

**IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI  
UHLA LWEZINHLOBO ZEPHILISI ILISORETIC**

**ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI**

S3

**1. IGAMA LOMUTHI**

**Iphilisi iLISORETIC 10/12,5**

**Iphilisi iLISORETIC 20/12,5**

***Ilisinopril kanye nehydrochlorothiazide***

**ILISORETIC iqukethe ushukela (*imannitol* engama-18,70 nama-38,30 mg ephilisini ngalinye ngokulandelana)**

**Ngaphambi kokuba uqale ukusebenzisa iLISORETIC 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.
- ILISORETIC 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 iLISORETIC futhi isetshenziselwani?
2. Okumele ukwazi ngaphambi kokuba usebenzise iLISORETIC
3. Indlela yokusebenzisa iLISORETIC
4. Imithelela engathandeki okungenzeka ibe khona
5. Indlela yokugcina iLISORETIC
6. Okuqukethwe ephaketheni lamaphilisi kanye nolunye ulwazi

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**1. Iyini iLISORETIC futhi isetshenziselwani?**

*lisinopril* iyingxenye yeqoqwana lemithi ebizwa ngama-*ACE inhibitors*. Isebenza ngokuthi inwebe ububanzi bemithambo yakho yegazi.

*hydrochlorothiazide* iyingxenye yeqoqwana lemithi ebizwa ngama-*diuretics* (amaphilisi amanzi). Ilekelela umzimba wakho ukukhipha amanzi nosawoti, njenge-*sodium*, emchameni wakho.

ILISORETIC isetshenziselwa ukwelapha umfutho wegazi othanda ukuphakama kancane kanye nomfutho wegazi ophakeme kakhulu (*hypertension*).

Ngokuvamile udokotela wakho uzokunikeza iLISORETIC lapho usulawulekile kakade umfutho wakho wegazi emuva kokusebenzisa zombili izithako zalo muthi, ngokwehlukana.

**2. Okumele ukwazi ngaphambi kokuba usebenzise iLISORETIC**

**Ungalokothi usebenzise iLISORETIC:**

- uma umzimba wakho ungezwani nesithako *lisinopril* noma *hydrochlorothiazide* noma uma ungezwani nanoma yisiphi esinye isithako seLISORETIC (bheka isigaba 5)
- uma uke waphathwa wumdlavuza wesikhumba noma uma umilwa yizisihla zesikhumba ezingalindelekile ngenkathi welashwa ngeLISORETIC
- uma umzimba wakho ungezwani nama-*sulphonamides* (asetshenziselwa ukwelapha ukutheleleka okuthile) kanye nemithi eyenziwe nge-*sulphonamide*
- uma wena nanoma ngubani omunye emndenini wakho ninomlando wokuphathwa yi-*angioedema* (ukuvuvukala okufana nama-*hives* okwenzeka ngaphansi kwesikhumba) okuhlobene nokwelashwa ngeLISORETIC esikhathini esedlule noma ngeminye imithi equkethe izithako zokwelapha ezifanayo neLISORETIC noma eminye imithi esetshenziselwa ukwelapha izifo eziphathelelene nenhliziyo, ebizwa ngama-*ACE inhibitors* (*angiotensin-converting enzyme inhibitors*), noma ama-*ARBs* (*angiotensin receptor blockers*).

Uma kunjalo-ke, ungalokothi uphinde uyisebenzise futhi le mithi

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- uma uphethwe yi *hypertrophic obstructive cardiomyopathy* (HOCM - inkinga yokuba wugqinsi komsipha wenhliziyo)
- uma ungachami noma uma uchama umchamo omncane kakhulu ngosuku
- uma une-*anuria* (inkinga lapho izinso zakho zingakwazi ukukhiqiza umchamo, futhi okwenza ungabe usakwazi ukuchama)
- uma uxinwe kakhulu yisifo sezinso esinamandla, unenkinga yokuncipha kwemithambo yegazi yazo zombili izinso, uma kuwena kwenziwa i *haemodialysis* (inqubokwelapha yokuhlazwa kwegazi ngomshini ngenxa yokungasebenzi kahle kwezinsos noma uma ususele nenso eyodwa kuphela futhi enemithambo yegazi enciphile)
- uma unesifo samavalvu enhliziyo esibizwa nge-*aortic stenosis* lapho kunokuncipha kwembobo
- uma futhi welashwa ngemithi ebizwa ngama *potassium sparing diuretics* (isibonelo, *spironolactone*, *triamterene* noma *amiloride*) ekhuphula izinga lokuchama
- uma une *porphyria* (isifo sofuzo esiyivelakancane lapho umbala womchamo wakho uba mnyama futhi isikhumba sakho sibe nokuzwela kakhulu ekukhanyeni)
- uma unesifo i-*Addison's disease* (isifo samahomoni esinezimpawu ezinjengokukhathala okunamandla okuyisimbelambela, ukuphelelwa wuthando lokudla kanye nokuncipha emzimbeni)
- uma uthola ukwelashwa ngeli *lithium* (isizinzisi sesimo sengqondo nomphefumulo) kanyekanye neLISORETIC lokho kungaholela ekutheni ukhuphuke kakhulu umthamo we *lithium* egazini okungadala ubuthi
- uma unenkinga yesibindi esingasebenzi kahle noma une *cirrhosis* (isifo sesibindi esesibhebhethetheke kakhulu esinezimpawu ezinjengokuguquka kwesikhumba sibe nombala ophuzi, ukuhuzuka kalula kanye nokukhathala kakhulu)
- uma unesifo sokuvaluka komgudu wenyongo, phecelezi i *biliary obstruction* (okuyinkinga yokungaphumi kwenyongo kwingqalathi yenyongo (*gall bladder*))
- uma usebenzisa umuthi wokwelapha umfutho wegazi ophakeme oqukethe i-*aliskiren*
- uma usebenzisa umuthi oyi-antibhayothikhi oqukethe ama *fluoroquinolones* (isibonelo,

