

**IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI
PEPLOC OTC**

ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI

S2

PEPLOC OTC, 20 mg amaphilisi

Pantoprazole

IPEPLOC OTC iqukethe uhlobo lukashukela olunotshwala (*imannitol* engama-70,50 mg ephilisini ngalinye)

Funda lonke leli pheshana ngokucophelela ngoba liqukethe ulwazi olubalulekile kuwena IPEPLOC OTC iyatholakala ngaphandle kwencwadi kadokotela, uma ufuna ukwelapha ukugula okuncane, okusho, ukugula okungekhona lokho okunamandla kakhulu noma okubucayi. Kepha-ke noma kunjalo, kumele uyisebenzise ngokucophelela iPEPLOC OTC ukuze usizakale ngokuphelele kuyona.

- Ligcine leli pheshana lolwazi. Kungenzeka ukuthi kudingeke ukuba uphinde futhi ulifunde.
- Ungabelani nanoma yimuphi omunye umuntu ngePEPLOC OTC.
- Buza umhlinzeki wakho wosizo lwezempilo nokwelashwa noma usokhemisi wakho uma udinga ulwazi oluthe xaxa noma iseluleko.
- Kumele ubonane nodokotela uma ziba zimbi kakhulu izimpawu ezikuphethe noma uma ungabi ngcono emuva kwezinsuku eziyi-14.

Okuqukethwe kuleli phashana lolwazi

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

Ipantoprazole iwumuthi onciphisa ukukhiqizwa kwe-esidi esiswini (phecelezi, *iproton pump inhibitor*) osetshenziselwa ukwelapha ukugula okuthile okubangelwa ukuba khona kwe-esidi ephakeme ngokweqile esiswini.

IPEPLOC OTC isetshenziselwa lokhu:

- Ukwelapha okwesikhashana isilungulela noma ukugula okubangelwa yi-esidi ephakeme ngokweqile esiswini, ngokuphuza umthamosilinganiso ophелеle ongama-20 mg njalo ngosuku, futhi ukwelashwa ngalokhu akumele kube ngaphezu kwezinsuku eziyi-14.

2. Okumele ukwazi ngaphambi kokuba usebenzise iPEPLOC OTC

Ungalokothi usebenzise iPEPLOC OTC:

- uma umzimba wakho ungezwani nesithako *ipantoprazole* noma uma ungezwani nanoma yisiphi esinye isithako samaphilisi iPEPLOC OTC (bheka isigaba 6)
- uma singasebenzi kahle isibindi sakho
- iPEPLOC OTC akumele inikezwe izingane
- uma usebenzisa i-*atazanavir* (okungumuthi osetshenziselwa ukwelapha iHIV).

Izixwayiso kanye nezinto okumele uziqikelele

Qaphela kakhulu uma usebenzisa iPEPLOC OTC:

- uma unenkinga yezinso ezingasebenzi kahle
- uma usebenzisa i-*warfarin* (umuthi onciphisa ubungozi bokuguquka kwegazi libe ngamahlule)
- uma unesifo sesibindi
- uma unamazinga aphansi e-*magnesium* egazini lakho
- uma njengamanje uthola ukwelashwa noma esikhathini esedlule uke wathola

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- ukwelashelwa noma yikuphi ukugula okuphathelene nesimila esinobungozi (umdlavuza noma isimila somdlavuza) esiswini nendawo ezungeze isisu
- uma unomlando wokuntuleka kuka *Vitamin B12* emzimbeni
- uma uphethwe yisifo sohudo esinganqamuki (xhumana ngokushesha nodokotela wakho noma ungoti wosizo lwezempilo nokwelashwa)
- uma uneminyaka engaphezu kwama-50 ubudala noma uma sekuphele isikhathi eside usebenzisa iPEPLOC OTC noma uma usebenzisa umthamosilinganiso wayo ophakeme (kungenzeka idale ukwehla kwezinga le *magnesium* emzimbeni futhi lokhu kungabangela ukukhula kwengcuphe yokuphuka kwamathambo esinqeni, esihlakaleni noma emgogodleni)
- uma njengamanje uphukelwe noma esikhathini esedlule uke waphukelwa yithambo enqulwini, esihlakaleni noma emgogodleni ngenxa ye *magnesium* ephansi
- uma kunokuncipha komthamo womchamo owuchamayo noma uma kunegazi emchameni wakho.

