

**IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI
PEARINDA PLUS 8**

ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI

S3

PEARINDA PLUS 8, iphilisi

Perindopril kanye ne-Indapamide

IPEARINDA PLUS 8 iqukethe ushukela (*lactose* engama-123,060 mg ephilisini ngalinye)

Ngaphambi kokuba uqale ukusebenzisa iPEARINDA PLUS 8 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.
- IPEARINDA PLUS 8 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 iPEARINDA PLUS 8 futhi isetshenziselwani?
2. Okumele ukwazi ngaphambi kokuba usebenzise iPEARINDA PLUS 8
3. Indlela yokusebenzisa iPEARINDA PLUS 8
4. Imithelela engathandeki okungenzeka ibe khona
5. Indlela yokugcina iPEARINDA PLUS 8
6. Okuqukethwe ephaketheni lamaphilisi kanye nolunye ulwazi

1. Iyini iPEARINDA PLUS 8 futhi isetshenziselwani?

Iperindopril iyingxenywe yeqoqwana lemithi ebizwa ngama-*ACE inhibitors* (*angiotensin converting enzyme inhibitors*). Isebenza ngokuvimbela i-*ACE*, okuyisikhuthazalushintsho esibandakanyekayo ekunciphiseni imithambo yegazi futhi okudala ukunqwabelana nokugcwala kwesodium kanye

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noketshezi emzimbeni, okwenziwa yizinso. Lokhu kwenza ukuthi imithambo yegazi ithambe, okuvumela ukuthi igazi ligeleze ngokukhululeka futhi ngomfutho ophansi, futhi okukhuphula amandla enhliziyi okupompa igazi maqondana nezinhlobo ezithile zokuhluleka kwenhliziyi ukusebenza ngendlela efanele.

I-indapamide iyidiuretic (okuyiphilisi kwesinye isikhathi elibizwa ngephilisi lamanzi). Amadiuretics asebenza ngokuthi enze izinso zikhiphe umchamo othe xaxa emzimbeni.

IPEARINDA PLUS 8 iyinhlanganisela yezithako zokwelapha ezimbili, okuyi*perindopril tert-butylamine* kanye ne-*indapamide*. Isetshenziselwa ukwelapha umfutho wegazi ophakeme (*hypertension*).

IPEARINDA PLUS 8 inikezwa iziguli lapho umfutho wegazi ungalawulekile ngokwanele ngokusebenzisa amaphilisi *iperindopril* noma *i-indapamide*.

2. Okumele ukwazi ngaphambi kokuba usebenzise IPEARINDA PLUS 8

Ungalokothi usebenzise IPEARINDA PLUS 8

- uma umzimba wakho ungezwani ne*perindopril tert-butylamine*, noma uma ungezwani nanoma iyiphi enye *i-ACE inhibitor*, noma ungezwani ne-*indapamide* noma ungezwani nanoma iyiphi *isulphonamide* noma ungezwani nanoma yiziphi ezinye izithako zePEARINDA PLUS 8 (bheka isigaba 6)
- uma uke waba nezimpawu ezinjengokuvuvukala kobuso, ulimi noma umphimbo, ukubefuzela, ukuqubuka esikhunjani, isikhumba esiluma kakhulu, isiyenzi noma ukuquleka ngenxa yokwelashwa kwakho esikhathini esedlule nge-*ACE inhibitor* noma nge-*Angiotensin receptor blocker (ARB)* noma ngerenin *inhibitor* noma uma uke waba nalezi zimpawu kunoma yiziphi ezinye izimo (isifo esibizwa nge-*angioedema*) noma uma wena noma ilungu lomndeni wakho nika naba nalezi zimpawu kunoma yiziphi ezinye izimo
- xhumana nodokotela wakho ukuze abuyekeze kabusha imithi akwelapha ngayo uma welashwa ngama-*ACE inhibitors/Angiotensin receptor blockers* kanyekanye ne-antibhayothikhi ewuhlobo lwe*fluoroquinolone* enjenge*ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin* kanye ne*norfloxacin*
- uma unenkinga yokuncipha komthambo wegazi omkhulu osuka enhliziyweni (*aortic stenosis*),

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mitral valve stenosis noma isifo somsipha wenhliziyo (*ihypertrophic cardiomyopathy*) noma ukuncipha komthambo ophakela inso ngegazi (*irenal artery stenosis*)

