

320 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

ELIQMAK 2,5 (film coated tablet)
ELIQMAK 5 (film coated tablet)
Apixaban
Contains sugar – lactose monohydrate
ELIQMAK 2,5: contains 50,25 mg lactose monohydrate.
ELIQMAK 5: contains 100,50 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking ELIQMAK
- 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.
- **ELIQMAK** 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 **ELIQMAK** is and what it is used for
2. What you need to know before you take **ELIQMAK**
3. How to take **ELIQMAK**
4. Possible side effects
5. How to store **ELIQMAK**
6. Contents of the pack and other information

1. What ELIQMAK is and what it is used for

ELIQMAK contains apixaban.

ELIQMAK belongs to a group of medicines called anticoagulants. It helps to prevent blood clots from forming by blocking Factor Xa, which is an important component of blood clotting.

ELIQMAK is used in adults:
- to prevent a blood clot from forming in the heart in patients with an irregular heart beat (atrial fibrillation) and at least one additional risk factor. Blood clots may break off and travel to the brain and lead to a stroke or to other organs and prevent normal blood flow to that organ (also known as a systemic embolism). A stroke can be life-threatening and requires immediate medical attention.
- to prevent blood clots in the veins of your legs (deep vein thrombosis) and in the blood vessels of your lungs (pulmonary embolism), and to prevent blood clots from re-occurring in the blood vessels of your legs and/or lungs.
- to treat blood clots in the veins of your legs (DVT) and in the blood vessels of your lungs (PE), and to prevent blood clots from re-occurring in the blood vessels of your legs and/or lungs.

2. What you need to know before you take ELIQMAK

Do not take ELIQMAK:
- If you are allergic to apixaban or any of the other ingredients of this medicine, listed in **section 6**.
- If you have excessive bleeding.
- If you have a liver disease which leads to increased risk of bleeding (hepatic coagulopathy);
- you are taking medicines to prevent blood clotting (e.g., warfarin, rivaroxaban, dabigatran or heparin), except when changing anticoagulant treatment, while having a venous or arterial line and you get heparin through this line to keep it open, or if a tube is inserted into your blood vessel (catheter ablation) to treat an irregular heartbeat (dysrhythmia).
- You have severe kidney failure.
- You have a condition that causes your blood to clot too easily.

Warnings and precautions
Talk to your doctor or healthcare provider before taking **ELIQMAK**
Take special care if an increased risk of bleeding, such as:
- bleeding disorders, including conditions resulting in reduced platelet activity; an active or recent ulcer of your stomach or bowel, infection of the heart (bacterial endocarditis), recent bleeding in your brain (haemorrhagic stroke), uncontrolled high blood pressure (hypertension) and recent brain, spinal or eye surgery.
- if you are older than 75 years;
- if you weigh 60 kg or less; you may have an increased risk of bleeding
- If you have a severe kidney disease or if you are on dialysis;
- if you have a liver problem or a history of liver problems;
- This medicine will be used with caution in patients with signs of altered liver function.
- if you have a prosthetic heart valve;
- if your doctor determines that your blood pressure is unstable or another treatment or surgical procedure to remove the blood clot from your lungs is planned.
- if you know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk of blood clots), tell your doctor who will decide if the treatment may need to be changed.

If you need to have surgery or a procedure which may cause bleeding, including the insertion of an epidural or intrathecal catheter your doctor might ask you to temporarily stop taking this medicine prior to surgery or invasive proedures. If you are not sure whether a procedure may cause bleeding ask your doctor.
If you have an active cancer, your healthcare provider must consider the risks versus the benefit of using ELIQMAK.
If you are using certain medicines to treat fungus such as ketoconazole, voriconazole or antiretroviral such as ritonavir, medicines to prevent epilepsy or seizures (e.g., phenytoin, etc.); St John's Wort (a herbal supplement used for depression); medicines to treat tuberculosis or other infections (e.g., rifampicin) you may have an increased risk of bleeding.

Use in children and adolescents
The use of **ELIQMAK** in children and adolescents (below the age of 18 years) is not recommended.