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*iciprofloxacin, ilevofloxacin*) futhi unomlando wokulimala kwenso okumaphakathi ngokwamandla noma lokho osekukubi kakhulu

- uma ukhulelwe noma uma ucabanga ukuthi kungenzeka ukuthi mhlawumbe usukhulelwe noma uma uhlela ukukhulelwa noma uma uncelisa

**Izixwayiso kanye nezinto okumele uziqikelele**

**Qaphela kakhulu uma usebenzisa iLISORETIC:**

Uma kwenzeka ukhulelwa ngenkathi usebenzisa iLISORETIC, kumele uyeke ngokushesha ukusebenzisa iLISORETIC futhi wazise udokotela wakho. Kungenzeka kudingeke ukuthi akushintshele komunye umuthi ohlukile.

- uma kamuva nje usanda kufakwa inso yokufakelwa, noma udinga inqubokwelapha yokuhlazwa kwegazi ngomshini ngenxa yezinso ezingasebenzi kahle noma uma unenkinga yokuhluleka kwezinsu ukusebenza ngendlela efanele
- uma welashwa nge*diuretic* (iphilisi lamanzi) noma uyalelwe ukuthi ulandele uhlelo lokudla okungenawo usawoti noma okunosawoti omncane kakhulu njengoba kungenzeka ube nenkinga yokwehla kakhulu komfutho wegazi (*hypotension*)
- uma unenkinga yenhliziyu, ebizwa nge*mitral valve stenosis* (ukuncipha kwevalvu yenhliziyu okudala ukuvimbeleka kokuhamba nokugeleza kwegazi)
- uma unenkinga yokungasebenzi kahle kwamahomoni, ebizwa nge*primary aldosteronism*
- uma usebenzisa umuthi obizwa nge-*aliskiren*, njengoba kungenzeka wehlise umfutho wakho wegazi. (bheka isigatshana esithi Ukusebenzisa eminye imithi ngesikhathi esifanayo neLISORETIC)
- uma unezinkinga zezinsu

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- uma usebenzisa ama-antibhayothikhi abizwa ngama*fluoroquinolones* (isibonelo, *iciprofloxacin*, *levofloxacin*), ngokuhlanganyela neLISORETIC lokho kungakhuphula ubungozi bokulimala kwenso kungazelelwe futhi okubi kakhulu, ikakhulukazi uma unenkinga yokungasebenzi kahle kwezinsu, okuyinkinga emaphakathi ngokwamandla noma embi kakhulu, njengasezigulini esezikhulile ngokweminyaka yobudala
- uma usebenzisa noma yimaphi amanye amaphilisi amanzi njengoba kudingeka ukuthi uyeke ukuwasebenzisa ngaphambi kokuba usebenzise iLISORETIC
- uma unamazinga ekholesteroli aphakeme futhi uthola ukwelashwa okubizwa nge'*LDL apheresis*' (inqubokwelapha yokususa ikholesteroli egazini lakho)
- uma unezinkinga zesibindi, ezibandakanya izimpawu ezinjengokuguquka kwesikhumba namehlo kube nombala ophuzi
- njengoba ukwelashwa nge*hydrochlorothiazide* enjengeLISORETIC, ikakhulukazi uma usuyisebenzise isikhathi eside futhi uthatha imithamosilinganiso ephakeme, kungakhuphula ubungozi bokuphathwa yizinhlobo ezithile zomdlavuzwa wesikhumba noma wodebe lomlomo (*non-melanoma skin cancer*), sivikele isikhumba sakho singashiswa yilanga futhi singahlatshwa yimisebe yelanga enobungozi ngenkathi usebenzisa iLISORETIC
- uma sekusondele isikhathi sokuthi kuwena kwenziwe inqubokwelapha yokuhlinzwa okukhulu noma yokulaliswa ngomuthi olalisayo ngaphambi kokuba uhlinzwe
- uma unesifo igawuthi
- uma uphathwa wukukhathala okukhulu, ubuthakathaka bemisipha yomzimba, ukozela, isicanucanu, ukuhlanza noma amajaqamba, njengoba kungenzeka lokhu kube yizimpawu zenkinga ebizwa nge-*electrolyte imbalance*. Udokotela wakho kungenzeka afune ukuhlola igazi lakho njalo futhi ngokuqhubekayo
- uma sekusondele isikhathi sokuthi wenze ukuhlolwa kokusebenza kwendlala yegilo
- uma uba nokuvuvukala kunoma iyiphi ingxenye yomzimba wakho

