IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI

PEARLOC

ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI

S3

IGAMA LOMUTHI

Amaphilisi i**PEARLOC 4 mg/5 mg**

Amaphilisi i**PEARLOC 4 mg/10 mg**

Amaphilisi i**PEARLOC 8 mg/5 mg**

Amaphilisi i**PEARLOC 8 mg/10 mg**

Perindopril tert-butylamine kanye ne-*amlodipine* njenge*besilate*

IPEARLOC ayinawo ushukela.

Iphilisi ngalinye elingama-4 mg/5 mg liqukethe i*sodium* engama-0,277 mg

Iphilisi ngalinye elingama-4 mg/10 mg liqukethe i*sodium* engama-0,554 mg

Iphilisi ngalinye elingama-8 mg/5 mg liqukethe i*sodium* engama-0,554 mg

Iphilisi ngalinye elingama-8 mg/10 mg liqukethe i*sodium* engama-0,554 mg

Ngaphambi kokuba uqale ukusebenzisa iPEARLOC funda ngokucophelela lonke leli pheshana lolwazi

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

Okuqukethwe kuleli pheshana lolwazi

1. Iyini iPEARLOC futhi isetshenziselwani?
2. Okumele ukwazi ngaphambi kokuba usebenzise iPEARLOC

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PEARLOC

3. Indlela yokusebenzisa iPEARLOC
4. Imithelela engathandeki okungenzeka ibe khona
5. Indlela yokugcina iPEARLOC
6. Okuqukethwe ephaketheni lamaphilisi kanye nolunye ulwazi

1. Iyini iPEARLOC futhi isetshenziselwani?

IPEARLOC iyinhlanganisela yezithako zokwelapha ezimbili, i*perindopril* kanye ne-*amlodipine*. I*perindopril* yi-*ACE* (*angiotensin converting enzyme*) *inhibitor*. I-*amlodipine* ngumuthi ovimbela i*calcium* ingangeni emithanjeni yenhliziyo (oyingxenye yeqoqwana lemithi ebizwa ngama*dihydropyridines*). Ngokuhlanganyela le mithi inweba futhi ithambise imigudu yegazi, okuholela ekuncipheni komfutho wegazi.

IPEARLOC unikezwa yona ngenhloso ukwelapha umfutho wegazi ophakeme (*hypertension*). Iziguli esezivele zisebenzisa i*perindopril* kanye ne-*amlodipine* eziyithola emaphilisini ahlukene zinganikezwa iphilisi elilodwa lePEARLOC eliqukethe zombili izithako esikhundleni samaphilisi amabili eziwasebenzisayo.

2. Okumele ukwazi ngaphambi kokuba usebenzise iPEARLOC

Ungalokothi usebenzise iPEARLOC:

- uma umzimba wakho ungezwani ne*perindopril*, noma uma ungezwani nanoma iyiphi enye i-*ACE inhibitor*, noma i-*amlodipine* nanoma iyiphi enye i*dihydropyridine derivative*, noma uma ungezwani nanoma yiziphi izithako zePEARLOC (bheka isigaba 6).
- uma uke waba nezimpawu ezinjengokuvuvukala kobuso, ulimi noma umphimbo, ukubefuzela, ukuqubuka esikhunjeni, ukuluma kakhulu, isiyezi noma ukuquleka ngenxa yokwelashwa kwakho esikhathini esedlule nge-*ACE inhibitor* noma nge-*Angiotensin receptor blocker* (ARB) noma nge*renin inhibitor* noma uma uke waba nalezi zimpawu kunoma yiziphi ezinye izimo (isifo esibizwa nge-*angioedema*) noma uma wena noma ilungu lomndeni wakho nike naba nalezi zimpawu kunoma yiziphi ezinye izimo