- uma uxinwe kakhulu yisifo sezinsu esinamandla noma ungaphansi kohlelo lokwelashwa ngokuthi kuhlanzwe igazi lakho ngomshini ngenxa yokungasebenzi kahle kwezinsu
- uma usebenzisa ama*diuretics* (amaphilisi amanzi) onga *ipotassium* anjenges*spironolactone*, *triamterene* kanye ne-*amiloride*
- uma uneporphyria (inkinga yegazi eyivelakancane)
- uma usebenzisa *ilithium* (ukwelapha izinkinga zesimo sengqondo nomphefumulo)
- uma usebenzisa i-*aliskiren* (okuyi*renin inhibitor* enciphisa umfutho wegazi)
- uma unenkinga yesifo esiphathelene nezindlala zakho ama-*adrenal glands* esibizwa nge-*Addison's disease*
- uma unenkinga yokugula okungalawulekile kahle kokuhluleka kwenhliziyo ukusebenza ngendlela efanele, noma uma usebenzisa noma iyiphi imithi engadala ukuthi inhliziyo yakho ishaye ngesigqi esixakile futhi esingahambelani kahle
- uma welashwa nge*sacubitril/valsartan* (esetshenziselwa ukwelapha inkinga yokuhluleka kwenhliziyo ukusebenza kahle)
- uma uxinwe kakhulu yinkinga yesifo sesibindi esinamandla, noma uma uphethwe yisifo esibizwa nge*hepatic encephalopathy* (isifo sokuwohloka kobuchopho)
- uma umzimba wakho unamazinga aphansi e*potassium*
- uma ungaphansi kohlelo lokuhlanzwa kwegazi ngomshini ngenxa yokungasebenzi kahle kwezinsu
- uma kuwena kwenziwa inqubokwelapha yokufakelwa igazi
- uma ukhulelwe noma uncelisa (bheka isigatshana esithi Ukukhulelwa kanye nokuncelisa)

Izixwayiso kanye nezinto okumele uziqikelele

Qaphela kakhulu uma usebenzisa iPEARINDA PLUS 8

- uma uphethwe yisifo se*collagen* (isifo sesikhumba) esinjenges*systemic lupus erythematosus* noma *iscleroderma*

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- uma ungumuntu wohlanga olumnyama njengoba usengcupheni enkulu yokuphathwa yi-*angioedema* (ukuvuvukala kongwengwezi olungaphansi lwesikhumba nethishu yomzimba) futhi iPEARINDA PLUS 8 kungenzeka ingabi namandla kahle ekwehliseni umfutho wakho wegazi uma kuqhathaniswa neziguli okungezona ezohlanga olumnyama
- uma ungaphansi kohlelo lokuhlanzwa kwegazi ngomshini ngenxa yokungasebenzi kahle kwezinsu, kungenzeka ube nezinkinga emzimbeni wakho uma usebenzisa iPEARINDA PLUS 8
- uma ufakelwe inso yokufakelwa noma uma ungaphansi kohlelo lokuhlanzwa kwegazi ngomshini ngenxa yokungasebenzi kahle kwezinsu, kungenzeka ube nenkinga ye-anemiya (isibalo sezingqalampilo zegazi ezibomvu esingaphansi kwesejwayelekile)
- uma uxinwe kakhulu yisifo sesibindi esinamandla noma isifo sokuhluleka kwesibindi ukusebenza ngendlela efanele
- uma unesifo sezinsu, noma uma odokotela bethole ukuthi wena unerenal *artery stenosis* (inkinga yokuncipha komunye wemithambo ephakela inso ngegazi)
- uma uphelelwa amanzi emzimbeni (*volume depleted*), isibonelo, uma kade uhlanza, noma uma kade unesifo sohudo noma ujuluka kakhulu
- uma unezinkinga zenhliziyo noma isifo sokuhluleka kwenhliziyo ukusebenza ngendlela efanele
- uma uphethwe yisifo sikashukela esingalawulekile kahle, noma uma uthembele ekwelashweni nge-*insulin* ngenxa yokuhluleka kwamanyikwe akho ukukhiqiza i-*insulin*
- uma unezinkinga eziphazamisa ukuphakelwa kwegazi ebuchosheni bakho (isifo senkinga yemithambo yegazi ebuchosheni nokugeleza kwegazi *cerebrovascular disease* esinjenge-*atherosclerosis*) noma isifo esiphazamisa ukuphakelwa kwegazi enhliziyweni (*ischaemic heart disease*)
- uma unenkinga i*hyperparathyroidism* (okusho ukusebenza ngokweqile kwendlala i*parathyroid gland*)
- uma uphethwe yisifo igawuthi

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- uma unenkinga yamehlo lapho ingcindezi ngaphakathi kwehlo lakho iphakama okubangela izinhlungu ehlweni, ikhanda elibuhlungu, isicanucanu/ukuhlanza, ukubona izindingilizi zokukhanya ezizungeze izibani.

