

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

ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI

S4

Iphilisi elinongwengwezana iSIMVACOR 10 mg

Iphilisi elinongwengwezana iSIMVACOR 20 mg

Iphilisi elinongwengwezana iSIMVACOR 40 mg

Simvastatin

ISIMVACOR iqukethe ushukela (iphilisi ngalinye elingama-10 mg liqukethe *i/lactose monohydrate* engama-67,92 mg, iphilisi ngalinye elingama-20 mg liqukethe *i/lactose monohydrate* engama-135,84 mg futhi iphilisi ngalinye elingama-40 mg liqukethe *i/lactose monohydrate* engama-271,68 mg)

Ngaphambi kokuba uqale ukusebenzisa iSIMVACOR 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.
- ISIMVACOR 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

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2. Okumele ukwazi ngaphambi kokuba usebenzise iSIMVACOR
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1. Iyini iSIMVACOR futhi isetshenziselwani

ISIMVACOR isetshenziswa, ngokuhlanganyela nohlelo lokudla olwehlisa ikholesteroli, ngenhloso yokwehlisa ikholesteroli kanye nokwehlisa amazinga *etriglyceride* (okusamafutha) egazini.

ISIMVACOR isebenza ngokuthi ivimbele isikhuthazalushintsho esidingwa ngumzimba ukwakha ikholesteroli, futhi ngalokho-ke inciphise umthamo wekholesteroli egazini. Ukusebenzisa iSIMVACOR kungalekelela ekuvimbeleni izinkinga zezempilo ezidalwa yilokhu okusamafutha okuvala imithambo yegazi.

ISIMVACOR ingasetshenziswa futhi ukuvimbela izinhlobo ezithile zezinkinga zenzhliziyo kubantu abadala abasengcupheni yokuhlaselwa yizifo zenzhliziyo, abangabi ngcono nakuba sebekushintshile ukudla abakudlayo.

2. Okumele ukwazi ngaphambi kokuba usebenzise iSIMVACOR

Ungalokothi usebenzise iSIMVACOR:

- uma umzimba wakho ungezwani nesithako *isimvastatin*, noma eminye imithi esetshenziselwa ukunciphisa amazinga ekholesteroli noma uma ungezwani nanoma yisiphi esinye isithako seSIMVACOR (bheka isigaba 6).
- uma unesifo sesibindi esinamandla futhi esikuxinayo noma esiyisimbelambela.
- uma uphethwe *yiporphyria* (inkinga yegazi eyivelakancane).
- uma ukhulelwe noma uncelisa (bheka isigatshana esithi Ukukhulelwa kanye nokuncelisa).
- uma usebenzisa umuthi noma imithi enesithako sokwelapha esiyinhloko esisodwa noma ngaphezulu kulezi ezilandelayo:
 - *i-itraconazole, ketoconazole, posaconazole* noma *ivoriconazole* (esetshenziselwa ukwelapha ukutheleleka okubangelwa wukhunta (*funga infections*)),
 - amaHIV protease inhibitors anjenge*indinavir, nelfinavir, ritonavir*, kanye nesaquinavir (amaHIV protease inhibitors asetshenziselwa ukudodobalisa ukutheleleka okubangelwa yisandulelangculazi),
 - *iboceprevir* noma *itelaprevir* (esetshenziselwa ukwelapha isifo sesibindi *ihepatitis C*),

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- *i-erythromycin, clarithromycin, noma itelithromycin* (esetshenziselwa ukwelapha ukutheleleka ngamagciwane abanga izifo),
- *inefazodone* (esetshenziselwa ukwelapha ingcindezi yengqondo),
- *icobicistat* (esetshenziselwa ukudodobalisa isandulelangculazi),
- *igemfibrozil* (esetshenziselwa ukwehlisa ikholesteroli),
- *icyclosporin* (esetshenziswa ezigulini ezifakwe isitho somzimba sokufakelwa),
- *idanazol* (ihomoni yokuzenzela eyenziwe ngabantu esetshenziselwa ukwelapha i-*endometriosis*, isifo lapho ulwelwesi lwesibeledo lumila ngaphandle kwesibeledo),
- *ilomitapide* (esetshenziselwa ukwehlisa ikholesteroli ephatha amalungu omndeni).