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- uma uke waphathwa yisifo esibizwa nge*systemic lupus erythematosus* (SLE) esinezimpawu ezinjengamajoyinti omzimba abuhlungu, ukukhathala ngokweqile kanye nomqubuko phezu kwekhala nezihlathi)
- uma unezinkinga zemithambo yakho yegazi (*collagen vascular disease*)
- uma sekusondele isikhathi sokuthi uthole ukwelashwa okubizwa nge*desensitisation therapy* (ngenxa ye-aleji, isibonelo, edalwe wukulunywa yizinambuzane). Uma usebenzisa iLISORETIC ngenkathi uthola lokhu kwelashwa, lokho kungadala inkinga yama-aleji enamandla
- uma uphethwe yisifo esiwuhlobo lwe-*arthritis* esibizwa nge*collagen vascular disease*
- uma utheleleka ngesifo
- kungenzeka uphathwe wukukhwehlela okulokhu kuqhubeka njalo ngenkathi usebenzisa iLISORETIC. Ngokuvamile ukukhwehlela kuyaphela lapho usukuphuthulile ukwelashwa kwakho ngeLISORETIC
- uma uba nenkinga yokuzwela elangeni, isibonelo, uma isikhumba sakho siluma noma siba bomvu futhi sivuvukala lapho sihlathwa yilanga. Mazise umhlinzeki wakho wosizo lwezempilo nokwelashwa mayelana nanoma yimaphi ama-aleji akuphathayo abangelwa wukuhlathwa yilanga. Uma umhlinzeki wakho wosizo lwezempilo nokwelashwa ekweluleka ukuthi uqhubeka nokusebenzisa iLISORETIC, kudingeka ukuthi uzivikele elangeni lezo zindawo zomzimba wakho ezingambozekile
- uma uba nenkinga yokuphazamiseka kokusebenza kwamehlo noma ingcindezi emehlweni, amehlo abuhlungu kakhulu, ikhanda elibuhlungu, isicanucanu kanye nokuhlanza, futhi uma amehlo akho ehlala ekhala izinyembezi njalo
- uma uyisiguli esingumuntu omnyama njengoba kungenzeka ukuthi iLISORETIC ingawehlisi kahle umfutho wakho wegazi. Futhi kungenzeka uphathwe kalula wumthelela ongathandeki i-*“angioedema”* (i-aleji enamandla ehambisana nokuvuvukala kwezandla, izinyawo, amaqakala, ubuso, izindebe, ulimi noma umphimbo)

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- *Hydrochlorothiazide* equkethwe kuLISORETIC kungenzeka ikhiqize imiphumela yokuhlola ukusetshenziswa kwezikhuthazamzimba ezingekho emthethweni ebonisa ukuthi wena kukhona okuthile okusebenzisile okungekho emthethweni.

Udokotela wakho kungadingeka ukuthi enze ukuhlolwa (amathesti) ukuze aqaphe isimo sakho ngaphambi kokwelashwa noma ngenkathi welashwa.

Akuqinisekiswa ukuphepha kanye nokusebenza kahle kweLISORETIC ezinganeni.

**Ukusetshenziswa kweminye imithi neLISORETIC**

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

ILISORETIC kungenzeka iguqule indlela esebenza ngayo imithi elandelayo:

- *Lithium*, ingaholela ekukhuphukeni kobuthi egazini uma isetshenziswa ngokuhlanganyela neLISORETIC (bheka isigatshana esithi Ungalokothi usebenzise iLISORETIC).
- Eminye imithi eyingxenywe yeqoqwana lemithi elifanayo (okungama-*angiotensin II receptor antagonists* noma ama-*ACE inhibitors*) yokwehlisa umfutho wegazi, kubandakanya naleyo equkethe i-*aliskiren*.
- Amanye amaphilisi amanzi noma imithi yokwehlisa umfutho wakho wegazi kungenzeka ikhuphule amandla eLISORETIC okwehlisa umfutho wakho wegazi, kungenzeka uphathwe yizimpawu ezinjengenzululwane noma isiyenzi, ukuquleka, isicanucanu, ukukhathala kakhulu kanye nokuhluleka ukugxilisa ingqondo. (Tshela udokotela wakho uma kukhona noma yimuphi owusebenzisayo kule mithi).
- Izondlamzimba ze*potassium* noma imikhiqizo esetshenziswa esikhundleni sikasawoti equkethe i*potassium* (lokhu kungaholela kumthamo ophakeme we*potassium* egazini).
- Imithi eguqula izinga lokushaya kwenhliziyo kanye nemithi ethile esetshenziselwa ukwelapha ukugula okuphathelene nokusebenza kwengqondo, imithi yokwelapha ingcindezi yengqondo

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kanye nemithi ethile yokulalisa umuntu ukuze angabuzwa ubuhlungu ngenkathi ehlinzwa, njengoba lokhu kungenzeka kwehlise umfutho wakho wegazi ube ngaphansi kwalowo ofanelekile. (Xoxisana nodokotela wakho uma ungaqinisekile ngalokhu).