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

Kumele umazise udokotela wakho, usokhemisi noma omunye umhlinzeki wosizo lwezempilo nokwelashwa ukuthi wena usebenzisa iPEARINDA PLUS 8:

- uma ucabanga ukuthi wena ukhulelwe, noma kungenzeka ukhulelwe, njengoba iPEARINDA PLUS 8 ingakulungele neze ukusetshenziswa ngowesifazane okusaphele isikhathi esincane ekhulelwe ngoba uma isetshenziswa kulesi sigaba sokukhulelwa kungenzeka idale umonakalo omubi kakhulu emntwaneni (bheka isigatshana esithi Ukukhulelwa kanye nokuncelisa)
- uma uzohlinzwa noma uzonikezwa umuthi olalisayo ukuze ungazizwa izinhlungu lapho uhlinzwa
- uma kuzokwenziwa kuwena inqubo yokususa ikholesteroli egazini lakho kusetshenziswa umshini (*LDL apheresis*)
- uma uzothola ukwelashwa nenghloso yokunciphisa imithelela ye-aleji edalwe wukutinyelwa yinyosi noma umnyovu
- uma unanoma yiziphi izimpawu zokutheleleka ngesifo esinjengomphimbo obuhlungu, imfiva kanye nokuqhaqhaazela 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 emchamweni wakho noma endleni yakho, noma uma uhuzuka kalula (umthamo wamaplathelethi ophansi, phecelezi i*thrombocytopenia*, eholela ekutheni kube nezinkinga zokuhluleka kwegazi ukujiya liphenduke amahlule)

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- uma ubukeka uphaphathekile ebusweni, uma uzizwa ukhathele noma unesiyezi futhi uphelelwa wumoya ngenxa ye-anemiya (ukuncipha kwezingqalampilo zegazi ezibomvu noma *ihaemoglobin* egazini)
- uma uphathwa wukukhwehlela okomile ngenkathi usebenzisa iPEARINDA PLUS 8 njengoba lo muthi unokuhlobana okuthile nokukhwehlela okomile okubeleselayo
- uma uba nenkinga yokuzwela kakhulu kwesikhumba elangeni (*photosensitivity*)
- uma ungumsubathi, njengoba ukusebenzisa iPEARINDA PLUS 8, kungaholela emiphumeleni yokuhlolwa ebonisa ukuthi kukhona okuthile okusebenzisile okuyisikhuthazi
- uma uke watshelwa ngudokotela ukuthi wena unamazinga aphansi e*sodium* noma e*potassium* egazini lakho noma amazinga aphakeme e*calcium* egazini lakho

Izingane kanye namabhungu namatshitshi

IPEARINDA PLUS 8 akumele inikezwe izingane kanye namabhungu namatshitshi.

Ukusetshenziswa kweminye imithi nePEARINDA PLUS 8

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

Akumele usebenzise iPEARINDA PLUS 8 kanyekanye nanoma yimiphi kule mithi elandelayo:

- Ama-antibhayothikhi ohlobo lwe*fluoroquinolone* (uma esetshenziswa kanyekanye nePEARINDA PLUS 8 angadala izinkinga zezinso).
- *Lithium* (yokwelapha *mania* kanye negcindezi yengqondo).
- Izondlamzimba ze*potassium*, imikhiqizo esetshenziswa esikhundleni sikasawoti equkethe *ipotassium*, kanye namadiuretics (amaphilisi amanzi) onga *ipotassium* anjenge*spironolactone*, *triamterene* noma *i-amiloride*.
- *l-aliskiren* (umuthi oyi*direct renin inhibitor*) ingaholela emfuthweni wegazi ophansi, amazinga e*potassium* aphansi egazini kanye nokuncipha kokusebenza kwezinsos uma isetshenziswa kanyekanye nePEARINDA PLUS 8.

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- *Isacubitril/valsartan* (esetshenziselwa ukwelapha isifo sokuhluleka kwenhliziyo ukusebenza ngendlela efanele).

