

**IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI  
UHLA LWEZINHLOBO ZEPHILISI I-AMLOC**

**ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI:**

**S3**

**IGAMAKUHWEDA LOMKHIQIZO KANYE NESIMO SOMTHAMOSILINGANISO:**

**AMLOC 5 mg** amaphilisi

**AMLOC 10 mg** amaphilisi

**1. OKUQUKETHWE YI-AMLOC:**

Isithako sokwelapha esiyinhloko esiqukethwe ku-**AMLOC** yi-*amlodipine*.

Iphilisi i-**AMLOC 5 mg** ngalinye liqukethe isithako i-*amlodipine maleate* esilingana ne-*amlodipine* engama-5 mg.

Iphilisi i-**AMLOC 10 mg** ngalinye liqukethe isithako i-*amlodipine maleate* esilingana ne-*amlodipine* engama-10 mg.

Ezinye izithako yicollodial anhydrous silica, magnesium stearate, microcrystalline cellulose, pregelatinised starch, sodium starch glycolate.

Amaphilisi i-**AMLOC** awanawo ushukela.

**Ngaphambi kokuba uqale ukusebenzisa i-AMLOC funda ngokucophelela  
lonke leli pheshana lolwazi.**

- Ligcine leli pheshana lolwazi. Kungenzeka ukuthi kudingeke ukuba uphinde futhi ulifunde.
- Uma uneminye imibuzo engeziwe, buza udokotela wakho noma usokhemisi.
- I-**AMLOC** iqondene nawe kuphela futhi inikezwe wena, ngakho-ke ungalokothi wabelane ngayo nabanye abantu. Kungenzeka bona ibalimaze, nakuba nabo benezimpawu ezifana nezakho.

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**2. I-AMLOC ISETSHENZISELWA LOKHU:**

- Ukwelapha umfutho wegazi ophakeme, phecelezi, *ihypertension*
- Ukwelapha ukugula okuphathelene nenkinga yenhliziyo, phecelezi, *i-angina pectoris*, ezibonakalisa ngezimpawu ezinjengobuhlungu nokungaphatheki kahle esifubeni.

**3. NGAPHAMBI KOKUBA USEBENZISE I-AMLOC:**

**Ungalokothi usebenzise i-AMLOC:**

- Uma umzimba wakho ungezwani nesithako *i-amlodipine*, neminye imithi evimbela *icalcium* ingangeni emithanjeni yenhliziyo kanye nanoma yisiphi esinye isithako esiqukethwe ngamaphilisi **i-AMLOC**.
- Uma uke waphathwa wukugula okubucayi kakhulu okubandakanya *icardiogenic shock* (leli yitemu elisetshenziswa lapho umfutho wegazi uphansi kakhulu kangokuthi nenhliziyo ize iyeke ukusebenza ngendlela efanele futhi kudingeke ukuthi uthole ukwelashwa).
- Uma usanda kuhlaselwa yisifo senhliziyo (kulezi zinsuku ezingama-28 ezedlule).
- Uma unenkinga edalwa wukungafinyeleli kwegazi ne-oksijini eyanele enhliziyweni, ebizwa phecelezi nge-*unstable angina* (izinhlungu esifubeni ezikuhlasela nalapho uphumulile ungenzi lutho).
- Uma ukhulelwe noma uncelisa umntwana wakho (bheka isigatshana esithi **Ukukhulelwa kanye nokuncelisa**).

**Qaphela kakhulu uma usebenzisa i-AMLOC:**

- Uma uhloliwe kwatholakala ukuthi unenkinga yokukhuphuka ngamandla nangokushesha okukhulu komfutho wegazi, okubizwa nge-*hypertensive crisis*.
- Uma unomfutho wegazi ophansi noma uma unezinye izinkinga eziphathelene nenhliziyo.
- Uma uhlushwa yizinkinga zesibindi.

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- Uma uxinwa kakhulu yizinkinga zezinso ezibucayi.
- Uma uneporphyrria (izinkinga zokugula eziningana ezingumphumela wokunqwabelana kwamakhemikhali abizwa ngamaporphyrins emzimbeni wakho).
- Uma uneminyaka engaphansi kweyi-18 ubudala.
- Uma unokuhlushwa yizinhlungu esifubeni uma usebenzisa i-**AMLOC**.
- Uma usebenzisa *ilithium*.
- Uma unesifo sikashukela.
- Uma uneminyaka engaphezu kwama-65 ubudala.