- Imithi ethile esetshenziselwa ukwelapha izinhlungu nokuvuvukala ebizwa ngama *NSAIDs* (*non-steroidal anti-inflammatory drugs*, isibonelo, *i-aspirin*) njengoba kungenzeka inciphise amandla okusebenza kweLISORETIC.
- Imithi equkethe igolide, enjengesodium *aurothiomalate*, okungenzeka unikezwe yona njengomjovo, ingadala ukuthi ufikelwe wukushisa okukhulu esikhunjeni siguquke sibe bomvu, isicanucanu kanye nenzululwane.
- imithi ebizwa ngama *sympathomimetics*, esetshenziselwa ukwelapha ukucinana noma ukuvaleka kwezimbotshana zomoya emakhaleni noma amanye amakhambi okwelapha umkhuhlane (kubandakanya leyo mithi ongayithenga ekhemisi ngaphandle kwencwadi kadokotela), kungenzeka ivimbele iLISORETIC ingakwazi ukwehlisa umfutho wakho wegazi.
- Imithi esetshenziselwa ukwelapha isifo sikashukela (isibonelo, *metformin*, *insulin* kanye ne *diazoxide*), uma isetshenziswa kanyekanye neLISORETIC, kungenzeka lokho kuwehlise kakhudlwana impela amazinga kashukela egazini lakho okungaholela ku *hypoglycaemia*, kungenzeka uphathwe yizimpawu ezinjengesiyenzi, ikhanda elibuhlungu kanye nokuguquka kwesimo sengqondo nomphefumulo.
- Amacorticosteroids (asetshenziselwa ukunciphisa ukuvuvukala, ukucindezela amasosha omzimba kanye nokwelapha ngendlela ebandakanya ukufakwa kwehomoni noma kwesondlamzimba esingekho noma esishodayo emzimbeni).
- Imithi equkethe i *calcium* kanye nezondlamzimba eziqukethe u *Vitamin D* kungenzeka kukhuphule amazinga e *calcium* egazini okungaholela ekutheni ube nenkinga yokuphelelwa amanzi emzimbeni, ukukhathala kakhulu, ukuphelelwa wuthando lokudla noma ukoma.
- Amapressor amines, isibonelo, *i-epinephrine* (*adrenaline*) asetshenziselwa ukwelapha umfutho wegazi ophansi, ukuthuthumela komzimba (okungaba inhliziyi eshaya ngamandla,



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ukuphefumula ngendlela engajwayelekile noma izandla ezijulukile), inkinga yokuhluleka kwenhliziyo ukusebenza ngendlela efanele, isifuba somoya noma ama-aleji, kungenzeka angasebenzi kahle uma esetshenziswa kanyekanye neLISORETIC.

- Izithambisimisipha yomzimba (isibonelo, *itubocurarine*), amandla okusebenza ale mithi kungenzeka akhuphuke uma isetshenziswa kanyekanye neLISORETIC.
- Ama-antibhayothikhi athile (anjengetrimethoprim) kanye nemithi enciphisa ikholesteroli ephakeme (enjenge*lovastatin*), kungenzeka kukhuphule ubungozi bokwehla kwamazinga *epotassium* egazini, okungabandakanya izimpawu ezinjengobuthakathaka, ukukhathala kakhulu, ukunsonsotha nobundikindiki kanye nobunzima bokuphefumula.
- Imithi yokwelapha igawuthi noma ubuhlungu bemisipha yomzimba (enjenge-*indomethacin* noma *i-allopurinol*), kungenzeka ibangele ubungozi bokuncipha komthamo womchamo owuchamayo noma ukugcwala nokunqwabelana kwamanzi emzimbeni futhi lokhu kungehlisa namandla okusebenza kwamasosha akho omzimba.
- Imithi esetshenziselwa ukucindezela amandla okusebenza ngokweqile kwamasosha omzimba) (ama-*immunosuppressants*, anjenge*cyclosporin*), amaNSAIDs kanye nemithi engama-*anti-convulsion medicines* yokwelapha ukudlikiza komzimba ngendlela engalawuleki (enjengama-*ACE inhibitors* kungenzeka ibangele ukuncipha komthamo womchamo owuchamayo, ukugcwala nokunqwabelana kwamanzi emzimbeni, okungadala ukuvuvukala emilenzeni yakho kanye nobungozi bokwehla kwe*potassium* egazini okungabangela izimpawu ezinjengobuthakathaka, ukukhathala kakhulu, ukunsonsotha noma ubundikindiki kanye nobunzima bokuphefumula.
- Imithi yokulawula isigqi sokushaya kwenhliziyo (enjenge*procainamide*) kanye naleyo esetshenziselwa *ichemotherapy* yokwelapha umdlavuza (enjengama*cytostatics*), kungenzeka yehlise amandla amasosha akho omzimba futhi kungenzeka kudale ukuthi uthetheleke kalula ngezifo.
- Umjovo *i-Amphotericin B* (osetshenziselwa ukwelapha ukutheleleka okubangelwa wukhunta (*fungal infections*)), *icarbenoxolone* (esetshenziselwa ukwelapha izilonda esiswini,