Tshela udokotela wakho uma ubona okunye kwalokhu okulandelayo

- Eminye imithi yokwelapha umfutho wegazi ophakeme ebizwa ngama-*angiotensin receptor blockers*, isibonelo, *valsartan*, *telmisartan* kungenzeka iwehlise kakhudlwana umfutho wakho wegazi uma isetshenziswa kanyekanye nePEARINDA PLUS 8.
- *I-estramustine* (esetshenziselwa ukwelapha umdlavuzwa wendlala yabesilisa engezansi kwesinye) ingabukhuphula ubungozi be-*angioedema* (ukuvuvukala kolwelwesi olungaphansi kwesikhumba namathishu emzimbeni).
- *Ibaclofen* (yokwelapha ukuqina kwemisipha yomzimba okwenzeka ezifweni ezinjenge*multiple sclerosis*) ingadala ukuthi umfutho wegazi wehle kakhulu kunokwejwayelekile.
- Ama*Non-Steroidal Anti-inflammatory Drugs (NSAIDs)*, kubandakanya i-*aspirin*, *ibuprofen* uma kuphuzwa ngomthamosilinganiso ophakeme, kanye ne-*indomethacin* kunciphisa amandla ePEARINDA PLUS 8 okwehlisa umfutho wegazi.
- Imithi yokwelapha isifo sikashukela enjenge-*insulin*, *imetformin* noma amaglipitins (*linagliptin*, *saxagliptin*, *sitagliptin*, *vildagliptin*) kungenzeka iwehlise kakhudlwana amazinga kashukela egazini uma isetshenziswa kanyekanye nePEARINDA PLUS 8.
- Imithi engadala izinkinga zesigqi senhliziyo uma ephansi amazinga *epotassium* egazini lakho enjenge*procainamide*, *sotalol*, *digoxin*, *quinidine*, *hydroquinidine*, *disopyramide*, *amiodarone*, *dofetilide*, *ibutilide*, *bretylum*.
- Ama*neuroleptics* athile (asetshenziselwa ukwelapha ukugula kwengqondo) anjenge*chlorpromazine*, *cyamemazine*, *levomepromazine*, *thioridazine*, *trifluoperazine*, *pimozide*, *amisulpride*, *sulpiride*, *tiapride*, *droperidol* kanye ne*haloperidol* angabangela ukushaya kwenhliziyo ngesigqi esingahambelani kahle uma kunamazinga aphantsi *epotassium* egazini.
- Imithi enjenge*bepiridil* (yokwelapha izinhlungu esifubeni), *icisapride* (yokwelapha isifo

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sokuyokoza), *idiphebanil* (yokwelapha ukujuluka ngokweqile), *i-intravenous erythromycin* (eyi-antibhayothikhi), *ihalofantrine* (yokwelapha izinhlobo ezithile zikamalaleveva) kanye ne*pentamidine* (yokwelapha izinhlobo ezithile zesifuba samakhaza, inyumoniya), *imizolastin*, *terfenadine*, *astemizole* (esetshenziselwa ukwelapha *ihay fever*), *imoxifloxacin* (eyi-antibhayothikhi) kanye ne*methadone* ingadala ukushaya kwenhliziyo ngesigqi esingahambelani kahle uma unepotassium ephansi egazini lakho.

- Imithi enciphisa amazinga epotassium egazini kubandakanya nemithi ehlambulula isisu eyizikhuthazimathumbu enjengesenna, *amphotericin B* (yokwelapha izifo ezibangelwa wukhunta (*fungus diseases*)) kungenzeka inciphise amazinga epotassium egazini lakho.
- *Idigoxin* (yokwelapha izinkinga zenhliziyo) ingaba nemithelela enobungozi uma ephansi amazinga epotassium egazini lakho.
- *I-Allopurinol* (esetshenziselwa ukwelapha isifo igawuthi).
- Imithi yokucindezela amasosha omzimba esetshenziselwa ukwelapha inkinga yamasosha omzimba lapho amasosha omzimba ehlasela ngephutha amathishu omzimba aphilile noma esetshenziswa kulandela ukufakelwa isitho somzimba ngenhloso yokuvimbela ukwalana komzimba nesitho lesi (isibonelo, *ciclosporin*).
- *I-Ciclosporin* (umuthi wokucindezela amasosha omzimba osetshenziselwa ukwelapha *irheumatoid arthritis*, *psoriasis*, *Crohn's disease*, *nephrotic syndrome* kanye nokuvimbela ukwalana komzimba nesitho sokufakelwa) ingadala ukuphakama kwamazinga e*creatinine* okuyinto ebonisa ukuthi mhlawumbe kunezinkinga zezinso okungenzeka ukuthi zikhona.
- Imithi esetshenziselwa ukwelapha ukugula kwengqondo, okunjengengcindezi yengqondo, itwetwe nexhala, *ischizophrenia* (*amaticyclic antidepressants*, *namaneuroleptics*) isibonelo, *imipramine*, kungenzeka iwehlise kakhudlwana umfutho wakho wegazi uma isetshenziswa kanyekanye nePEARINDA PLUS 8.
- *Amacorticosteroids*, anjenge*prednisone* esetshenziselwa ukwelapha izifo ezihlukahlukene kubandakanya nesifuba somoya esinamandla kanye ne*rheumatoid arthritis*, *itetracosactide* (yokwelapha *iCrohn's disease*) kungenzeka anciphise amandla okusebenza kwePEARINDA PLUS 8 futhi kungenzeka anciphise namazinga epotassium egazini lakho.