Izixwayiso kanye nezinto okumele uziqikelele

Qaphela kakhulu uma usebenzisa iSIMVACOR:

Ukukhohlwa kanye nokudideka kubikiwe njengemithelela engathandeki ebangelwa wukusebenzisa imithi yokwehlisa ikholesteroli enjengeSIMVACOR. Lezi zingameko zokukhohlwa nokudideka esikhathini esiningi bezingenawo amandla kakhulu futhi zaphela emuva kokuthi kuyekiwe ukusebenzisa lo muthi.

Uma kukhona noma yikuphi okuqondene nawe kulezi zimo ezilandelayo, kumele umtshale udokotela wakho ngaphambi kokusebenzisa iSIMVACOR:

- uma uzama ukukhulelwa.
- uma uphuza utshwala obuningi kakhulu.
- uma unomlando wokuphathwa yisifo sesibindi. Udokotela wakho kungenzeka ahlole igazi lakho ngaphambi kokuba uqale ukusebenzisa iSIMVACOR futhi angakwenza lokhu uma kwenzeka uphathwa noma yiziphi izimpawu eziphathelele nezinkinga zesibindi ngenkathi usebenzisa lo muthi. Lokhu kwenzelwa ukubheka nokuthola ukuthi sisebenza kahle kangakanani isibindi sakho. Udokotela wakho kungenzeka futhi afune ukuthi wenze ukuhlwa kwegazi ukuze abheke futhi athole ukuthi sisebenza kahle kangakanani isibindi sakho emuva kokuba uqale ukusebenzisa iSIMVACOR.

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- umu ungumuntu okunamathuba okuthi abe nenkinga yokuhluleka kwezinsu ukusebenza ngendlela efanele kulandela ukuphathwa kwakho *yirhabdomyolysis* (ukuwohloka kwethishu yemisipha yomzimba okukhipha iphrotheyini engadala umonakalo ingene egazini), umfutho wegazi ophakeme, izinkinga ezinamandla zokuhluleka komzimba ukugaya nokuguqula ukudla kube ngamandla, nezinkinga zokuhluleka ukusebenza kohlelo lomzimba olukhiqiza amahomoni kanye nenkinga yamazanga oketshezi angalingani kahle emzimbeni, ukudlikiza komzimba okungalawuleki (isifo sokuwa), ukuhlinzwa okukhulu noma ukulimala.
- uma uxinwe kakhulu yisifo sezinsu esibucayi.
- uma uzohlinzwa, njengoba kuzodingeka ukuthi uyeke ukusebenzisa iSIMVACOR ezinsukwini ezimbalwa ngaphambi kokuba uhlinzwe.
- uma usebenzisa noma iyiphi eminye imithi enjengama-*immunosuppressants*, *amafibrates* (ngaphandle kwe*fenofibrate*), imithamosilinganiso yokwehlisa okusamafutha ye*niacin*, *amiodarone*, *amlodipine*, *verapamil*, *diltiazem* noma ye*daptomycin* (bheka futhi isigatshana esithi Ungalokothi usebenzise iSIMVACOR).
- uma ungumuntu ongowomdabu wase-*Asia*.
- uma uxinwe kakhulu yisifo samaphaphu esinamandla.

Uma kwenzeka uphathwa noma yiziphi izinhlungu zemisipha yomzimba, uma uba nezindawo ezibuhlungu lapho zithintwa noma zicindezelwa noma ubuthakathaka okungaziwa ukuthi kubangelwa yini ngenkathi welashwa ngeSIMVACOR kumele wazise udokotela wakho ngokushesha noma omunye ungoti wosizo lwezempilo nokwelashwa. Uma unanoma yiziphi kulezi zinkinga ezilandelayo kungenzeka ube sengcupheni yokuphathwa yizinkinga zemisipha yomzimba (ezidala ukukhiqizwa kwesakha-mbala semisipha yomzimba emchameni) ezingadala ukuthi izinso zihluleke ukusebenza:

- uma unokuphathwa yinkinga engalawulekile kahle yokudlikizela komzimba noma ukugula okwenzeka ngokushesha kungazelelwe okudalwa wukuhamba kukagesi ngamandla ebuchosheni.
- uma unenkinga yokushoda noma yokungasebenzi kahle kwamazinga oketshezi angalingani kahle emzimbeni noma kwesikhuthazalushintsho sokuguqula ukudla kube ngamandla.