Other medicines and ELIQMAK
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Tell your doctor or pharmacist if you are taking any of the following medicines:
The following medicines may increase the effects of **ELIQMAK** and increase the chance for unwanted bleeding:
- some medicines for fungal infections (e.g., ketoconazole, itraconazole, voriconazole and posaconazole, fluconazole);
- some antiviral medicines for HIV / AIDS (e.g., ritonavir);
- other medicines that are used to reduce blood clotting (e.g., enoxaparin, clopidogrel or ticagrelor);
- anti-inflammatory or pain medicines (e.g., acetylsalicylic acid or naproxen). Especially, if you are older than 75 years and are taking aspirin, you may have an increased chance of bleeding;
- medicines for high blood pressure or heart problems (e.g., diltiazem);

The following medicines may reduce the ability of **ELIQMAK** to help prevent blood clots from forming:
- medicines to prevent epilepsy or seizures (e.g., phenytoin, carbamazepine or phenobarbital);
- St John's Wort (a herbal supplement used for depression);
- medicines to treat tuberculosis or other infections (e.g., rifampicin).
- Amiodarone, quinidine, verapamil (used to treat heart conditions), and medicines associated with serious bleeding such as unfractionated heparins, dipyradimole, warfarin, rivaroxaban and dabigatran

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 **ELIQMAK**.

The effects of **ELIQMAK** on pregnancy and the unborn child are not known. You should not take this medicine if you are pregnant. Contact your doctor immediately if you become pregnant while taking this medicine.
It is not known if **ELIQMAK** passes into human breast milk. Do not take **ELIQMAK** while breastfeeding.

Driving and using machines
ELIQMAK has no or negligible influence on the ability to drive and use machines.

3. How to take ELIQMAK

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

Always take **ELIQMAK** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
ELIQMAK may be taken with or without food.
Swallow the tablet with a drink of water.
The recommended dose is one tablet of **ELIQMAK 5** twice a day.

Your doctor will decide the dose depending on your condition and how long you must continue treatment for.

If you have the impression that the effect of **ELIQMAK** is too strong or too weak, talk to your doctor or pharmacist.

If you take more ELIQMAK than you should
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ELIQMAK
It is important to take your **ELIQMAK** regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take two doses at the same time, to make up for a missed dose.

If you stop taking ELIQMAK
If **ELIQMAK** is stopped earlier than your doctor has prescribed, your symptoms of may return or worsen. Always take **ELIQMAK** for as long as your doctor has prescribed.

4. Possible side effects

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

If any of the following happens, stop taking **ELIQMAK** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Excessive bleeding
- Allergic reactions (hypersensitivity) which may cause: swelling of the face, lips, mouth, tongue and/or throat and difficulty breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to **ELIQMAK**. 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:
- Nosebleeds, anal bleeding, blood in your urine
- An increase in bilirubin, a breakdown product of red blood cells, which can cause yellowing of the skin and eyes.
- Itching;
- Hair loss;
- Skin rash which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (*erythema multiforme*).

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

Tell your doctor if you notice any of the following:
Frequently occurring:
Bleeding including:
- in your eyes;
- in your stomach or bowel;
- from your rectum;
- from your gums;
- blood in the urine;
- from your nose;
- bruising and swelling;

Anaemia which may cause tiredness or paleness;
Low blood pressure which may make you feel faint or have a quickened heartbeat;
Nausea (feeling sick);
Blood tests may show:
- an abnormal liver function – an increase in some liver enzymes
- an increase in bilirubin, a breakdown product of red blood cells – which can cause yellowing of skin and eyes.

Less frequently occurring:
Bleeding:
- in your brain or in your spinal column;
- in your mouth or blood in your spit when coughing;
- into your abdomen, or from the vagina;
- bright/red blood in the stools;
- bleeding occurring after your operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion) or injection site;
- from a haemorrhoid;
- in your lungs or your throat;
- into the space behind your abdominal cavity;
- into a muscle.

Tests showing blood in the stools or in the urine;
Reduced number of platelets in your blood (which can affect clotting);
Blood tests may show:
- abnormal liver function;
- an increase in some liver enzymes;

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
Should your general health worsen or if you experience any untoward effects while taking **ELIQMAK**, please consult your healthcare provider for advice.