- uma une*cardiogenic shock* noma i*Hypertrophic obstructive cardiomyopathy* (*HOCM*) (lapho inhliziyo ingakwazi ukuthumela igazi elanele emzimbeni), i-*aortic stenosis* (ukuncipha kwemigudu emikhulu yegazi esuka enhliziyweni)
- uma uxinwe kakhulu yinkinga yezinso enamandla, uma unenso eyodwa noma uma unenkinga yokuncipha komthambo ophakela inso ngegazi (i*renal* noma *bilateral artery stenosis*)
- uma welashwa ngama-*ACE inhibitors*/*Angiotensin receptor blockers* kanyekanye ne-antibhayothikhi ewuhlobo lwe*fluoroquinolone* enjenge*ciprofloxacin*, *gemifloxacin*, *levofloxacin*, *moxifloxacin* kanye ne*norfloxacin* xhumana nodokotela wakho ukuze abuyekeze kabusha imithi akwelapha ngayo
- uma usebenzisa ama*diuretics* (amaphilisi amanzi) onga i*potassium* anjenge*spironolactone*, *triamterene* kanye ne-*amiloride,* osawoti be*potassium*
- uma une*porphyria* (inkinga yegazi eyivelakancane)
- uma usebenzisa i*lithium* (ukwelapha izinkinga zesimo sengqondo nomphefumulo)
- uma usebenzisa i-*aliskiren* (okuyi*renin inhibitor* enciphisa umfutho wegazi)
- uma unomfutho wegazi ophansi kakhulu (*hypotension*)
- uma unenkinga yokugula okungalawulekile kahle kokuhluleka kwenhliziyo ukusebenza ngendlela efanele emuva kokuhlaselwa yisifo senhliziyo
- uma ukhulelwe noma usancelisa umntwana wakho
- uma usebenzisa i*sacubitril/valsartan*, umuthi osetshenziselwa ukwelapha uhlobo lwenkinga yesikhathi eside (eyisimbelambela) yokuhluleka kwenhliziyo ukusebenza kahle kubantu abadala, njengoba lokhu kukhuphula ubungozi bokuphathwa yi-*angioedema* (ukuvuvukala okusheshayo ngaphansi kwesikhumba endaweni enjengomphimbo)
- uma kuwena kwenziwa noma yiluphi uhlobo lokwelashwa olubandakanya ukuhlungwa kwegazi lakho, isibonelo, ukususwa kwekholesteroli egazini lakho noma inqubokwelapha yokuhlanzwa kwegazi ngomshini ngenxa yezinso ezingasebenzi kahle (*dialysis*). Maqondana nalokhu kungenzeka iPEARLOC ingakulungeli wena, kepha lokho kuzoncika emshinini osetshenziswayo.

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PEARLOC

Izixwayiso kanye nezinto okumele uziqikelele

Qaphela kakhulu uma usebenzisa iPEARLOC:

Khuluma nodokotela wakho noma usokhemisi ngaphambi kokuthi usebenzise iPEARLOC:

- uma usebenzisa imithi eyingxenye yeqoqwana lemithi ama*mTOR inhibitors*, esetshenziselwa ukuvimbela ukwalana komzimba nesitho sokufakelwa (isibonelo, *sirolimus, everolimus, temsirolimus*), njengoba kungenzeka kube nobungozi obuphakeme bokuphathwa yi-*angioedema* (isibonelo, ukuvuvukala kwemigudu yomoya noma ulimi).
- uma uphelelwa amanzi emzimbeni (*volume depleted*), isibonelo, uma kade uhlanza, noma uma kade uphethwe yisifo sohudo noma ujuluka kakhulu
- uma uphethwe yi*mitral valve stenosis* (ukuncipha kwe*mitral valve* yenhliziyo, okudala ukuvimbeleka kokuhamba nokugeleza kwegazi)
- uma uxinwe kakhulu yisifo sesibindi esinamandla noma ukuhluleka kwesibindi ukusebenza ngendlela efanele
- uma ungumuntu wohlanga olumnyama kungenzeka ube sengcupheni enkulu yokuphathwa yi-*angioedema* (ukuvuvukala kongwengwezi olungaphansi lwesikhumba kanye nethishu) futhi iPEARLOC kungenzeka ingabi namandla kahle ekwehliseni umfutho wakho wegazi uma kuqhathaniswa neziguli okungezona ezohlanga olumnyama
- uma usebenzisa i*heparin* (ukuvimbela ukushuba nokuguquka kwegazi lakho libe ngamahlule) noma i*dantrolene* (yokunciphisa izinhlungu nokuqina kwemisipha yomzimba)
- uma unesifo sikashukela, noma uma kudingeka ukuthi uthole i-*insulin* njalo futhi ngokuqhubekayo
- uma ungaphansi kohlelo lokuhlanzwa kwegazi ngomshini ngenxa yokungasebenzi kahle kwezinso

Kumele umazise udokotela wakho, usokhemisi noma umhlinzeki wosizo lwezempilo nokwelashwa ukuthi wena usebenzisa iPEARLOC:

- uma kuzokwenziwa kuwena inqubo yokususa ikholesteroli egazini lakho kusetshenziswa umshini (*LDL apheresis*)