Ungalokothi uyeke ukusebenzisa i-**AMLOC** ungakabonani nodokotela wakho ngoba kungenzeka ukuthi izimpawu ezikuphethe zibe zimbi kakhulu.

**Ukuphuza i-AMLOC nokudla kanye nophuzo:**

I-**AMLOC** ungayiphuza nokudla noma uyiphuze ngaphandle kokudla.

**Ukukhulelwa kanye nokuncelisa:**

Ungalokothi usebenzise i-**AMLOC** uma ukhulelwe, noma uma usola sengathi ukhulelwe noma uma usancelisa umntwana wakho. Bonisana nomhlinzeki wakho wosizo lwezempilo nokwelashwa ukuze akweluleke ngaphambi kokuba uqale ukusebenzisa i-**AMLOC**. Uma ukhulelwe, noma kwenzeka ukhulelwa ngenkathi usebenzisa i-**AMLOC**, yeka ukusebenzisa i-**AMLOC** futhi ukhulume nodokotela ngokushesha okukhulu.

**Ukushayela kanye nokusebenzisa imishini:**

I-**AMLOC** ingakwenza uphathwe yisiyezi. Ungalokothi ushaye imoto noma usebenzise imishini emikhulu kuze kufike isikhathi lapho usubonile ukuthi i-**AMLOC** ikuphatha kanjani.

**Ukusebenzisa eminye imithi ngesikhathi esifanayo ne-AMLOC:**

Kumele ngaso sonke isikhathi umazise umhlinzeki wakho wosizo lwezempilo nokwelashwa

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uma kukhona nanoma iyiphi eminye imithi oyisebenzisayo.

(Lokhu kubandakanya nemithi eyizondlamzimba kanye nemithi yesintu.)

Imithi engaba nomthelela ekusebenzeni kwe-**AMLOC**:

- Eminye imithi yokwelapha *ihypertension* (umfutho wegazi ophakeme) noma *i-angina* (izinhlungu esifubeni) njengamaphilisi *initro-glycerine* ashuthekwa ngaphansi kolimi, *amanitrates* asebenza isikhathi eside emzimbeni, *amabeta-blockers* noma *amacalcium channel blockers* (njenge*verapamil, diltiazem*), njengoba lokhu kungakhuphula amazinga e-**AMLOC** egazini.
- *I-aldesleukin* esetshenziswa ekwelapheni umdlavuza wezinso kanye nomdlavuza wesikhumba obizwa ngeskin *melanoma* noma imithi esetshenziselwa ukwelapha ukugula okuphathelene nokusebenza kwengqondo, phecelezi, *i-antipsychotics*, njengoba lokhu kungakhuphula amazinga e-**AMLOC** egazini.
- Imithi eguqula izinga lokushaya kwenhliziyo (njenge*quinidine* noma *iprocainamide*).
- Imithi ethile esetshenziselwa ukwelapha amafithi (isithuthwane) (okuyi*carbamazepine, phenobarbital, phenytoin*), njengoba le mithi kungenzeka inciphise amandla okusebenza kwe-**AMLOC** emzimbeni.
- *Isodium valproate* (esetshenziselwa ukwelapha isifo sokuwa) njengoba lokhu kungakhuphula amazinga e-**AMLOC** egazini. (Xoxisana nodokotela wakho uma ungaqinisekile ngalokhu).
- Imithi esetshenziselwa ukwelapha izifo ezibangelwa ngamagciwane (*viral*), ukhunta (*fungal*) kanye namabhakhthiriya (enjenge*clarithromycin, erythromycin, ketoconazole, itraconazole* noma *irifampicin*) njengoba le mithi kungenzeka iholele ekukhuphukeni noma ekwehleni kwamazinga e-**AMLOC** egazini.
- *Irifampicin* ne*St John's Wort* (eyaziwa futhi ngele*Hypericum perforatum*), kungenzeka inciphise umthamo we-**AMLOC** engxenyeni yegazi ewuketshezi (*plasma*).
- *Iritonavir* esetshenziswa ukudodobalisa isandulelangculazi (*HIV*) njengoba kungenzeka ukusetshenziswa kwayo kuholele ekukhuphukeni kwamazinga e-**AMLOC** egazini.

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- *Lithium*, njengoba lokhu kungaholela ekukhuphukeni kobuthi egazini uma isetshenziswa ngokuhlanganyela ne-**AMLOC**.