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 Med Safety APP (Medsafety X SAHPRA and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **ELIQMAK.**

5. How to store ELIQMAK

Store at or below 30 °C.
KEEP OUT OF THE REACH OF CHILDREN.
Store in the original package / container.
Keep the blisters in the carton until required for use.
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 pack and other information

The active ingredient is apixaban.
Contains sugar – lactose monohydrate

The other ingredients are:
Lactose monohydrate
Microcrystalline cellulose
Croscarmellose Sodium
Sodium lauryl sulfate
Povidone
Magnesium stearate
Instacoat Universal green which contains:
- Hypromellose
- Triacetin
- Titanium dioxide
- Yellow iron oxide

Instacoat Universal Pink which contains:
- Hypromellose
- Triacetin
- Titanium dioxide
- Red Iron Oxide

What ELIQMAK looks like and contents of the pack
ELIQMAK 2,5: Each film coated tablet contains 2,5 mg apixaban.
ELIQMAK 5: Each film coated tablet contains 5 mg apixaban.

Contents of the pack:
Tablets are packed in aluminium foil laminated on one side and laminated to clear PVC/PVdC on the other side. Pack sizes include 10, 20 and 60 tablets for apixaban 2.5 mg tablets and 20, 60, 14 and 56 tablets apixaban 5 mg tablets.
Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD
Ground Floor, Block 1,
Bassonia Estate Office Park (East),
1 Cussonia Drive,
Bassonia Rock Ext 12
Alberton
Gauteng

This leaflet was last revised in 06 May 2025

Registration numbers
ELIQMAK 2,5: 57/8.2/0020
ELIQMAK 5: 57/8.2/0021

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

Marketed by:
United Pharma Marketing (Pty) Ltd

2509A182

ELIQMAK 2.5 / 5
PM04341397

335 mm

Back Side

320 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

ELIQMAK 2,5 (filmbedekte tablet)
ELIQMAK 5 (filmbedekte tablet)
Apiksaban
Bevat suiker - laktosemonohidraat
ELIQMAK 2,5 : bevat 50,25 mg laktosemonohidraat.
ELIQMAK 5 : bevat 100,50 mg laktosemonohidraat.

Lees hierdie hele inligtingstuk noukeurig deur voordat jy ELIQMAK begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **ELIQMAK** 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 is in hierdie inligtingstuk

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

1. Wat ELIQMAK is en waarvoor dit gebruik word

ELIQMAK bevat apiksaban.
ELIQMAK behoort aan 'n groep van medisyne wat antikoagulante genoem word. Dit help om die vorming van bloedklonte te verhoed deur Faktor Xa, wat 'n belangrike komponent van bloedstolling is, te blokkeer.

ELIQMAK word in volwassenes gebruik:
- om te verhoed dat 'n bloedklont in die hart vorm in pasiënte met 'n onreëlmatige hartklop (arteriële fibrillasie) en ten minste een addisionele risikofaktor. Bloedklonte kan afbreek en na die brein beweeg en lei tot 'n beroerte of na ander organe en normale bloedvloei na daardie orgaan verhoed (ook bekend as 'n sistemiese embolisme). 'n Beroerte kan lewensgevaarlik wees en vereis onmiddellike mediese aandag.
- om bloedklonte in die are van jou bene (diep vene trombose) en in die bloedvate van jou longe (pulmonêre embolisme) te verhoed, en om te verhoed dat bloedklonte weer in die bloedvate van jou bene en / of longe voorkom.
- om bloedklonte in die are van jou bene (DVT) en in die bloedvate van jou longe (PE) te behandel, en om te verhoed dat bloedklonte weer in die bloedvate van jou bene en / of longe voorkom.