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ukuvuvukala ngaphakathi emlonyeni noma endaweni ezungeze umlomo), amacorticosteroids (imithi engama-steroid), icorticotropin (okuyihomoni) noma imithi ehlambulula isisu eyizikhuthazamathumbu (imithi esetshenziselwa ukwelapha ukuqunjelwa) kungenzeka iqinise i-electrolyte imbalance (ukungalingani kahle koketshezi oludingekayo emzimbeni) okungadala izimpawu ezinjengokushaya kwenhliziyo ngesigqi esingahambelani kahle, ukukhathala kakhulu, isicanucanu, ukuhlanza, isifo sohudo noma ukuqunjelwa.

- Imithi esetshenziselwa ukwelapha inkinga yokuhluleka kwenhliziyo ukusebenza ngendlela efanele (*digoxin*), ikhuphula ubungozi be*digitalis toxicity* okungadala izimpawu ezinjengokukhathala kakhulu, ukucobeka komzimba kanye nokuphazamiseka kokusebenza kwamehlo.
- Imithi esetshenziselwa ukwehlisa ikholesteroli yakho (*icholestyramine* kanye ne*colestipol*) kungenzeka ibambezele ukumunceka kweLISORETIC, ngakho-ke iLISORETIC kumele uyiphuze okungenani kusasele ihora elilodwa ngaphambi kokuphuza le mithi noma uyiphuze sekudlule amahora amane kuya kwayisithupha emuva kokuphuza le mithi.
- Imithi engama-antibhayothikhi ebizwa ngama*fluoroquinolones* (*iciprofloxacin*, *moxifloxacin* kanye ne*levofloxacin*) kungenzeka ikhulise ubungozi bokulimala kwezinsongo kungazelelwe futhi okubi kakhulu.
- Imithi elalisayo, izidakamizwa kanye nokuphuza utshwala ngokweqile kungenzeka kuholele ekwehleni kakhudlwana komfutho wegazi, okungenzeka ngokushesha kungazelelwe ngenxa yokuguquka kwesimo somzimba, njengalapho umuntu esukuma ngokushesha ema ngezinyawo.

**Ukuphuza iLISORETIC nokudla kanye nophuzo:**

ILISORETIC ungayiphuzwa nokudla noma uyiphuze ngaphandle kokudla.

**Ukukhulelwa, ukuncelisa kanye nokuba sesimweni sokuzala nokuthola abantwana**

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Uma ukhulelwe noma uncelisa umntwana wakho, bonisana nodokotela wakho, usokhemisi noma omunye ungoti wosizo lwezempilo nokwelashwa ngaphambi kokuba usebenzise iLISORETIC ukuze uthole ukwelulekwa.

Akumele usebenzise iLISORETIC uma ukhulelwe noma uncelisa (bheka isigatshana esithi Ungalokothi usebenzise iLISORETIC).

ILISORETIC akumele isetshenziswe ngowesifazane okusaphele isikhathi esincane ekhulelwe, futhi akumele isetshenziswe ngowesifazane osekuphele izinyanga ezingaphezu kwezintathu ekhulelwe, ngoba kungenzeka idale umonakalo omkhulu emntwaneni uma isetshenziswa emuva kwenyanga yesithathu yokukhulelwa.

Akulungile neze ukwelashwa kowesifazane oncelisayo ngeLISORETIC (bheka isigatshana esithi Ungalokothi usebenzise iLISORETIC).

**Ukushayela kanye nokusebenzisa imishini:**

Imithi eyehlisa umfutho wegazi kungenzeka ibangele isiyenzi noma ukozele.

Akulula ukubikezela njalo ukuthi iLISORETIC izoba nomthelela ongakanani emisebenzini yansukuzonke yesiguli. Iziguli kumele ziqinisekise ukuthi aziyenzi imisebenzi eshiwo ngenhla kuze kufike isikhathi lapho sezibonile ukuthi iLISORETIC iziphatha kanjani.

**3. Isetshenziswa kanjani iLISORETIC**

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

***Kubantu abadala:***

Umthamosilinganiso ojwayelekile yiphilisi elilodwa nsukuzonke, okumele uliphuze nokudla noma ngaphandle kokudla ngesikhathi esifanayo nsukuzonke.