Ukusetshenziswa kweminye imithi nePEPLOC OTC

Kumele ngaso sonke isikhathi umazise umhlinzeki wakho wosizo lwezempilo nokwelashwa uma kukhona nanoma iyiphi eminye imithi oyisebenzisayo.

(Lokhu kubandakanya nemithi eyizondlamzimba kanye nemithi yesintu.)

Eminye imithi okungenzeka kuphazamiseke ukusebenza kwayo ngenxa yePEPLOC OTC yilena:

- imithi yokuvimbela ukushuba nokuguquka kwegazi libe ngamahlule, njenge *warfarin*. IPEPLOC OTC kungenzeka ikuguqule ukusebenza kwale mithi ngakho-ke umhlinzeki wakho wosizo lwezempilo nokwelashwa uzobhekisisa ukuthi igazi lakho liphenduka kahle kangakanani libe ngamahlule.
- imithi ethile esetshenziselwa ukwelapha ukutheleleka okubangelwa wukhunta (*fungal infections*), enjenge *ketconazole*. IPEPLOC OTC kungenzeka inciphise ukumunceka kwale mithi emzimbeni.

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- *i-atazanavir*, okuyisithako esiyinxubemakhambi esitholakala emithini yokwelapha *iHIV*. IPEPLOC OTC kungenzeka inciphise amazinga omthamo walo muthi egazini. Ungalokothi usebenzise iPEPLOC OTC kanyekanye ne-*atazanavir* (Bheka isigatshana esithi Ungalokothi usebenzise iPEPLOC OTC).
- *imethotrexate* (imithamosilinganiso ephakeme esetshenziswa ekwelapheni imidlavuza ethile). IPEPLOC OTC kungenzeka ikhuphule amazinga alo muthi emzimbeni okungaholela ekutheni umzimba ungenwe wubuthi obubangelwa yi-*methotrexate*.
- *ifluvoxamine* (esetshenziselwa ukwelapha ingcindezi yengqondo kanye nezinye izifo zengqondo) – uma usebenzisa *ifluvoxamine* udokotela wakho kungenzeka awunciphise umthamosilinganiso.
- *iSt John's wort* (okungumkhiqizo oyikhambi, phecelezi *iHypericum perforatum*) (osetshenziselwa ukwelapha ingcindezi yengqondo engenawo amandla kakhulu).

Ukuphuza iPEPLOC OTC nokudla kanye nophuzo

Amaphilisi iPEPLOC OTC 20 mg okungamaphilisi aphuzwa nsukuzonke kumele aphuzwe ngaphambi kokudla, futhi kungaba kuhle uma ephuzwa ekuseni.

Ukukhulelwa, ukuncelisa kanye nokuba sesimweni sokuzala nokuthola abantwana

Akumele usebenzise iPEPLOC OTC uma ukhulelwe noma usancelisa umntwana wakho.

Uma ukhulelwe noma usancelisa umntwana wakho, noma uma ucabanga ukuthi mhlawumbe ukhulelwe noma uma uhlela ukuthola umntwana, bonisana nodokotela wakho, usokhemisi noma omunye umhlinzeki wosizo lwezempilo nokwelashwa ngaphambi kokuba usebenzise iPEPLOC OTC.

Akuqinisekiswa ukuphepha kwamaphilisi kwabesifazane abakhulelwe nabancelisayo.

Ukushayela kanye nokusebenzisa imishini

IPEPLOC OTC ingabangela ukufiphala kwamehlo noma isiyenzi.

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Akulula ukubikezela njalo ukuthi iPEPLOC OTC izoba nomthelela ongakanani emisebenzini yansukuzonke yesiguli. Iziguli kumele ziqinisekise ukuthi aziyenzi imisebenzi eshiwo ngenhla kuze kufike isikhathi lapho sezibonile ukuthi iPEPLOC OTC inomthelela ongakanani kuzona.

IPEPLOC OTC iqukethe *isodium* kanye *nemannitol*

IPEPLOC OTC iqukethe *isodium*. Udokotela wakho uzokubhekisisa futhi akufakele izibuko lokhu uma ungumuntu oyalelwe ukuba alandele uhlelo lokudla okunosawoti omncane kakhulu.

IPEPLOC OTC iqukethe *imannitol* futhi lokhu kungadala ukuthi ukhishwe yisisu.

3. Isetsheziwa kanjani iPEPLOC OTC

Ungalokothi wabelane nanoma yimuphi omunye umuntu ngemithi onikezwe yona ngumhlinzeki wakho wosizo lwezempilo nokwelashwa ngoba iqondene nawe kuphela.