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- Eminye imithi yokwehlisa umfutho wegazi, kubandakanya *initroglycerin*, amanye *amanitrates*, isibonelo, *isosorbide dinitrate* kanye namaloop *diuretics* noma *amathiazide diuretics* (amaphilisi amanzi), isibonelo, *hydrochlorothiazide*, kungenzeka ikhuphule amandla ePEARINDA PLUS 8 okwehlisa umfutho wegazi.
- Uma uzohlinzwa noma uma uzodinga ukuthi ulaliswe ngomuthi olalisayo ukuze ungabuzwa ubuhlungu ngenkathi uhlinzwa, njengoba kungenzeka akhuphuke amandla omuthi olalisayo.
- Osawoti begolide (*gold salts*), ikakhulukazi uma befakwa emzimbeni ngedriphu, isibonelo, *iauranofin*, ngenhloso yokwelapha *irheumatoid arthritis* bangadala ukuthi ube nenkinga yokuguquka ngokushesha kobuso bube bomvu, isicanucanu, ukuhlanza kanye nomfutho wegazi ophansi uma besetshenziswa kanyekanye nePEARINDA PLUS 8.
- Uma uzokwenza ukuhlolwa kwezokwelapha okudinga ukuthi ujoywe ngoketshezana olukhethekile oluzokwenza ukuthi izitho zakho ezinjengezinso noma isisu kubonakale kahle ezithombeni ze-eksireyi (*iodinated contrast agent*)
- Osawoti *becalcium* uma besetshenziswa kanyekanye nePEARINDA PLUS 8 bangadala ukukhuphuka kwamazinga *ecalcium* njengoba kuba nokwehla komthamo *wecalcium* ephumayo emzimbeni esemchamweni.
- *Ico-trimoxazole* (okuyi-antibhayothikhi esetshenziselwa ukwelapha ukugula okuthile okubangelwa ngamagciwane) kungadala izinga le*potassium* elingaphezulu kwalelo elejwayelekile egazini lakho okubonakala ngezimpawu ezinjengobubhakubhaku benhliziyo, ubuhlungu bemisipha yomzimba, ubuthakathaka bemisipha yomzimba noma ubundikindiki.
- *Traccedotril* (yokwelapha isifo sohudo) kanye ne*sirolimus*, *everolimus*, *temsirolimus* (imithi yokwelapha umdlavuzi) ingadala ukuvuvukala okukhulu ngaphansi kwesikhumba okuvamise ukubonakala ezandleni, ezinyaweni, emehlweni, ezihlathini kanye nasezindebeni zomlomo.

Ukuphuza iPEARINDA PLUS 8 nokudla kanye nophuzo

Kunconywa ukuthi iPEARINDA PLUS 8 iphuzwe kanye ngosuku emuva kokudla.

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Ukukhulelwa, ukuncelisa kanye nokuba sesimweni sokuzala nokuthola abantwana

Uma ukhulelwe noma uncelisa umntwana wakho, bonana nodokotela wakho, usokhemisi noma omunye ungoti wosizo lwezempilo nokwelashwa ngaphambi kokuba usebenzise iPEARINDA PLUS 8.

Akumele usebenzise iPEARINDA PLUS 8 uma ukhulelwe noma usancelisa umntwana wakho (bheka isigatshana esithi Ungalokothi usebenzise iPEARINDA PLUS 8).

Ukushayela kanye nokusebenzisa imishini

Kungenzeka uphathwe yisiyezi noma inzululwane ngenkathi usebenzisa iPEARINDA PLUS 8.

Akulula ukubikezela njalo ukuthi iPEARINDA PLUS 8 izoba nomthelela ongakanani emisebenzini yakho yansukuzonke. Kumele uqinisekise ukuthi awuyenzi imisebenzi eshiwo ngenhla kuze kufike isikhathi lapho usubonile ukuthi iPEARINDA PLUS 8 ikuphatha kanjani emzimbeni.