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Umthamosilinganiso weLISORETIC ungakhushulwa ube ngamaphilisi amabili ngosuku, futhi lokho kuzoncika ekutheni lukhona yini ushintsho olwenzekayo emfuthweni wakho wegazi. Udokotela wakho uzothatha isinqumo maqondana nomthamosilinganiso azokunikeza wona emuva kokuba esekuxilongile futhi wabukisisa isimo sakho. Iphilisi kumele ulehlise ngamanzi anele.

***Iziguli ezelashwa ngamadiuretic (amaphilisi amanzi):***

Tshela udokotela wakho uma usebenzisa amaphilisi amanzi njengoba kungenzeka afune ukukuyekisa amaphilisi amanzi ngaphambi kokuba uqale ukwelashwa ngeLISORETIC.

***Iziguli eziphethwe yisifo sezinsu esinamandla:***

ILISORETIC ayikulungele neze ukusetshenziswa yiziguli ezinezinkinga ezinamandla zezinsu (bheka isigatshana esithi Ungalokothi usebenzise iLISORETIC).

***Ukusetshenziswa kwamaphilisi kubantu asebekhulile ngokweminyaka yobudala:***

Ngokuvamile asikho isidingo sokuthi kwehliswe umthamosilinganiso kubantu asebekhulile ngokweminyaka yobudala.

***Izingane:***

ILISORETIC ayikulungele neze ukusetshenziswa ezinganeni kanye namabhungu namatshitshi ngenxa yokuntuleka kolwazi maqondana nokuphepha kwayo kanye nokusebenza kahle kwayo kubona.

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

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

**Uma uphuze iLISORETIC engaphezulu kwaleyo okumele uyiphuze:**

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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:

- *ihypotension* (isiyezi, ukuquleka, isicanucanu), ukuphefumula ngokushesha (*hyperventilating*), isikhumba esiphaphathekile noma esijulukayo, izindebe nezinzapho ezinombala othi mawube luhlaza okwesibhakabhaka (*circulatory shock*), ukuncipha komthamo womchamo owuchamayo, ukunqwabelana nokugcwala koketshezi emzimbeni, okudala ukuvuvukala emilenzeni, emaqakaleni noma ezinyaweni, ukushaya kwenhliziyo kancane kakhulu, ukushaya kwenhliziyo ngamandla noma ngesigqi esingahambelani kahle noma itwetwe nexhala kanye nokukhwehlela.

Izinkomba ezivame kakhulu zomthamosilinganiso oweqile, ezihlobene nokwehla komthamo wama-elekthrolayithi emzimbeni, wubuthakathaka, ukukhathala, ukubanjwa amajaqamba emisipheni yomzimba, ukunsonsotha noma ubundikindiki, isisu esiqumbile noma ukuqunjelwa, ukuphelelwa amanzi emzimbeni, isifo sohudo noma ukuhlanza, ukudideka, ukudlikiza komzimba ngendlela engalawuleki kanye nokuphelelwa amanzi emzimbeni ngenxa yokuchama njalo. Umhlinzeki wakho wosizo lwezempilo nokwelashwa uzokweluleka maqondana nezinyathelo zokuphepha okumele uzithathe uma kwenzekile waphuza umthamosilinganiso oweqile.

**Uma kwenzeka ukhohlwa ukuphuza umthamosilinganiso weLISORETIC:**

Uma kwenzekile wakhohlwa ukuphuza iLISORETIC, yiphuze ngokushesha emuva kokukhumbula ukuthi kumele uyiphuze. Uma sekusondele isikhathi sokuphuza umthamosilinganiso olandelayo, ungabe usawuphuza lowo mthamosilinganiso ongawuphuzanga futhi uqhubeke uphuze iphilisi noma amaphilisi ngesikhathi esijwayelekile. Ungalokothi uphuze imithamosilinganiso ephindwe kabili ngenhloso yokuvala isikhala semithamosilinganiso okhohliwe ukuyiphuza.

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**Uma uyeka ukusebenzisa iLISORETIC:**

Kusemqoka ukuthi uqhubeke nokuphuza amaphilisi akho ngisho usuzizwa usungcono emzimbeni emuva kwezinsuku ezimbadlwana.