**4. ISETSHEZISWA KANJANI I-AMLOC:**

Ungalokothi wabelane nanoma yimuphi omunye umuntu ngemithi onikezwe yona ngumhlinzeki wakho wosizo lwezempilo nokwelashwa ngoba iqondene nawe kuphela. Kumele njalo i-**AMLOC** uyiphuze ncimishi ngendlela akuyalele ngayo udokotela wakho. Kumele ubuze udokotela wakho noma usokhemisi uma ungaqinisekile.

Umthamosilinganiso ojwalelekile we-AMLOC yilona:

***Kubantu abadala:***

Umthamosilinganiso ojwayelekile onikezwa wona uma usaqala ukudla amaphilisi ngumthamosilinganiso wephilisi le-**AMLOC** elingama-5 mg kanye ngosuku, okumele uliphuze nokudla noma ngaphandle kokudla ngesikhathi esifanayo nsukuzonke.

Iphilisi kumele uligwinye lonke liphelele, ulehlise ngamanzi.

Uma bungekho ubungcono obubonakalayo emuva kwezinsuku eziyi-10 kuya kweziyi-14, udokotela wakho kungenzeka awukhuphule umthamosilinganiso ufinyelele kumthamosilinganiso ophela we-**AMLOC** ongama-10 mg ngosuku (okumele uthathwe njengomthamosilinganiso owodwa).

***Kubantu asebekhulile ngokweminyaka (ogogo nomkhulu):***

Kungenzeka kudingeke ukuthi baqale ngomthamosilinganiso ophansi.

***Iziguli ezinezinkinga zezinso:***

Zinganikezwa umthamosilinganiso ojwayelekile wabantu abadala.

Uma ungaphansi kohlelo lokuhlazwa kwegazi ngomshini ngenxa yokungasebenzi kahle kwezinsu (*idialysis*) khuluma nodokotela wakho noma usokhemisi ngaphambi kokusebenzisa i-**AMLOC**.

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***Iziguli ezinezinkinga zesibindi:***

Kungenzeka kudingeke ukuthi ziqale ngomthamosilinganiso ophansi.

Udokotela wakho uzothatha isinqumo maqondana nomthamosilinganiso azokunikeza wona emuva kokuba esekuxilongile futhi wabukisisa isimo sakho.

Uma ubona sengathi i-**AMLOC** inamandla ngokweqile noma sengathi ayinawo neze amandla, tshela udokotela wakho noma usokhemisi.

**Uma uphuze i-AMLOC engaphezulu kwaleyo okumele uyiphuze:**

Uma kwenzekile waphuza umthamosilinganiso wamaphilisi oweqile, futhi unezimpawu ezinjengesiyenzi esinamandla noma uquleka, xhumana nodokotela wakho noma usokhemisi.

Uma uhluleka ukuthola omunye walaba, xhumana nesibhedlela esiseduze nawe noma isikhungo esilawula ubuthi/ushevu. Udokotela wakho uzokwelapha izimpawu zemithelela engathandeki nokungaphatheki kahle okukhona emzimbeni wakho, okungenzeka kube yizimpawu ezibandakanya ukwehla ngokweqile komfutho wegazi, okuyinto okungenzeka iqhubeke isikhathi eside.

**Uma kwenzeka ukhohlwa ukuphuza umthamosilinganiso we-AMLOC:**

Uma kwenzeka ukhohlwa ukuphuza umthamosilinganiso we-**AMLOC**, waphuze ngokushesha amaphilisi akho emuva kokukhumbula ukuthi kumele uwaphuze. Uma sekusondele isikhathi sokuphuza umthamosilinganiso wamaphilisi olandelayo, ungabe usawuphuza lowo mthamosilinganiso wamaphilisi okhohliwe ukuwuphuza futhi uqhubeke uphuze umthamosilinganiso wephilisi noma wamaphilisi olandelayo ngesikhathi esijwayelekile. Ungalokothi uphuze imithamosilinganiso yamaphilisi ephindwe kabili ngenhloso yokuvala isikhala semithamosilinganiso yamaphilisi okhohliwe ukuwaphuza.

**Imithelela ongahlangabezana nayo uma uyeka ukwelashwa nge-AMLOC:**

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Kusemqoka ukuthi uqhubeke nokuphuza amaphilisi akho ngisho usuzizwa ungcono emzimbeni emuva kwezinsuku ezimbadlwana. Uma uyeka esithubeni nje ukusebenzisa i-**AMLOC** kungenzeka zibe zimbi kakhulu izinhlungu esifubeni sakho.