IPEARINDA PLUS 8 iqukethe ushukela wobisi, *ilactose*.

Uma uke watshelwa ngudokotela wakho ukuthi umzimba wakho uyahluleka ukubekezelela nokugaya izinhlobo ezithile zikashukela, xhumana nodokotela wakho ngaphambi kokusebenzisa lo muthi.

3. Isetshenziswa kanjani iPEARINDA PLUS 8

Ungalokothi wabelane nanoma yimuphi omunye umuntu ngemithi onikezwe yona ngumhlinzeki wakho wosizo lwezempilo nokwelashwa ngoba iqondene nawe kuphela. Kumele njalo iPEARINDA PLUS 8 uyisebenzise ncimishi ngendlela akuyalele ngayo udokotela wakho. Kumele ubuze udokotela wakho noma usokhemisi uma ungaqinisekile.

Kubantu abadala:

Umthamosilinganiso ojwayelekile wePEARINDA PLUS 8 yiphilisi elilodwa eliphuzwa kanye njalo ngosuku ekuseni ngaphambi kokudla.

Iphilisi ligwinye ulehlise ngengilazi yamanzi, futhi kungaba kuhle uma uliphuza ngesikhathi esifanayo nsukuzonke.

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Udokotela wakho uzokutshela ukuthi kuzothatha isikhathi eside kangakanani ukwelashwa kwakho ngePEARINDA PLUS 8. Ungalokothi uyeke ukudla amaphilisi akho ngaphambi kwesikhathi ngoba umfutho wegazi ophakeme obukuphethe kungenzeka uphinde ubuye futhi.

Uma ubona sengathi iPEARINDA PLUS 8 inamandla ngokweqile noma sengathi ayinawo neze amandla, tshela udokotela wakho noma usokhemisi.

Uma uphuze iPEARINDA PLUS 8 engaphezulu kwaleyo okumele uyiphuze

Uma kwenzekile waphuza umthamosilinganiso oweqile, bonana nodokotela wakho noma usokhemisi.

Uma uhluleka ukuthola omunye walaba, xhumana nesibhedlela esiseduze nawe noma isikhungo esilawula ubuthi/ushevu.

Izimpawu zomthamosilinganiso wamaphilisi oweqile kungenzeka zibandakanye lokhu:

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

Uma kwenzekile wakhohlwa ukuphuza iPEARINDA PLUS 8

Uma kwenzekile wakhohlwa ukuphuza iPEARINDA PLUS 8, phuza umthamosilinganiso wakho ojwayelekile ngosuku olulandelayo. Ungalokothi uphuze umthamosilinganiso ophindwe kabili ngenhloso yokuvala isikhala semithamosilinganiso okhohliwe ukuyiphuza.

Uma uyeka ukusebenzisa iPEARINDA PLUS 8

Njengoba ukwelashwa komfutho wegazi ophakeme kuyinto eqhubeka impilo yakho yonke, kumele uxoxisane nodokotela wakho ngaphambi kokuba uyeke ukusebenzisa iPEARINDA PLUS 8.

4. Imithelela engathandeki okungenzeka ibe khona

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Akuyona yonke imithelela engathandeki ebikiwe yePEARINDA PLUS 8 equkethwe kuleli pheshana lolwazi. Uma siba sibi isimo sakho sempilo jikelele, noma uma uzwa umthelela ongemnandi futhi ongathandeki emzimbeni ngenkathi usebenzisa iPEARINDA PLUS 8, bonisana nomhlinzeki wakho wosizo lwezempilo nokwelashwa ukuze uthole ukwelulekwa.

Uma kwenzeka noma yikuphi kulokhu okulandelayo, yeka ukusebenzisa iPEARINDA PLUS 8 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 isikhumba esilumayo
- isiyezi esinamandla noma ukuquleka

Konke lokhu kuyimithelela engathandeki ebucayi kakhulu futhi enobungozi. Uma unayo, kusho ukuthi kunokwenzeka ukuthi umzimba wakho awuzwananga neze nePEARINDA PLUS 8 oyisebenzisile. 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)
- ukushaya kwenhliziyo ngokushesha noma ngesigqi esingahambelani kahle
- ubuso obulengayo, ingalo ebuthakathaka, ukukhuluma unambuluke futhi unkwankwaze kungazwakali kahle okushoyo (isifo sohlangothi)
- izinkinga zezinso (ukuphuma komchamo omncane kunalokho okujwayelekile kuwena lapho uchama)
- ijondisi (isifo sokuguquka kwesikhumba namehlo kube nombala ophuzi)