- uma uzothola ukwelashwa ngenhloso yokunciphisa imithelela ye-aleji edalwe wukutinyelwa yinyosi noma umnyovu
- uma unanoma yiziphi izimpawu zokutheleleka ngesifo ezinjengomphimbo obuhlungu, imfiva kanye nokuqhaqhazela okubangelwa ukuzwa amakhaza (izimpawu ze*neutropenia* noma i-*agranulocytosis*, lapho umnkantsha ungakhiqizi izingqalampilo zegazi ezimhlophe ezanele ezilekelela ekulwisaneni nokutheleleka ngesifo)
- uma uba nenkinga yokopha ezinsinini zakho noma emakhaleni, inkinga yegazi emchameni wakho noma endleni yakho, noma uma uhuzuka kalula (i*thrombocytopenia*, eholela ekutheni kube nezinkinga zokuhluleka kwegazi ukujiya liphenduke amahlule)
- uma ubukeka uphaphathekile, uzizwa ukhathele noma unesiyezi futhi unephika ngenxa ye-anemiya (ukuncipha kwezingqalampilo zegazi ezibomvu noma i*haemoglobin* egazini)
- uma uphathwa wukukhwehlela okomile ngenkathi usebenzisa iPEARLOC njengoba lo muthi unokuhlobana okuthile nokukhwehlela okomile okubeleselayo
- uma uzohlinzwa noma uzonikezwa umuthi olalisayo ukuze ungazizwa izinhlungu lapho uhlinzwa

Kungenzeka udokotela akuhlole njalo futhi ngokuqhubekayo ukusebenza kwezinso zakho, umfutho wegazi kanye nomthamo wama-*electrolytes* (isibonelo, umthamo we*potassium*) egazini lakho.

Ukusetshenziswa kweminye imithi nePEARLOC

Kumele ngaso sonke isikhathi umazise umhlinzeki wakho wosizo lwezempilo nokwelashwa uma kukhona noma yimiphi eminye imithi oyisebenzisayo. (Lokhu kubandakanya nemithi eyizondlamzimba kanye nemithi yesintu.)

- I-*aliskiren* (umuthi oyi*direct renin inhibitor*) ingaholela emfuthweni wegazi ophansi, amazinga e*potassium* aphansi kanye nokuncipha kokusebenza kwezinso uma isetshenziswa kanyekanye nePEARLOC (bheka isigatshana esithi Ungalokothi usebenzise iPEARLOC).
- I*sacubitril/valsartan* (umuthi osetshenziselwa ukwelapha uhlobo lokuhluleka kwenhliziyo ukusebenza ngendlela efanele okuqhubeka isikhathi eside kubantu abadala), njengoba buphakama ubungozi bokuphathwa yi-*angioedema* (ukuvuvukala okusheshayo ngaphansi

kwesikhumba endaweni enjengomphimbo) (bheka isigatshana esithi Ungalokothi usebenzise iPEARLOC).

- I-*estramustine* (yokwelapha izinhlobo ezithile zomdlavuza wendlala engaphansi kwesinye kwabesilisa) kungenzeka ikhuphule ubungozi bokuphathwa yimithelela engathandeki.
- Ukusebenzisa i*co-trimoxazole* (eyi-antibhayothikhi) kanyekanye nePEARLOC kungakhuphula amazinga e*potassium* egazini lakho.
- Ama-antibhayothikhi ohlobo lwe*fluoroquinolone* uma esetshenziswa kanyekanye nePEARLOC angabangela izinkinga zezinso (bheka isigatshana esithi Ungalokothi usebenzise iPEARLOC).
- Izondlamzimba ze*potassium*, imikhiqizo esetshenziswa esikhundleni sikasawoti equkethe i*potassium*, kanye nama*diuretics* (amaphilisi amanzi) onga i*potassium* anjenge*spironolactone, triamterene* noma i-*amiloride.*
- I*lithium* (yokwelapha i*mania* kanye nengcindezi yengqondo).
- I*ciclosporin* ingadala ukuphakama kwamazinga e*creatinine*, okungaba yinkomba yezinkinga zezinso futhi iPEARLOC kungenzeka iguqule umthamo walo muthi egazini lakho.
- I*heparin* (yokuvimbela ukushuba nokuguquka kwegazi libe ngamahlule) kungenzeka iphazamise ukuba khona komthamo okahle nofanelekile woketshezi emzimbeni (*electrolyte balance*), udokotela wakho kungenzeka afune ukuwabhekisisa futhi awaqaphe ngokuqhubekayo lawa mazinga ngenkathi wena uqhubeka nokuthola ukwelashwa ngePEARLOC.
- Ama*Non-steroidal Anti-Inflammatory Medicines* (*NSAIDs*) kubandakanya ne-*aspirin* uma kuphuzwa ngomthamosilinganiso ophakeme, kanye ne-*indomethacin* kunciphisa amandla ePEARLOC okwehlisa umfutho wegazi.
- Imithi yokwelapha isifo sikashukela enjenge-*insulin* noma i*metformin* kungenzeka iwehlise kakhudlwana amazinga kashukela egazini uma isetshenziswa kanyekanye nePEARLOC.
- Eminye imithi yokwelapha umfutho wegazi ophakeme, kubandakanya ama*diuretics* (amaphilisi amanzi) kungenzeka iwehlise kakhudlwana umfutho wakho wegazi uma isetshenziswa kanyekanye nePEARLOC.