2. Wat jy behoort te weet voordat jy ELIQMAK neem

Moet nie ELIQMAK neem nie:
- Indien jy allergies is vir apiksaban of enige van die ander bestanddele van hierdie medisyne, gelys in **afdeling 6**.
- Indien jy oormatige bloeding het.
- Indien jy 'n lewersiekte het wat lei tot verhoogde risiko van bloeding (hepatiese koagulopatie);
- jy medisyne neem om bloedstolling te verhoed (bv. warfarien, rivaroksaban, dabigatran of heparien), behalwe wanneer antikoagulant behandeling verander word, terwyl jy 'n veneuse of arteriële lyn kry, en jy heparien deur hierdie lyn ontvang om dit oop te hou, of as 'n buis in jou bloedvat geplaas word (kateter ablasie) om 'n onreëlmatige hartklop (disritmie) te behandel.
- Jy ernstige nierversaking het.
- Jy 'n toestand het wat veroorsaak dat jou bloed te maklik stol.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter of gesondheidsorgverskaffer voordat jy **ELIQMAK** neem
Neem spesiale sorg indien daar 'n verhoogde risiko van bloeding is, soos:
- bloedingsversteurings, insluitend toestande wat lei tot verminderde bloedplaatjieaktiwiteit; 'n aktiewe of onlangse ulkus van jou maag of derm, ontsteking van die hart (bakteriële endokarditis), onlangse bloeding in jou brein (hemorragiese beroerte), ongekontroleerde hoë bloeddruk (hipertensie) en onlangse brein, ruggraat of oog chirurgie.
- indien jy ouer as 75 jaar is;
- indien jy 60 kg of minder weeg; kan jy 'n verhoogde risiko van bloeding hê
- indien jy 'n ernstige niersiekte het of as jy op dialise is;
- indien jy 'n lewerprobleem of 'n geskiedenis van lewerprobleme het;
- Hierdie medisyne sal met omsigtigheid gebruik word in pasiënte met tekens van veranderde lewerfunksie.
- indien jy 'n prostetiese hartklep het;
- indien jou dokter bepaal dat jou bloeddruk onstabiel is of 'n ander behandeling of chirurgiese prosedure word beplan om die bloedklont uit jou longe te verwyder.
- indien jy weet dat jy 'n siekte naamlik antifosfolipiedsindroom ('n versteuring van die immuunstelsel het wat 'n verhoogde risiko van bloedklonte veroorsaak), vertel jou dokter wat sal besluit of die behandeling moontlik moet verander word.

Indien jy 'n operasie of 'n prosedure moet ondergaan wat bloeding kan veroorsaak, insluitend die invoeging van 'n epidurale of intratekale kateter, jou dokter kan jou vra om tydelik op te hou om hierdie medisyne te gebruik voor die chirurgie of indringende prosedures. Indien jy nie seker is of 'n prosedure bloeding kan veroorsaak nie, vra jou dokter.
Indien jy 'n aktiewe kanker het, moet jou gesondheidsorgverskaffer die risiko's teenoor die voordeel van die gebruik van ELIQMAK opweeg.
Indien jy sekere medisyne gebruik om swamme te behandel, soos ketokonasool, vorikonasool of antiretrovirale middels soos ritonavir, medisyne om epilepsie of aanvalle te verhoed (bv. fenitoïen, ens.); St Johannes se Kruid ('n kruie aanvulling wat vir depressie gebruik word); medisyne om tuberkulose of ander infeksies te behandel (bv. rifampisien) kan jy 'n verhoogde risiko van bloeding hê.

Gebruik in kinders en adolessente
Die gebruik van **ELIQMAK** in kinders en adolessente (onder die ouderdom van 18 jaar) word nie aanbeveel nie.

Ander medisyne en ELIQMAK
Vertel altyd jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel jou dokter of apteker indien jy enige van die volgende medisyne neem:
Die volgende medisyne kan die effekte van **ELIQMAK** verhoog en die kans op ongewenste bloeding verhoog:
- sommige medisyne vir swambesmettings (bv. ketokonasool, itrakonasool vorikonasool en posakonasool, flukonasool);
- sommige antivirale medisyne vir MIV / VIGS (bv. ritonavir);
- ander medisyne wat gebruik word om bloedstolling te verminder (bv. enoksaparien, klopidogrel of tikagrelor);
- anti-inflammatoriese of pynmedisyne (bv. asetielsalisielsuur of naproksen). Veral as jy ouer as 75 jaar is en aspirien neem, kan jy 'n groter kans op bloeding hê;
- medisyne vir hoë bloeddruk of hartprobleme (bv. diltiasem);

Die volgende medisyne kan die vermoë van **ELIQMAK** om te help verhoed dat bloedklonte vorm, verminder:
- medisyne om epilepsie of aanvalle te verhoed (bv. fenitoïen, karbamasepien of fenobarbitoon);
- St Johannes se Kruid ('n kruie aanvulling wat vir depressie gebruik word);
- medisyne om tuberkulose of ander infeksies te behandel (bv. rifampisien).
- Amiodaroon, kinidien, verapamil (gebruik om harttoestande te behandel), en medisyne wat geassosieer word met ernstige bloeding soos ongefraksioneerde hepariene, dipiradimool, warfarien, rivaroksaban en dabigatran

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat **ELIQMAK** geneem word.