**5. IMITHELELA ENGATHANDEKI OKUNGENZEKA IBE KHONA:**

I-**AMLOC** kungenzeka ibe nemithelela engathandeki emzimbeni. Akuyona yonke imithelela engathandeki ebikiwe ye-**AMLOC** equkethwe kuleli pheshana lolwazi. Uma siba sibi isimo sakho sempilo jikelele, noma uma uzwa umthelela ongemnandi futhi ongathandeki emzimbeni ngenkathi usebenzisa i-**AMLOC**, bonisana nomhlinzeki wakho wosizo lwezempilo nokwelashwa ukuze uthole ukwelulekwa.

Uma kwenzeka noma yikuphi kulokhu okulandelayo, yeka ukusebenzisa i-**AMLOC** futhi utshele udokotela wakho ngokushesha noma uphuthume emnyangweni wezimo eziphuthumayo esibhedlela esiseduze nawe:

- Ukuvuvukala kwezandla, izinyawo, amaqakala, izindebe, umlomo noma umphimbo okungenza kube nzima ukugwinya noma ukuphefumula.
- Ukuqubuka noma isikhumba esilumayo.

Konke lokhu kuyimithelela engathandeki ebucayi kakhulu futhi enobungozi. Uma unayo le mithelela, kusho ukuthi kunokwenzeka ukuthi umzimba wakho awuzwananga neze ne-**AMLOC**. Kungenzeka udinge usizo lokwelashwa oluphuthumayo noma ukulaliswa esibhedlela.

Tshela udokotela wakho ngokushesha noma uphuthume emnyangweni wezimo eziphuthumayo esibhedlela esiseduze nawe uma ubona okunye kwalokhu okulandelayo:

- Ukushaya kwenhliziyo kancane (okubizwa nge*bradycardia*) noma ukushaya kwenhliziyo ngamandla (okubizwa nge*tachycardia*), ukubhakuza kwenhliziyo ngendlela engajwayelekile, phecelezi, ama*palpitations*.
- Umfutho wegazi ophansi (i*hypotension*) okubonakala ngezimpawu ezinjengokuquleka

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noma uzizwe unesiyezi futhi uzwe sengathi uzoquleka.

- Amazinga aphakeme kashukela egazini (*ihyperglycaemia*).
- Ijondisi (isifo esibonakala ngesikhumba esinombala ophuzi kanye namehlo anombala ophuzi).
- Ukuvuvukala kwesibindi (*ihepatitis*), okuyisifo sesibindi esibonakala ngezimpawu ezinjengezinhlungu esiswini, imfiva, isicanucanu, ukuhlanza noma ukuphelelwa wuthando lokudla.
- Ubuthakathaka emzimbeni, ukukhathala okukhulu, ukwehla emzimbeni, ikhanda elibuhlungu (okuyizimpawu zesifo esibizwa nge*vasculitis*).
- Ukuquleka (okubizwa nge*syncope*).
- Izinkinga zezinso (ukuphuma komchamo omncane kunalokho okujwayelekile kuwena lapho uchama).
- Ukuvuvukala kwamanyikwe, *ipancreatitis* (okuyisifo sokuvuvukala kwamanyikwe esibonakala ngezimpawu ezinjengezinhlungu esiswini, inhliziyi eshaya ngamandla kanye nemfiva).

Konke lokhu kuyimithelela engathandeki ebucayi futhi enobungozi. Kungenzeka kudingeke ukuba uthole usizo lokwelashwa oluphuthumayo.

Tshela udokotela wakho ngokushesha uma ubona okunye kwalokhu okulandelayo:

Imithelela engathandeki evamile ukubonakala:

- Ikhanda elibuhlungu, isiyenzi kanye nokukhathala okukhulu.
- Ukufikelwa wukushisa okukhulu esikhunjeni nasebusweni.
- Izinhlungu esiswini, isicanucanu.
- Ukuvuvukala kunoma iyiphi ingxenye yomzimba.

Imithelela engathandeki engavamile ukwenzeka:

- Imiphumela yokuhlolwa kwegazi ebonisa okungajwayelekile.
- Ukukhukhumala kwezibele kubantu besilisa.