Ngaso sonke isikhathi iPEPLOC OTC kumele uyisebenzise ncamashi ngendlela echazwe kuleli pheshana lolwazi noma ngendlela oyalelwe ngayo ngudokotela wakho, usokhemisi noma umhlengikazi. Kumele ubuze udokotela wakho, usokhemisi noma umhlengikazi uma ungaqinisekile.

Iphilisi kumele uligwinye lonke liphelele futhi ulehlise ngamanzi.

Ungaligayi, ulinqamule noma ulihlafune iphilisi.

Kungathatha izinsuku ezimbadlwana ngaphambi kokuba iPEPLOC OTC iqale ukwenza uzizwe usungcono. Ukulekelela ekudambiseni nokwelapha izimpawu ezikuphethe ungawasebenzisa amaphilisi okuqeda i-esidi kanyekanye namaphilisi iPEPLOC OTC , ngaphandle-ke uma udokotela wakho ekutshela ukuthi ungawasebenzisi.

Umthamosilinganiso ojwayelekile yiphilisi elingama-20 mg eliphuzwa kanye ngosuku, ongalisebenzisa kuze kuphele isikhathi esingekho ngaphezu kwezinsuku eziyi-14.

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Izingane:

Akuqinisekiswa ukuphepha kanye nokusebenza kahle kwayo ezinganeni.

Uma uphuze iPEPLOC OTC engaphezulu kwaleyo okumele uyiphuze:

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

Ngenkathi uyobonisana nodokotela, phatha leli pheshana lolwazi kanye namaphilisi akho asele ukuze azi ukuthi yimaphi amaphilisi owasebenzisile.

Uma kwenzeka ukhohlwa ukuphuza umthamosilinganiso wePEPLOC OTC

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

4. Imithelela engathandeki okungenzeka ibe khona

IPEPLOC OTC kungenzeka ibe nemithelela engathandeki emzimbeni.

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

Uma kwenzeka noma yikuphi kulokhu okulandelayo, yeka ukusebenzisa iPEPLOC OTC futhi utshale udokotela wakho ngokushesha noma uphuthume emnyangweni wezimo eziphuthumayo

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esibhedlela esiseduze nawe:

- ukuvuvukala kwezandla, izinyawo, amaqakala, ubuso, 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 nePEPLOC OTC. 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:

- izinhlungu esiswini (ezinamandla)
- imfiva, ukuqubuka, kanye nezinsongo ezivuvukile zaba zinkulu, kwesinye isikhathi okuhambisana nezinhlungu lapho uchama kanye nezinhlungu esinqeni (ukuvuvukala kakhulu kwezinsongo), okungenzeka kuholele ekutheni izinsongo zihluleke ukusebenza
- ukuvela kwamabhamuza esikhunjani, isikhumba esinwebekile futhi esilengayo, esixebukayo noma esibomvu, i*Stevens-Johnson syndrome* noma ezinye izinkinga zesikhumba ezibucayi kakhulu (eziqala ngokubonakala kwezimpawu ezinjengezomkhuhlane, kulandele umqubuko obuhlungu obomvu noma osabukhwebezane ngokombala (*purplish*) osabalalayo kanye namabhamuza)
- umbala wesikhumba ophuzi kanye/noma amehlo anombala ophuzi, indle emnyama ngokusatiyela (okuyizimpawu zesifo sesibindi)
- amehlo afiphele.

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

Tshela udokotela wakho uma ubona okunye kwalokhu okulandelayo:

Imithelela engathandeki evamile ukubonakala:

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- isifo sohudo noma ukuqunjelwa, izinhlungu esiswini nendawo ezungeze isisu, ukugcwala komoya esiswini
- ikhanda elibuhlungu.