Die uitwerking van **ELIQMAK** op swangerskap en die ongebore kind is nie bekend nie. Jy moet nie hierdie medisyne neem indien jy swanger is nie. Kontak onmiddellik jou dokter as jy swanger raak terwyl jy hierdie medisyne neem.
Dit is nie bekend of **ELIQMAK** in menslike borsmelk oorgaan nie. Moet nie **ELIQMAK** neem terwyl jy borsvoed nie.

Bestuur en gebruik van masjinerie
ELIQMAK het geen of weglaatbare invloed op die vermoë om te bestuur of masjinerie te gebruik.

3. Hoe om ELIQMAK te neem

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

Neem altyd **ELIQMAK** presies soos wat jou dokter vir jou opdrag gegee het. Jy moet met jou dokter of apteker bevestig indien jy nie seker is nie.
ELIQMAK kan met of sonder kos geneem word.
Sluk die tablet met 'n glas water.
Die aanbevole dosis is een tablet van **ELIQMAK 5** twee keer per dag.

Jou dokter sal die dosis bepaal, afhangende van jou toestand en hoe lank jy moet voortgaan met behandeling.

Indien jy die indruk kry dat die effek van **ELIQMAK** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer ELIQMAK 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 ELIQMAK te neem
Dit is belangrik om jou **ELIQMAK** gereeld, elke dag op dieselfde tyd te neem. Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy daarvan onthou, tensy dit tyd is vir jou volgende dosis. Moet nie twee dosisse op dieselfde tyd neem, om op te maak vir 'n vergete dosis nie.

Indien jy ophou om ELIQMAK te neem
Wanneer **ELIQMAK** vroeër gestaak word as wat jou dokter voorgeskryf het, kan jou simptome terugkeer of vererger. Neem altyd **ELIQMAK** vir so lank as wat jou dokter dit voorgeskryf het.

4. Moontlike newe-effekte

ELIQMAK kan newe-effekte hê.
Nie alle newe-effekte wat vir **ELIQMAK** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verswak of indien jy enige ongunstige effekte ervaar terwyl jy **ELIQMAK** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om **ELIQMAK** te neem en kontak onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- Oormatige bloeding
- Allergiese reaksies (hipersensitiwiteit) wat kan veroorsaak: swelling van die gesig, lippe, mond, tong, en / of keel en probleme met asemhaling.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit kry, het jy moontlik 'n ernstige reaksie op **ELIQMAK** gehad. Jy benodig moontlik dringende mediese aandag of hospitalisering.

Vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
- Neusbloedings, anale bloeding, bloed in jou uriene
- 'n Toename in bilirubien, 'n afbreekproduk van rooibloedselle, wat vergeling van die vel en oë kan veroorsaak.
- Gejeuk;
- Haarverlies;
- Veluitslag wat blase kan vorm en lyk soos klein teikens (sentrale donker kolle omring deur 'n ligter area, met 'n donker ring om die rand) (*veelvuldige eriteem*).

Hierdie is alles ernstige newe-effekte. Jy benodig moontlik dringend mediese aandag.

Vertel jou dokter indien jy enige van die volgende opmerk:
Kom gereeld voor:
Bloeding insluitend:
- in jou oë;
- in jou maag of derm;
- van jou rektum;
- van jou tandvleis;
- bloed in die uriene;
- van jou neus;
- kneusplekke en swelling;

Bloedarmoede wat moegheid of bleekheid kan veroorsaak;
Lae bloeddruk wat jou flou kan laat voel, of 'n vinniger hartklop het;
Naarheid (siek voel);
Bloedtoetse kan toon:
- 'n abnormale lewerfunksie – 'n toename in sommige lewerensieme
- 'n toename in bilirubien, 'n afbreekproduk van rooibloedselle – wat vergeling van vel en oë kan veroorsaak.