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- uma uphethwe wukutheleleka okunamandla.
- uma unomfutho wegazi ophansi.
- uma kamuva nje kuwena kusanda kwenziwa inqubokwelapha yokuhlinzwa okukhulu noma uma uthole ukulimala okukhulu.

Ingcuphe yokuwohloka kwemisipha yomzimba iba nkulu uma uphuza umthamosilinganiso ophakeme weSIMVACOR, ikakhulukazi umthamosilinganiso ongama-80 mg. Ingcuphe yokuwohloka kwemisipha yomzimba iba nkulu futhi ezigulini ezithile. Tshela udokotela wakho uma kukhona noma yikuphi kulokhu okulandelayo okuqondene nesimo sakho:

- uma ungumuntu osekhulile ngokweminyaka (iminyaka engaphezu kwama-65 ubudala).
- uma ungumuntu wesifazane.
- uma unezinkinga zezinso.
- uma uphethwe yinkinga engalawulekile kahle lapho indlala yegilo ingakhiqizi ihomoni yegilo eyanele, phecelezi *ihypothyroidism*.
- uma wena noma ilungu lomndeni esikhathini esedlule nika naba nezinkinga zokungasebenzi kahle kwemisipha yomzimba.
- uma esikhathini esedlule uke waba nenkinga yemisipha yomzimba engasebenzi kahle ngenxa yokusebenzisa imithi yokwehlisa ikholesteroli embi egazini (*statin*) noma imithi yokukhuphula ikholesteroli enhle egazini (*fibrate*).
- uma uphuza utshwala obuningi kakhulu.

Amazinga akho ajwayelekile kashukela egazini kungenzeka akhuphuke ngenkathi usebenzisa iSIMVACOR. Ngenkathi usebenzisa lo muthi udokotela uzosiqapha futhi asibhekisise ngokuqhubekayo isimo sakho uma ungumuntu onesifo sikashukela noma uma usengcupheni yokuphathwa yisifo sikashukela.

Kungenzeka ube sengcupheni yokuphathwa yisifo sikashukela uma unamazinga aphakeme kashukela kanye namafutha egazini lakho, uma ukhuluphele ngokweqile noma uma unomfutho wegazi ophakeme.

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Izingane kanye namabhungu namatshitshi

Lukhona ucwaningo olwenziwe maqondana nokuphepha kanye nokusebenza kahle kwesithako *isimvastatin* esiqukethwe emaphilisini iSIMVACOR kubafana abaneminyaka eyi-10 kuya kweyi-17 ubudala kanye nasemantombazaneni aqale ukuya esikhathini okungenani esikhathini esingangonyaka owodwa ngaphambi kwalokho. Alukho ucwaningo mayelana neSIMVACOR olwenziwe ezinganeni ezineminyaka engaphansi kwe-10 ubudala. Ukuze uthole ulwazi oluthe xaxa, khuluma nodokotela wakho.

Ukusetshenziswa kweminye imithi neSIMVACOR

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

Uma kukhona noma yimuphi owusebenzisayo kule mithi elandelayo, cela iseluleko kudokotela wakho, usokhemisi noma omunye ungoti wosizo lwezempilo nokwelashwa:

- *amafibrates* aqukethe isithako sokwelapha esiyinhloko esinjenge*gemfibrozil* kanye ne*bezafibrate* noma *inicotinic acid* (asetshenziselwa ukwehlisa ikholesteroli).
- *i-erythromycin*, *clarithromycin* noma *itelithromycin* (eyi-antibhayothikhi).
- *i-itraconazole*, *ketoconazole*, *fluconazole*, *posaconazole*, noma *ivoriconazole* (umuthi wokwelapha izifo ezibangelwa wukhuntha)
- umuthi wokudodobalisa isandulelangculazi onjenge*nelfinavir* (osetshenziselwa ukwelapha ukutheleleka okuphathelene nesandulelangculazi).
- *inefazodone* (umuthi wokwelapha ingcindezi yengqondo).
- imishanguzo ye*hepatitis C* enjenge*boceprevir*, *telaprevir*, *elbasvir* noma *igrazoprevir* (esetshenziselwa ukwelapha ukutheleleka okubangelwa yigciwane le*hepatitis C*).
- imithi equkethe isithako sokwelapha esiyinhloko *icobicistat* (esetshenziselwa ukwelapha ukutheleleka okuphathelene nesandulelangculazi).
- *iciclosporin* (umuthi osetshenziswa emuva kwenqubokwelapha yokufakelwa isitho somzimba ukuze kuvinjelwe ukwalana komzimba nesitho sokufakelwa).