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- Izinga eliphakeme lokusamafutha (ikholesteroli) egazini.
- Ukuncipha kokusebenza kwezinzwa zokuthinta (ubundikindiki).
- Ukuhlaba nokunsonsotha kwezandla, izinyawo noma izindebe (umuzwa ohlabayo osanalithi obizwa phecelezi ngama-“*pins and needles*”).
- Ukungqangqazela okuzenzekelayo futhi okungalawuleki (ukuthuthumela).
- Izinkinga zokuguquguquka kwesimo semizwa nengqondo kanye/noma ukungalali kahle.
- Ukujuluka.
- Ukubona ngendlela efiphele, ukungaboni kahle emehlweni okulokhu kuqhubeke njalo nokuba kubi.
- Ukukhala kwezihlonono ezindlebeni (okubizwa phecelezi nge*tinnitus*).
- Ukukhwehlela.
- Ukuvuvukala kolwelwesana olungaphakathi emakhaleni (*irhinitis*).
- Ukuqunjelwa, ukuhlanza, isifo sohudo, inkinga yokungagayeki kahle kokudla.
- Umlomo owomille, ukuvuvukala kwezinsini.
- Izinkinga zesikhumba ezinjengokuqubuka, ukuguquka ngokweqile kombala wesikhumba, umqubuko obangelwa wukungezwani nokudla/nomuthi othile (phecelezi ama*hives*), isikhumba esilumayo.
- Ubuhlungu bamajoyinti omzimba, ubuhlungu bomhlane, ubuhlungu bemisipha, amajaqamba noma ubuthakathaka emzimbeni.
- Izinkinga eziphathelene nokungayi kahle ocansini.
- Ukuguquka kwendlela onambitha ngayo (kubandakanya ukulahleka komuzwa wokunambitha).

Uma ubona noma yimiphi eminye imithelela engathandeki engabhaliwe kuleli pheshana lolwazi, tshela udokotela wakho noma usokhemisi.

**6. UKUGCINWA NOKUL AHLWA KWE-AMLOC:**

I-AMLOC kumele igcinwe kwibhokisana noma iphakeshana efike nalo (uqwenjana

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oluyisigcinamaphilisi kumele lugcinwe kwibhokisana lamaphilisi kuze kufike isikhathi lapho sekudingeka ukuba uwasebenzise amaphilisi) ezingeni lokushisa elingama-25 °C noma ngaphansi kwalokho.

**YONKE IMITHI KUMELE UYIGCINE ENDAWENI EZINGAFINYELELI KUYONA IZINGANE.**

Ungawasebenzisi amaphilisi emuva kosuku lokuphelelwa kwawo yisikhathi olubhalwe kwibhokisana lawo.

Yiphindisele emuva kusokhemisi wakho yonke imithi engasetshenziswanga.

Ungalokothi ulahle imithi engasetshenziswanga ezinhlelweni zamapayipi okuchitha amanzi noma okuthutha indle (isibonelo, ezindlini zangasese).

**7. UKWETHULWA KWE-AMLOC:**

**AMLOC 5 mg:** Itholakala kwizingqwenjana eziyizigcinamaphilisi ezakhiwe ngePVC / ifoyela le-*Aluminium* ezingakubonisi lokho okungaphakathi ezinamaphilisi angama-30, eziqukethwe kumabhokisana anemibhalo ngaphandle.

**AMLOC 10 mg:** Itholakala kwizingqwenjana eziyizigcinamaphilisi ezakhiwe ngePVC / ifoyela le-*Aluminium* ezingakubonisi lokho okungaphakathi ezinamaphilisi angama-30, eziqukethwe kumabhokisana anemibhalo ngaphandle.

**8. UKUHLONZWA KWE-AMLOC:**

**AMLOC 5 mg:** Iyiphilisi elimhlophe, eliyindingiliza, eliqumbile kancane nhlangothi zombili, elinonqenqema olutshekile, elinomugqa onqamula phakathi ohlangothini olulodwa. Ububanzi: 8,0 mm.

**AMLOC 10 mg:** Iyiphilisi elimhlophe, eliyindingiliza, eliqumbile kancane nhlangothi zombili, elinonqenqema olutshekile, elinomugqa onqamula phakathi ohlangothini olulodwa. Ububanzi: 10,0 mm.

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**9. IZINAMBA ZOKUBHALISWA:**

**AMLOC 5 mg** : A38/7.1/0183

**AMLOC 10 mg** : A38/7.1/0147

**10. IGAMA, IKHELI LENKAMPANI KANYE NENAMBA YOCINGO YOMNIKAZI**

**WESITIFIKETI SOKUBHALISWA:**

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**11. USUKU LOKUSHICILELWA:**

Usuku lokubhaliswa: 17 Mandulo 2004

Usuku lokugunyazwa kwakamuva: 29 Mandulo 2017

**NAMIBIA:**

**AMLOC 5 mg**: NS2/7.1/0011

**AMLOC 10 mg**: NS2/7.1/0012