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- isifo 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, umzimba olumayo, ukuphelelwa wuthando lokudla)
- I*toxic epidermal necrolysis (TEN)* (isifo sesikhumba esiyivelakancane esingambulala nokumbulala umuntu esibonakala ngezimpawu ezinjengesibhadu esibuhlungu esibomvu esisabalala ngokushesha, ukuxebuka kwesikhumba okungenawo amabhamuza, izindawo ezinesikhumba esingambozekile) noma i*Stevens-Johnson syndrome* noma ezinye izinkinga zesikhumba ezibucayi kakhulu (eziqala ngokubonakala kwezimpawu ezinjengezomkhuhlane, kulandele umqubuko obuhlungu obomvu noma osabukhwebezane ngokombala osabalalayo kanye namabhamuza)
- ukulahlekelwa/ukuphelelwa kakhulu amanzi emzimbeni
- ukuvuvukala kwamanyikwe, i*pancreatitis* (okuyisifo sokuvuvukala kwamanyikwe esibonakala ngezimpawu ezinjengezinhlungu esiswini, inhliziy oshaya 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:

- ubuthakathaka, amajaqamba emisipheni yengalo noma yomlenze, ukunsonsotha noma ubundikindiki (amazinga aphantsi e*potassium*)
- ikhanda elibuhlungu, ukuncipha kothando lokudla, isiyenzi, umuzwa ojikelezayo, umuzwa onsonsothayo a*mapins and needles*, umuzwa oshisayo/ondikindiki/obandayo esikhunjani
- izinguquko eziphathelene nokubona kanye nokusebenza kwamehlo
- ukukhala kwezihlonono ezindlebeni
- umfutho wegazi ophantsi lapho usukuma uma ngezinyawo kade uhlezi noma ulele phansi, umfutho wegazi ophantsi
- ukukhwehlela okomile

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- isifo sohudo, isicanucanu, inkinga yokungagayeki kahle kokudla, ukuhlanza, ukuphazamiseka komuzwa wokunambitha, umlomo owomile, ukuqunjelwa, isisu esibuhlungu kakhulu, isifo sokuzizacisa (ukwehla kakhulu futhi ngendlela exakile kwesisindo somzimba ngenxa yokudla ukudla okuncane)
- isikhumba esiluma kakhulu (*pruritus*), umqubuko obomvu esikhunjeni onamaqhubu amancane ngaphandle, ukuqubuka esikhunjeni
- amajaqamba

Imithelela engathandeki engavamile ukwenzeka:

- I-anemiya (ukuncipha kwenani lezingqalampilo zegazi ezibomvu okubonakala ngezimpawu ezinjengokuzizwa ukhathele noma ucobekile emzimbeni wonke, isikhumba esiphaphathekile), ukuncipha kwamaplathelethi egazi okungaholela ekutheni ube nenkinga yokuhuzuka okungajwayelekile noma wophe kalula (umonakalo wokulimala kwezingqalampilo zegazi ezibomvu, ukuhuzuka, ukutheleleka ngezifo njalo (*aplastic anaemia*), izinkomba zokugula ezinjengomphimbo obuhlungu, imfiva kanye nokuqhaq hazela okubangelwa ukuzwa amakhaza (isibalo esiphansi sezingqalampilo zegazi ezimhlophe)
- igawuthi, ukuvuvukala kwesibindi noma umonakalo esibindini, imiphumela yokuhlolwa kweglukhosi ebonisa ukukhuphuka noma ukwehla kwamazinga kashukela emzimbeni
- izinkomba zokuphazamiseka komthamo odingekayo nofanelekile woketshezi emzimbeni (imisipha yomzimba ebuhlungu, inkwantshu, ukudikiza kwezicubu zomzimba, ubuthakathaka, ukuzizwa wome kakhulu, ukungakwazi ukulala, imfiva, ububhakubhaku benhliziyo)
- ukuguquka kwesimo sengqondo nomphefumulo, ukungalali kahle, ukudideka kwengqondo
- ukucinana emakhaleni, umphimbo obuhlungu, umuzwa wokuphatheka kabi nobuhlungu lapho ugwinya, ukungenwa yizifo ezidalwa ngamagciwane (amavayirasi), isifo samaphaphu nemigudu yokuphefumula (isifo sesifuba), isifo sokuvuvukala kontwentwesana kanye nezimbobo zomoya emakhaleni (okubizwa nge*sinusitis*), ukuthimula/amafinyila okubangelwa wukuvuvukala kontwentwesana lwezimbobo zamakhala (*rhinitis*), ukuvuvukala kwamaphaphu, uketshezi oluningi ngokweqile emaphashini