- I*tacrolimus, sirolimus, temsirolimus* kanye ne-*everolimus* (imithi esetshenziselwa ukuguqula indlela asebenza ngayo amasosha akho omzimba) ingabangela imithelela engathandeki futhi iPEARLOC kungenzeka ikhuphule amazinga ale mithi egazini lakho.
- Imithi esetshenziselwa ukwehlisa amazinga kashukela egazini (*linagliptin, saxagliptin, sitagliptin, vildagliptin*) kungenzeka ibangele imithelela engathandeki.
- Osawoti begolide (*gold salts*), ikakhulukazi uma befakwa emzimbeni ngedriphu ngenhloso yokwelapha i*rheumatoid arthritis* bangadala ukuthi ube nenkinga yokuguquka ngokushesha kobuso bube bomvu futhi bushise, isicanucanu, ukuhlanza kanye nomfutho wegazi ophansi uma besetshenziswa kanyekanye nePEARLOC.
- I*dantrolene* (imbiza/ikhambi lokwelapha izinkinga zamazingakushisa omzimba axakile futhi angajwayelekile), i*rifampicin, erythromycin, clarithromycin* (ama-antibhayothikhi), i*verapamil, diltiazem* (imithi yenhliziyo), i*St John's Wort* (*Hypericum perforatum*), umuthi wokwelapha izifo ezibangelwa wukhunta (*anti-fungal medicines*) (isibonelo, i*ketoconazole, itraconazole*) kungenzeka iphazamise indlela esebenza ngayo iPEARLOC.
- Amandla okusebenza kwe*simvastatin* (umuthi wokunciphisa amazinga ekholesteroli) kungenzeka aphazanyiswe yiPEARLOC.
- I*baclofen* (yokwelapha ukuqina kwemisipha yomzimba okwenzeka ezifweni ezinjenge*multiple sclerosis*). Kungenzeka iwehlise kakhudlwana umfutho wakho wegazi uma isetshenziswa kanyekanye nePEARLOC.
- Eminye imithi eyehlisa umfutho wegazi, kubandakanya i*nitroglycerin*, amanye ama*nitrates* kanye nama*diuretics* (amaphilisi amanzi) kungenzeka ikhuphule amandla ePEARLOC okwehlisa umfutho wegazi.
- Ama*corticosteroids*, anjenge*prednisone* esetshenziselwa ukwelapha izifo ezihlukahlukene kubandakanya nesifuba somoya esinamandla kanye ne*rheumatoid arthritis*, i*tetracosactide* (yokwelapha i*Crohn's disease*) kungenzeka anciphise amandla okusebenza kwePEARLOC.
- Ama-*alpha-blockers* asetshenziselwa ukwelapha indlala engezansi kwesinye kwabesilisa ekhukhumele anjenge*prazosin, alfuzosin, doxazosin, tamsulosin, terazosin.*

- I-*amifostine* (esetshenziselwa ukuvimbela noma ukunciphisa imithelela engathandeki ebangelwa ngeminye imithi noma ebangelwa yinqubokwelapha yokushisa izinhlayiyana zomdlavuza ngemisebe enamandla, phecelezi i*radiation therapy,* esetshenziselwa ukwelapha umdlavuza).
- Imithi esetshenziselwa ukwelapha ukugula kwengqondo, okunjengengcindezi yengqondo, itwetwe nexhala, i*schizophrenia* (ama*tricyclic antidepressants, ama-antiphyschotics*) kungenzeka iwehlise kakhudlwana umfutho wakho wegazi uma isetshenziswa kanyekanye nePEARLOC.