Imithelela engathandeki engavamile ukwenzeka:

- inani eliphansi lezingqalampilo ezimhlophe egazini lakho
- umthamo ophakeme wemikhiqizo esamafutha egazini, izingakushisa lomzimba eliphakeme
- inkinga yokungafikelwa wubuthongo, ingcindezi yengqondo, ukudideka kwengqondo
- ukuphathwa isiyenzi, ukuphazamiseka noma ukuphela nya komuzwa wokunambitha
- isicanucanu kanye/noma ukuhlanza, umlomo owomile, isisu esiqumbile, isisu esibuhlungu nokungaphatheki kahle
- ezinye izinkinga zokugula okuphathelene nesikhumba
- ubuhlungu emajoyintini noma emisipheni yomzimba, ukuphuka kwenqulu, isihlakala noma umgogodla
- ukuvuvukala nokukhukhumala kwezibele kubantu besilisa
- ukuzizwa ubuthakathaka, ukukhathala okukhulu, nokucobeka komzimba (ukuzizwa ungemnandi), ukuvuvukala kwezandla kanye nezinyawo
- ukuqina kwemisipha nezicubu zomzimba
- uhlobo lwenkinga yezinso (phecelezi i-*acute interstitial nephritis*). Abantu abathile abasebenzisa imithi yokunciphisa i-esidi esiswini *amaprotin pump inhibitor (PPI)*, kubandakanya nePEPLOC, kungenzeka babe nenkinga yezinso ebizwa nge-*acute interstitial nephritis*, okuyinkinga engenzeka noma nini ngenkathi umuntu elashwa ngemithi engamaPPI. Fonela udokotela wakho ngokushesha uma ubona ukunciphisa komthamo womchamo wakho kunokwejwayelekile lapho uchama noma uma kunegazi emchameni wakho.

Le mithethelela elandelayo ibikiwe kodwa akwaziwa ukuthi ivamise kangakanani ukwenzeka:

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- ukuvuvukala kwethumbu elikhulu esiswini, okudala uhudo olungamanzi olunganqamuki
- amazinga aphansi kasawoti noma *emagnesium* noma *ecalcium* egazini
- ukubona izinto ezingekho, ukuzizwa udidekile
- umuzwa onsonsothayo, ohlabayo, osanalithi (*pins and needles*), oshisayo noma ubundikindiki.

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. 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 kwePEPLOC OTC.

5. Indlela yokugcina iPEPLOC OTC

Yonke imithi kumele uyigcine endaweni ezingafinyeleli kuyona izingane.

Amaphilisi wagcine ezingeni lokushisa elingama-25 °C noma ngaphansi kwalokho

Wavikele kumswakama.

Izingqwenjana eziyizigcinimaphilisi kumele zigcinwe kwibhokisana lamaphilisi kuze kufike isikhathi lapho sekudingeka ukuba asetshenziswe.

Ungawasebenzisi amaphilisi emuva kosuku lokuphelelwa kwawo yisikhathi olubhalwe kwilebula noma kuqwenjana oluyisigcinamaphilisi. Yiphindisele emuva kusokhemisi wakho yonke imithi

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engasetshenziswanga.

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

6. Okuqukethwe ephaketheni lamaphilisi kanye nolunye ulwazi

Okuqukethwe yiPEPLOC OTC

Isithako sokwelapha esiyinhloko esiqukethwe yiphilisi iPEPLOC OTC ngalinye yipantoprazole sodium sesquihydrate elingana nepantoprazole engama-20 mg.

Ezinye izithako yilezi:

Ezisengxenyeni engaphakathi yephilisi:

Carmellose sodium, colloidal anhydrous silica, magnesium stearate, mannitol, sodium carbonate anhydrous, sodium starch glycolate type A.

Engxenyeni ewungwengwezana lwephilisi:

Hypromellose, methacrylic acid-ethyl acrylate copolymer, propylene glycol, titanium dioxide, triethyl citrate, yellow iron oxide.

7. Indlela ebukeka ngayo iPEPLOC OTC kanye nalokho okuqukethwe ephaketheni layo

PEPLOC OTC: Iyiphilisi elinombala osawolintshi, eliqumbile kancane nhlangothi zombili futhi eliyindingilizi, elikwaziyo ukumelana ne-esidi esiswini. Ububanzi: 4,7 mm x 9,0 mm.

Amaphilisi iPEPLOC OTC agcinwe kuqwenjana olungumsweswana oluyisigcinamaphilisi olwaxhiwe nge-*aluminium-polyamide-PVC/aluminium*.

Kwibhokisana eliqukethe amaphilisi ngalinye kunamaphilisi ayisi-7 noma ayi-14.

8. Umnikazi Wesitifiketi Sokubhaliswa

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PEPLOC OTC**

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9. Leli pheshana lolwazi lagcina ukubuyezwa mhla zingama-

23 kuMandulo 2021

10. Inamba yokubhaliswa

A43/11.4.3/0344

NAM:

PEPLOC OTC: NS1 18/11.4/0081