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- *i-alopecia* (izibhadu zokuqothuka kwezinyele), *ipsoriasis* (isifo sesikhumba esiyisimbela esidala izibhadu ezilumayo noma ezibuhlungu zesikhumba esiwugqinsi esibomvu esinezimpephelezi ezibukeka njengombala osiliva, isikhumba esizwelayo ekukhanyeni, *i-urticaria*, *ipurpura* (amachashazi amancane abomvu esikhunjani), *ivasculitis* (ukuvuvukala kwemithambo yegazi), ukujuluka ngokweqile
- isifo esinamandla sesikhumba esidala umqubuko, isikhumba esibomvu, amabhamuza ezindebeni, emehlweni noma emlonyeni, ukuxebuka kwesikhumba, imfiva (*erythema multiforme*), umqubuko ebusweni, izinhlungu emajoyintini omzimba, izinkinga zemisipha yomzimba, imfiva (*lupus erythematosus*), umqubuko wamaqhubu ayindingilizi, abomvu aluma kakhulu, futhi kwesinye isikhathi ohambisana nokuvuvukala okunobungozi
- ukungavuki kwenduku kowesilisa, ukuhluleka ukuhlala uqhanyelwe uze uqede ukwenza ucansi.

Le mitholela elandelayo ibikiwe kodwa akwaziwa ukuthi ivamise kangakanani ukwenzeka:

- ukubona kahle izinto eziseduzane kuphela hhayi ezikude, amehlo afiphele
- umphumela wokuhlolwa kwesigqi senhliziyo nokusebenza kwayo (*EGC*) obonisa okuthile okungahambi kahle
- ukuba nomkhuba wokuwa njalo
- amabhamuza amakhulu esikhunjani anoketshezi ngaphakathi

Uma ubona noma yimiphi eminye imitholela engathandeki engabhalwe kuleli pheshana lolwazi, tshela udokotela wakho noma usokhemisi.

Ukubika imitholela engathandeki

Uma uphathwa yimitholela engathandeki, khuluma nodokotela wakho noma usokhemisi. Lokhu kubandakanya ngisho noma yimiphi imitholela engathandeki engabhalwe kuleli pheshana. Futhi ungayibika imitholela engathandeki kwabakwaSAHPRA ngokusebenzisa ifomu lokubika imitholela

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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 kwePEARINDA PLUS 8.

5. ISETSHENZISWA KANJANI IPEARINDA PLUS 8

Yonke imithi kumele uyigcine endaweni ezingafinyeleli kuyona izingane.

Yigcine endaweni epholile neyomile ezingeni lokushisa elingama-30°C noma ngaphansi kwalokho.

Amaphilisi wagcine kwizingqwenjana eziyizigcinamaphilisi kuze kufike isikhathi lapho sekudingeka ukuba asetshenziswe.

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 YIPPEARINDA PLUS 8

Izithako zokwelapha eziyinhloko eziqokethwe lapha *yiperindopril tert-butylamine* kanye ne-*indapamide*.

Iphilisi ngalinye liqukethe *yiperindopril tert-butylamine* engama-8 mg kanye ne-*indapamide* engama-2,5 mg.

7. Ezinye izithako yilezi

Ezisengxenyeni engaphakathi yephilisi:

Lactose monohydrate, magnesium stearate, microcrystalline cellulose, silica colloidal anhydrous.

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8. Indlela ebukeka ngayo iPEARINDA PLUS 8 kanye nalokho okuqukethwe ephaketheni layo
Ingamaphilisi amhlophe noma acishe abe mhlophe ngokombala, ayindingilizi, anomugqa onqamula phakathi ohlangothini olulodwa.

Amaphilisi iPEARINDA PLUS 8 atholakala kwizigcinamaphilisi ezinombala osiliva ezakhiwe nge*polyamide*, *aluminium* kanye ne*PVC*. Amaphilisi agcinwe kwibhokisana likakhadibhodi eliqukethe amaphilisi angama-30 (6 x 5 noma 10 x 3).

9. Umnikazi Wesitifiketi Sokubhaliswa

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Inamba yocingo: 021 707 7000

10. Leli pheshana lolwazi lagcina ukubuyezwa mhla zingama-
20 kuMbasa 2021

11. Inamba yokubhaliswa

A49/7.1.3/0013