Ukuphuza iPEARLOC nokudla kanye nophuzo:
Ukuphuza ujusi we*grapefruit* kanyekanye nePEARLOC kungawakhuphula amandla okusebenza kwePEARLOC futhi lokho kungaholela emfuthweni wegazi ophansi kakhulu.

Ukukhulelwa, ukuncelisa kanye nokuba sesimweni sokuzala nokuthola abantwana
Uma ukhulelwe noma uncelisa, noma uma ucabanga ukuthi mhlawumbe ukhulelwe noma uma uhlela ukuthola umntwana, bonisana nodokotela wakho, usokhemisi noma omunye ungoti wosizo lwezempilo nokwelashwa ngaphambi kokuba usebenzise iPEARLOC ukuze uthole ukwelulekwa. Akumele usebenzise iPEARLOC uma ukhulelwe noma usancelisa umntwana wakho (bheka isigatshana esithi Ungalokothi usebenzise iPEARLOC).
Ngokujwayelekile udokotela wakho uzokuyekisa ukwelashwa ngePEARLOC futhi akushintshele komunye umuthi.

Ukushayela kanye nokusebenzisa imishini:
IPEARLOC ayiwaphazamisi amandla akho okuhlala uphapheme futhi uqaphile ubona kahle konke okwenzekayo kodwa kungenzeka uphathwe yisiyezi noma ubuthakathaka ngenxa yomfutho wegazi ophansi okungaphazamisa amandla nekhono lakho lokushayela imoto nokusebenzisa imishini.

Akulula ukubikezela njalo ukuthi iPEARLOC izoba nomthelela ongakanani emisebenzini yakho

yansukuzonke. Kumele uqinisekise ukuthi awuyenzi imisebenzi eshiwo ngenhla kuze kufike isikhathi lapho usubonile ukuthi iPEARLOC ikuphatha kanjani.

3. Isetshenziswa kanjani iPEARLOC

Ungalokothi wabelane nanoma yimuphi omunye umuntu ngemithi onikezwe yona ngoba iqondene nawe kuphela. Kumele njalo iPEARLOC uyisebenzise ncimishi ngendlela akuyalele ngayo udokotela wakho. Kumele ubuze udokotela wakho noma usokhemisi uma ungaqinisekile.

Kubantu abadala:

Umthamosilinganiso ojwayelekile wePEARLOC yiphilisi elilodwa eliphuzwa kanye njalo ngosuku ekuseni ngaphambi kokudla. Iphilisi ligwinye lonke liphelele, ulehlise ngengilazi yamanzi, futhi kungaba kuhle uma uliphuza ngesikhathi esifanayo nsukuzonke.

Udokotela wakho uzokutshela ukuthi kuzothatha isikhathi eside kangakanani ukwelashwa kwakho ngePEARLOC. Ungalokothi uyeke ukudla amaphilisi akho ngaphambi kwesikhathi ngoba umfutho wegazi ophakeme obukuphethe kungenzeka ubuye.

Uma ubona sengathi iPEARLOC inamandla ngokweqile noma sengathi ayinawo neze amandla, tshela udokotela wakho noma usokhemisi.

Uma uphuze iPEARLOC engaphezulu kwaleyo okumele uyiphuze:

Uma kwenzekile waphuza umthamosilinganiso oweqile, bonisana nodokotela wakho noma usokhemisi. Uma uhluleka ukuthola omunye walaba, xhumana nesibhedlela esiseduze nawe noma isikhungo esilawula ubuthi/ushevu.

Izimpawu zomthamosilinganiso oweqile kungenzeka zibandakanye lokhu:

- Umfutho wegazi ophansi. Uma kwenzeka wehla ngokuphawulekayo umfutho wegazi kungenzeka ube nezimpawu ezinjengesiyezi noma uzizwe sengathi uzoquleka, isicanucanu, ukuhlanza, amajaqamba, ukudideka kwengqondo, ukwehla komthamo womchamo owuchamayo. Kungenzeka kube nokuphazamiseka komthamo odingekayo nofanelekile woketshezi emzimbeni.

Uma kwenzeka ukhohlwa ukuphuza iPEARLOC:

Uma kwenzekile wakhohlwa ukuphuza iPEARLOC, phuza umthamosilinganiso wakho ojwayelekile ngosuku olulandelayo. Ungalokothi uphuze imithamosilinganiso ephindwe kabili ngenhloso yokuvala isikhala semithamosilinganiso okhohliwe ukuyiphuza.