**4. Imithelela engathandeki okungenzeka ibe khona**

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

Uma kwenzeka noma yikuphi kulokhu okulandelayo, yeka ukusebenzisa iLISORETIC 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 neLISORETIC. 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:

- imfiva, ubuhlungu besikhumba obusabalele obungaziwa ukuthi bubangelwa yini, umqubuko obomvu noma osabukhwebezane ngokombala osabalalayo noma amabhamuza esikhunjeni sakho kanye nasolwelwesini lomlomo wakho, ikhala, amehlo, izitho zangasese noma

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ukwebuza/ukuxebuka kwesikhumba sakho emuva kwezinsuku ezimbadlwana emuva kokumilwa ngamabhamuza, okuyizimpawu zesifo i *Stevens-Johnson Syndrome*

- ijondisi (isifo sokuguquka kwesikhumba namehlo kube nombala ophuzi)
- ukuhlaselwa yisifo senhliziyo noma isifo sohlangothi
- ukushaya kwenhliziyo ngamandla noma ngesivinini esiphakeme (*itachycardia*)
- umfutho wegazi ophansi noma ukuquleka lapho usukuma uma ngezinyawo kade ulele phansi noma uhlezi (*i-orthostatic hypotension/isiyezi*)
- izinhlungu esifubeni (*i-angina*)
- ubuthakathaka emzimbeni, ukukhathala okukhulu, ukwehla/ukuncipha emzimbeni, ikhanda elibuhlungu (okuyizimpawu zesifo esibizwa nge *vasculitis*)
- izinkinga zezinso (ukuphuma komchamo omncane kunalokho okujwayelekile kuwena lapho uchama)
- ukuvuvukala kwesibindi, i *hepatitis* (okuhambisana nezimpawu ezinjengesicanucanu, imfiva engenawo amandla kakhulu, izinhlungu esiswini nendawo ezungeze isisu)

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
- ukukhwehlela
- ukuguquka kwamazinga amakhemikhali athile egazini nasemchameni okuvamise ukuhlonzwa ngokuhlolwa kwegazi nomchamo (*electrolyte imbalance*)
- i *vertigo* (ukungabi nayo ibhalansi emzimbeni), isiyezi, umuzwa onsonsothayo ezandleni, ezinyaweni noma ezindebeni (umuzwa osanalithi obizwa phecelezi ngama "*pins and needles*"), ukungalali kahle, inzululwane

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- izinhlungu noma ukungaphatheki kahle esiswini, ukuqunjelwa
- ukuqubuka esikhunjeni.

Imithelela engathandeki engavamile ukwenzeka:

- ukuphakama kokusebenza kwamasosha omzimba (isifo lapho amasosha omzimba ehlasela amathishu omzimba aphilile)
- izinkinga maqondana nomnkantsha wakho noma inani elinciphile lezingqalampilo zegazi ezibomvu kanye/noma amaplathelethi egazini lakho. Kungenzeka uphawule ukukhathala, ukutheleleka (okungenzeka kube namandla), imfiva, ukuzizwa uphelelwa umoya noma uhuzuke noma wophe kalula
- izinguquko kwezinye zezingqalampilo noma ezinye izingxenye zegazi lakho, imiphumela yokuhlolwa kwegazi ebonisa okungajwayelekile kubandakanya ne-anemiya
- amazinga aphansi kashukela egazini lakho (*ihypoglycaemia*)
- *ipancreatitis* (isifo sokuvuvukala kwamanyikwe esihambisana nezimpawu ezinjengezinhlungu esiswini, inhliziyo eshaya ngamandla kanye nemfiva)
- ukuntuleka kwe*potassium*, *sodium* kanye ne*magnesium*, amazinga ekholesteroli ephakeme kanye ne-*uric acid* eningi ngokweqile egazini (okubonakala ngokuhlolwa kwegazi)
- ukungafikelwa wubuthongo/ukuqwasha, ukungalali kahle, ukuguquka kwesimo sengqondo nomphefumulo, itwetwe nexhala, ingcindezi yengqondo, ukudideka, ama*hallucinations* (ukubona nokuzwa izinto ezingekho), ukungahlaliseki/ukungabi nasinqe
- ukufikelwa wukushisa okukhulu esikhunjeni siguquke sibe bomvu, ukuguquka kombala weminwe yakho noma izinzwane
- izifo ezibangelwa wukutheleleka ngamagciwane komgudu wokuphefumula ophezulu, ukucinana emakhaleni, izinkinga zokutheleleka nokungasebenzi kahle kwezimbotshana zomoya emakhaleni, umphimbo obuhlungu
- izinhlungu noma ukungaphatheki kahle esiswini, ukuvuvukala kwesisu, isisu esiqumbile,



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ukugcwala komoya esiswini (umsuzo)

- ukusuza, ukuqina nokudonseka kwemisipha yesisu, umlomo owomile, ukuvuvukala kwendlala yamathe
- isifo sohudo, ukuhlanza, umlomo owomile, isicanucanu, inkinga yokungagayeki kahle kokudla
- ukungasebenzi kwesibindi kahle nangendlela ejwayelekile (indle enombala wobumba, umchamo omnyama, ukuluma, ukuphelelwa wuthando lokudla, amehlo anombala ophuzi noma isikhumba esinombala ophuzi)
- amajaqamba, inkwantshu, ubuthakathaka noma izinhlungu
- amahives, ukuluma, ukuvuvukala kwesikhumba, ukuqubuka, ukushintsha kombala wesikhumba ube bomvu, ukuzwela kakhulu ekukhanyeni, isikhumba esomile, isikhumba esinamabhamuza noma esixebukayo, ukuqothuka kwezinele
- ukungasebenzi kwezinsoko kahle nangendlela ejwayelekile okubandakanya nokuvuvukala kwazo, ukutheleleka komgudu womchamo, ushukela emchameni
- amehlo afiphele, ukungaboni kahle emehlweni okulokhu kuqhubeka njalo nokuba kubi, ukubona sengathi izinto zinombala ophuzi
- izinkinga zokungaboni kahle emehlweni akho ezikuphatha isikhashana esincane, amehlo abomvu abuhlungu
- *ivertigo* (ukungabi nayo ibhalansi emzimbeni )
- izinkinga zokungayi kahle ocansini, ukukhukhumala kwezibele kubantu besilisa