Minder gereeld voorkom:
Bloeding:
- in jou brein of in jou ruggraat;
- in jou mond of bloed in jou spoeg wanneer jy hoes;
- in jou buik, of van die vagina;
- helder / rooi bloed in die stoelgang;
- bloeding wat na jou operasie voorkom, insluitend kneusplekke en swelling, bloed of vloeistof wat uit die chirurgiese wond / insnyding (wondafskeiding) of inspuitplek lek;
- van 'n aambei;
- in jou longe of jou keel;
- in die spasie agter jou buikholte;
- in 'n spier.

Toetse wat bloed in die ontlasting of in die uriene toon;
Verminderde aantal bloedplaatjies in jou bloed (wat stolling kan beïnvloed);
Bloedtoetse kan toon:
- abnormale lewerfunksie;
- 'n toename in sommige lewerensieme;

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis. Sou jou algemene gesondheid verswak of indien jy enige ongunstige effekte ervaar terwyl jy **ELIQMAK** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

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 deur middel van die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA se webwerf gevind word. Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **ELIQMAK.**

5. Hoe om ELIQMAK te bewaar

Bewaar by of benede 30 °C.
HOU BUITE DIE BEREIK VAN KINDERS.
Hou in die oorspronklike verpakking / houer
Hou die stulpstroke in die karton totdat dit benodig word vir gebruik.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat op die stulptrook / etiket / karton / bottel aangedui is nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Die aktiewe bestanddeel is apiksaban.
Bevat suiker – laktosemonohidraat

Die ander bestanddele is:
Laktosemonohidraat
Mikrokristallyne sellulose
Natriumkruiskarmellose
Natriumlaurielsulfaat
Povidoon
Magnesiumstearaat
Instacoat Universele groen wat bevat:
- Hipromellose
- Triasetien
- Titaandioksied
- Geel ysteroksied

Instacoat Universele Pienk wat bevat:
- Hipromellose
- Triasetien
- Titaandioksied
- Rooi ysteroksied

Hoe ELIQMAK lyk en inhoud van die pak
ELIQMAK 2,5: Elke filmbedekte tablet bevat 2,5 mg apiksaban.
ELIQMAK 5: Elke filmbedekte tablet bevat 5 mg apiksaban.

Inhoud van die pak:
Tablette word verpak in aluminiumfoelie wat aan die een kant gelamineer is en aan die ander kant gelamineer is tot deursigtige PVC / PVdC. Verpakkingsgroottes sluit in 10, 20 en 60 tablette vir apiksaban 2.5 mg tablette en 20, 60, 14 en 56 tablette apiksaban 5 mg tablette.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

7. HOUER VAN SERTIFIKAAT VAN REGISTRASIE

MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Grondvloer, Blok 1,
Bassonia Estate Kantoorpark (Oos),
1 Cussonia-rylaan ,
Bassonia Rock, Uitbr. 12,
Alberton
Gauteng

Hierdie inligtingstuk was laas hersien in

Registrasienommers
ELIQMAK 2,5: 57/8.2/0020
ELIQMAK 5: 57/8.2/0021

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

Bemark Deur:
United Pharma Marketing (Edms) Bpk

UNICORN

2509A182

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: ELIQMAK 2.5 / 5 (Apixaban Tablets 2.5 / 5 mg)						
2. Country: South Africa - UNICORN			**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: NA			**10. Item code No.: PM04341397**			
11. Artwork has been made: Actual Size			**12. Pharma code No.: 40875 mini**			
13. Barcode/NDC No: NA			**14. Supersedes Item code No: NA**			
15. Revision No: 00			**16. A/W File name:G:\Regulated_Artwork\SOUTH AFRICA\Apixaban\UNICORN\Eliqmak Leafelt - PM04341397.cdr**			
Approved By:			**17. Location: Baddi**			
PRD	**M.A. HOLDER**	**RAD**	**QC**	**PRODN**	**QA**	**UNICORN**
	26/01/2026					Jeanine Janse van Rensburg | Head of Technical Affairs | Responsible Pharmacist 2026.01.28 13:16:07 +02'00'

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 (UNICORN)	PM04341397		