Uma uyeka ukusebenzisa iPEARLOC

Njengoba ngokuvamile ukwelashwa komfutho wegazi ophakeme kuqhubeka impilo yomuntu yonke, kumele uxoxisane nodokotela wakho ngaphambi kokuba uyeke ukusebenzisa iPEARLOC.

4. Imithelela engathandeki okungenzeka ibe khona

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

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

- ukuvuvukala kwezandla, izinyawo, amaqakala, ubuso, izindebe, umlomo noma umphimbo okungenza kube nzima ukugwinya noma ukuphefumula
- ukuqubuka noma ukuluma
- ukuquleka

Konke lokhu kuyimithelela engathandeki ebucayi kakhulu futhi enobungozi. Uma unayo le mithelela, kusho ukuthi kunokwenzeka ukuthi umzimba wakho awuzwananga neze nePEARLOC. 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:

- umuzwa wokucindezeleka esifubeni, ukubefuzela kanye nephika, ukushaya kwenhliziyo ngesigqi esingahambelani kahle, izinhlungu esifubeni, ingcindezi engemnandi neze, umuzwa wokucindezeleka nokukhameka, umuzwa wokugcwala noma izinhlungu maphakathi nesifuba sakho (ukuhlaselwa yisifo senhliziyo)
- ububhakubhaku benhliziyo (inhliziyo eshaya ngamandla kakhulu)
- ubuso obulengayo, ingalo ebuthakathaka, kanye nokukhuluma unambuluke futhi unkwankwaze kungazwakali kahle okushoyo (isifo sohlangothi)
- izinkinga zezinso (ukuchama umchamo omncane kunalokho okujwayelekile kuwena), ukungasebenzi kwezinso kahle nangendlela ejwayelekile, ukuhluleka kwezinso ukusebenza ngendlela efanele
- ijondisi (isifo sokuguquka kwesikhumba namehlo kube nombala ophuzi)
- i*hepatitis* (ukuvuvukala kwesibindi okuhambisana nezimpawu ezinjengesicanucanu, imfiva engenawo kakhulu amandla, izinhlungu esiswini nendawo ezungeze isisu), ukungasebenzi kwesibindi kahle nangendlela ejwayelekile (indle enombala wobumba, umchamo omnyama, ukuluma, ukuphelelwa wuthando lokudla)
- i*Stevens-Johnson syndrome* noma ezinye izinkinga zesikhumba ezibucayi kakhulu (eziqala ngokubonakala kwezimpawu ezinjengezomkhuhlane, kulandelwe wumqubuko obuhlungu obomvu noma osabukhwebezane ngokombala osabalalayo kanye namabhamuza), i*Toxic epidermal necrolysis* (TEN) (isifo sesikhumba esibucayi futhi esinobungozi esibonakala ngokuvela kwamabhamuza esikhunjeni)
- i*pancreatitis* (isifo sokuvuvukala kwamanyikwe esihambisana nezimpawu ezinjengezinhlungu esiswini, inhliziyo eshaya ngamandla kanye nemfiva).

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

Tshela udokotela wakho uma ubona okunye kwalokhu okulandelayo:
Imithelela engathandeki evamile ukubonakala:

- isiyezi, ikhanda elibuhlungu, ukuphazamiseka komuzwa wokunambitha, ukulahleka komuzwa

wokunambitha, umuzwa osanalithi ama*pins and needle*s, ukuphathwa wubuthongo

- ukuphazamiseka kokusebenza kwamehlo nokubona, ukubona sengathi izinto ziphindaphindeke kabili
- i*tinnitus* (ukukhala kwemisindo noma izihlonono ezindlebeni), i*vertigo* (umuzwa ojikelezayo, ukungabi nayo ibhalansi emzimbeni)
- ukukhwehlela, i*dyspnoea* (ukuphefumula kanzima)
- ukufikelwa wukushisa okukhulu esikhunjeni nasebusweni (*hot flushes*)
- izinhlungu esiswini nendawo ezungeze isisu, isicanucanu, ukuhlanza, inkinga yokungagayeki kahle kokudla, isifo sohudo, ukuqunjelwa, ukuguquka kwendlela ovakashela ngayo endlini encane uyozikhululula
- ukuluma kakhulu kwesikhumba (*pruritus*), ukuqubuka
- amajaqamba, ukuvuvukala kwamaqakala
- umzimba obuthakathaka ngendlela engajwayelekile noma ukungabi namandla, ukuvuvukala emilenzeni noma emaqakaleni (*oedema*), ukukhathala kakhulu

Imithelela engathandeki engavamile ukwenzeka:

- ukuthimula/amafinyila okudalwa wukuvuvukala kontwentwesana olungaphakathi emakhaleni (*rhinitis*)
- ukuhuzuka okungajwayelekile noma ukopha kalula, ukuzizwa ukhathele noma ucobekile emzimbeni wonke, isikhumba esiphaphathekile, izinkomba zokutheleleka ngesifo ezinjengomphimbo obuhlungu, imfiva kanye nokuqhaqhazela okubangelwa ukuzwa amakhaza (lokhu kungenzeka kube yizinkomba zokuba khona kwezinguquko noma ukulimala kwizingqalampilo zakho zegazi)
- ukuguquka kwesimo sengqondo nomphefumulo, itwetwe nexhala, ukuphazamiseka kokulala, ingcindezi yengqondo, ukudideka kwengqondo, ukuthuthumela kwelunga noma kwamalunga omzimba okungalawuleki
- umfutho wegazi ophansi, i*vasculitis* (ukuvuvukala kwemigudu yegazi okubangela izinguquko ezindongeni zemigudu yegazi, okuhambisana nezimpawu ezibandakanya imfiva, ukukhathala

kakhulu, ukwehla/ukuncipha emzimbeni kanye nobuhlungu bemisipha noma amajoyinti omzimba

- i*bronchospasm* (umuzwa wokucindezeleka esifubeni, ukubefuzela kanye nephika), imfiva, izinhlungu esifubeni eziba namandla kakhulu lapho udonsa umoya kakhulu, iphika, ukukhwehlela, kanye nokuzizwa ugula emzimbeni wonke (i-*eosinophilic pneumonia*, uhlobo lwenyumoniya oluyivelakancane)
- umlomo owomile, i*gastritis* (ukuvuvukala kontwentwesana lwesisu), ukukhula ngokweqile kwamathishu ezinsini azungeze amazinyo
- i-*angioedema* (ukuvuvukala ngaphansi kwesikhumba okungebuhlungu), i-*erythema multiforme* (umqubuko wesikhumba ovamise ukuqala ngezibhadu ezibomvu ezilumayo ebusweni, ezingalweni noma emilenzeni), ukujuluka ngokweqile, ukuzwela ekukhanyeni, i*psoriasis* ebhebhethekayo ibe yimbi kakhulu (isifo sesikhumba esiyisimbelambela esidala izibhadu ezilumayo noma ezibuhlungu zesikhumba esiwugqinsi esibomvu esinezimpephelezi ezibukeka njengombala osiliva, i*pemphigoid* (imiqubuko yesikhumba kanye namabhamuza emilenzeni, ezingalweni, kanye nasesiswini nendawo ezungeze isisu), i-*alopecia* (izibhadu zokuqothuka kwezinwele), i*purpura* (amachashazi amancane abomvu esikhunjeni), ukuguquka kombala wesikhumba
- amajaqamba, ubuhlungu bamajoyinti omzimba, umhlane obuhlungu
- ukuchama kakhulu noma kancane kunokwejwayelekile kuwena, ukuchama kakhulu ebusuku
- ukungavuki kwenduku kowesilisa, inkinga yokungasebenzi kahle kwenduku kowesilisa (ukungaqhanyelwa kanye nokuhluleka ukuhlala uqhanyelwe uze uqede ukwenza ucansi), ukukhukhumala kwezibele kubantu besilisa
- ukuzizwa ungaphathekile kahle emzimbeni wonkana, ukuzizwa ugula, noma uzwe kunokuthile okungalungile emzimbeni okwenza ungakhululeki neze kahle, izingakushisa lomzimba eliphakeme (imfiva)
- ukukhuluphala, ukuzaca
- ukuwa ngengozi

Le mithelela elandelayo ibikiwe kodwa akwaziwa ukuthi ivamise kangakanani ukwenzeka:

- I*raynaud's phenomenon* (inkinga yamasosha omzimba ebangela ukuthi imigudu yegazi igongobale lapho ithola amakhaza okungaholela ekuguqukeni kombala weminwe kanye/noma wezinzwane)
- ISIADH (inkinga lapho umzimba wakho ukhiqiza i-*antidiuretic hormone* eningi ngokweqile, okuyihomoni elekelela izinso zilawule umthamo wamanzi olahlekayo emzimbeni wakho lapho uchama) yinkinga eyivelakancane edalwa yisithako esiqukethwe kuPEARLOC.
- Inkinga yokunyakaza okuzenzekelayo futhi okungalawuleki.