Le mithelala elandelayo ibikiwe kodwa akwaziwa ukuthi ivamise kangakanani ukwenzeka:

- umdlavuzwa wesikhumba kanye nodebe lomlomo (*inon-melanoma skin cancer*), ohambisana nezimila zesikhumba ezingajwayelekile, amaqhubu noma izilonda ezindebeni zomlomo ezingapholi futhi ezibeleselayo isikhathi eside
- ukuvuvukala kwendlala yamathe.

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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 mithethelela 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 abakwa-SAHPRA:

<https://www.sahpra.org.za/Publications/Index/8>. Ngokubika imithelela engathandeki, ungalekelela ekuhlinzekweni kolwazi oluthe xaxa maqondana nokuphepha kweLISORETIC.

**5. Indlela yokugcina iLISORETIC**

Yonke imithi kumele uyigcine endaweni ezingafinyeleli kuyona izingane.

Yigcine ezingeni lokushisa elingama-25 °C noma ngaphansi kwalokho. Yivikele ekukhanyeni.

Izingqwenjana eziyizigcinamaphilisi zigcine kwibhokisana lamaphilisi kuze kufike isikhathi lapho sekudingeka ukuba asetshenziswe.

Ungawasebenzisi 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 yiLISORETIC**

LISORETIC 10/12,5: Iphilisi ngalinye liqukethe *lisinopril* engama-10 mg (njenge*dihydrate*) kanye ne*hydrochlorothiazide* engama-12,5 mg.

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LISORETIC 20/12,5: Iphilisi ngalinye liqukethe *lisinopril* engama-20 mg (njenge*dihydrate*) kanye ne*hydrochlorothiazide* engama-12,5 mg.

**7. Ezinye izithako yilezi:**

*Ezisengxenyeni engaphakathi yephilisi:*

*Croscarmellose sodium, dibasic calcium phosphate dihydrate, magnesium stearate, mannitol, pregelatinised maize starch.*

Futhi kunezinikezimbala (*colourants*) ezilandelayo ezisetshenziswe ephilisini elingama-10/12,5 mg kuphela: *iron oxide red, iron oxide yellow.*

**8. Indlela ebukeka ngayo iLISORETIC kanye nalokho okuqukethwe ephaketheni layo**

LISORETIC 10/12,5: Iyiphilisi elinombala osapentshisi, eliyindingilizi, elingenalo ungwengwezana, eliqumbile kancane nhlangothi zombili, ohlangothini olulodwa kuqoshwe izinhlamvu 'LH' kanti ngakolunye uhlangothi akubhaliwe lutho.

LISORETIC 20/12,5: Iyiphilisi elinombala omhlophe, eliyindingilizi, elingenalo ungwengwezana, eliqumbile kancane nhlangothi zombili, ohlangothini olulodwa kuqoshwe izinhlamvu 'LH' kanti ngakolunye uhlangothi linomugqa onqamula phakathi.

LISORETIC 10/12,5: itholakala emaphaketheni ayizigcinamaphilisi ze-*PVC/PVDC/aluminium* eziqukethe amaphilisi angama-30 afakwe kwibhokisana elinemibhalo ngaphandle.

LISORETIC 20/12,5: itholakala emaphaketheni ayizigcinamaphilisi ze-*PVC/PVDC/aluminium* eziqukethe amaphilisi angama-30 afakwe kwibhokisana elinemibhalo ngaphandle.

**9. Umnikazi Wesitifiketi Sokubhaliswa**

Pharma Dynamics (Pty) Ltd

1<sup>st</sup> Floor, Grapevine House, Steenberg Office Park

Silverwood Close

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**10. Leli pheshana lolwazi lagcina ukubuyekezwa mhla lu-**

01 kuNhlolanja 2021

**11. Inamba yokubhaliswa**

LISORETIC 10/12,5: A37/7.1.3/0475

LISORETIC 20/12,5: A37/7.1.3/0476

**NAM:**

LISORETIC 10/12,5: NS2 06/7.1.3/0063

LISORETIC 20/12,5: NS2 06/7.1.3/0064

**MOZ:**

LISORETIC 10/12,5: 4648

LISORETIC 20/12,5: 4649