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

Ukubika imithelela engathandeki

Uma uphathwa yimithelela engathandeki, khuluma nodokotela wakho noma usokhemisi. Lokhu kubandakanya ngisho naleyo mithelela engathandeki okungenzeka ikuphathe kodwa engabhaliwe kuleli pheshana. Futhi ungayibika imithelela engathandeki kwabakwaSAHPRA ngokusebenzisa ifomu lokubika imithelela engathandeki (“***6.04 Adverse Drug Reporting Form***”), elitholakala ku-inthanethi ngaphansi kwemibhalo namaphepha ashicileliwe abakwaSAHPRA: https://www.sahpra.org.za/Publications/Index/8. Ngokubika imithelela engathandeki, ungalekelela ekuhlinzekweni kolwazi oluthe xaxa maqondana nokuphepha kwePEARLOC.

5. Indlela yokugcina iPEARLOC

Yonke imithi kumele uyigcine endaweni ezingafinyeleli kuyona izingane.
Yigcine endaweni epholile neyomile ezingeni lokushisa elingama-25 °C noma ngaphansi kwalokho.
Yigcine esitsheni sayo efike naso futhi uyivikele ekukhanyeni nomswakama.
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).

6. Okuqukethwe ephaketheni lamaphilisi kanye nolunye ulwazi

Okuqukethwe yiPEARLOC

PEARLOC 4 mg/5 mg: Iphilisi ngalinye liqukethe i*perindopril tert-butylamine* engama-4 mg kanye ne-*amlodipine* engama-5 mg.

PEARLOC 4 mg/10 mg: Iphilisi ngalinye liqukethe i*perindopril tert-butylamine* engama-4 mg kanye ne-*amlodipine* engama-10 mg.

PEARLOC 8 mg/5 mg: Iphilisi ngalinye liqukethe i*perindopril tert-butylamine* engama-8 mg kanye ne-*amlodipine* engama-5 mg.

PEARLOC 8 mg/10 mg: Iphilisi ngalinye liqukethe i*perindopril tert-butylamine* engama-8 mg kanye ne-*amlodipine* engama-10 mg.

7. Ezinye izithako yilezi

calcium hydrogen phosphate (anhydrous), cellulose microcrystalline, crospovidone, glycerol dibehenate, magnesium oxide light, magnesium stearate, sodium starch glycolate (type A) kanye ne*trehalose dihydrate.*

8. Indlela ebukeka ngayo iPEARLOC kanye nalokho okuqukethwe ephaketheni layo

PEARLOC 4 mg/5 mg: Iyiphilisi elinombala omhlophe kuya kumbala omhloshana, elimise okweqanda futhi eliqumbile kancane nhlangothi zombili, ohlangothini olulodwa linombhalo 4 I 5.

PEARLOC 4 mg/10 mg: Iyiphilisi elinombala omhlophe kuya kumbala omhloshana, elingunxande futhi eliqumbile kancane nhlangothi zombili, ohlangothini olulodwa linombhalo 4 I 10.

PEARLOC 8 mg/5 mg: Iyiphilisi elinombala omhlophe kuya kumbala omhloshana, elingunxantathu futhi eliqumbile kancane nhlangothi zombili, ohlangothini olulodwa linombhalo 8 I 5.

PEARLOC 8 mg/10 mg: Iyiphilisi elinombala omhlophe kuya kumbala omhloshana, eliyindingilizi futhi eliqumbile kancane nhlangothi zombili, ohlangothini olulodwa elinombhalo 8 I 10.

Amaphilisi atholakala emaphaketheni e-*Aluminium*/kwizigcinamaphilisi ze-*Aluminium* eziqukethwe kwibhokisana elinemibhalo ngaphandle. Ibhokisana ngalinye liqukethe amaphilisi angama-30.

Amaphilisi atholakala ezitsheni zamaphilisi ze*polyethylene* (HDPE) eziqinile, ezivalwe ngci ngefoyela kanye nesivalo se*polypropylene* esenziwe ngendlela yokuthi zingakwazi ukusivula izingane. Isitsha samaphilisi ngasinye siqukethe amaphilisi angama-30.

9. Umnikazi Wesitifiketi Sokubhaliswa

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10. Leli pheshana lolwazi lagcina ukubuyekezwa ngo

Nhlolanja 2021

11. Inamba yokubhaliswa

Pearloc 4 mg/5 mg: A50/7.1.3/0230

Pearloc 4 mg/10 mg: A50/7.1.3/0231

Pearloc 8 mg/5 mg: A50/7.1.3/0232

Pearloc 8 mg/10 mg: A50/7.1.3/0233