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- *idanazol* (ihomoni yokuzenzela eyenziwe ngabantu esetshenziselwa ukwelapha i-*endometriosis*, isifo lapho ulwelwesi lwesibeetho lumila ngaphandle kwesibeetho).
- *ifusidic acid* (enqunyelwe ukwelapha ukutheleleka okubucayi futhi okujulile), kuzodingeka ukuthi uyeke okwesikhashana ukusebenzisa iSIMVACOR. Udokotela wakho uzokutshela uma sekuphephile ukuthi ungaqala futhi usebenzise iSIMVACOR. Kuyinto eyivelakancane ukuthi ukusebenzisa lo muthi kanyekanye ne*fusidic acid* kudale ubuthakathaka bemisipha yomzimba, ubuhlungu ezindaweni ezithile lapho zithintwa noma zicindezelwa noma izinhlungu (*rhabdomyolysis*).
- *i-amiodarone* (esetshenziselwa ukwelapha inkinga yokungashayi kwenhliziyo ngesigqi esihambelanayo).
- *amalcium channel blockers* isibonelo, *iverapamil* kanye ne*diltiazem* noma *i-amlodipine* (esetshenziselwa ukwelapha umfutho wegazi ophakeme kanye nezinhlungu esifubeni).
- *ilomitapide* (esetshenziselwa ukwelapha isifo sekholesteroli esibucayi futhi esiyivelakancane esiphathelene nofuzo).
- *iniasin* (uhlobo luka*vitamin B3*). Uma ungowomdabu wase-*Asia* akumele usebenzise iSIMVACOR kanyekanye ne*iniasin*).
- *iticagrelor* (umuthi ovimbela ukuhlangana nokunamathelana kwamaplathelethi akhe amahlule).
- *icolchicine* (umuthi wokwelapha igawuthi).
- *idaptomycin* (umuthi osetshenziselwa ukwelapha ukutheleleka kwesikhumba kanye nesakhiwo sesikhumba, okungelula neze ukukwelapha ngemithi ejwayelekile, kanye ne*bacteraemia*). Kungenzeka ukuthi ikhuphuke imithelela engathandeki ethinta imisipha yomzimba uma lo muthi usetshenziswa kanyekanye ne*simvastatin* (enjengeSIMVACOR). Udokotela wakho kungenzeka anqume ukuthi kumele uyeke okwesikhashana ukusebenzisa iSIMVACOR.
- *irifampicin* (umuthi osetshenziselwa ukwelapha isifo sofuba).
- *iwarfarin* (umuthi ovimbela ukujija kwegazi libe ngamahlule) kungenzeka ukhuphule ubungozi bokopha.

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- ukusetshenziswa kwedigoxin (umuthi osetshenziselwa iheart dysrhythmia noma ukuhluleka kwenhliziyo ukusebenza ngendlela efanele) kanyekanye nalawa maphilisi kungaqinisa amandla okusebenza kwedigoxin.
- icolestipol kanye necholestyramine (imithi elawula i-esidi yenyongo kanye nekholesteroli) kungenzeka ukuthi yehlise amandla okusebenza kweSIMVACOR.

Ukuphuza iSIMVACOR nokudla kanye nophuzo

ISIMVACOR akumele iphuzwe nojusi wegrapefruit noma eminye imikhiqizo yegrapefruit ngoba igrapefruit ikhuphula umthamo wesimvastatin egazini.

Ungalokothi uphuze utshwala obuningi ngokweqile ngenkathi usebenzisa iSIMVACOR ngoba lokhu kungayenza ibe yimbi kakhulu imithelela emibi yeSIMVACOR esibindini.

Ukukhulelwa, ukuncelisa kanye nokuba sesimweni sokuzala nokuthola abantwana

Uma ukhulelwe noma usancelisa umntwana wakho, noma uma ucabanga ukuthi mhlawumbe ukhulelwe noma uma uhlela ukuthola umntwana, bonisana nodokotela wakho, usokhemisi noma omunye ungoti wosizo lwezempilo nokwelashwa ukuze uthole ukwelulekwa ngaphambi kokuba usebenzise iSIMVACOR.

ISIMVACOR akumele isetshenziswe ngabesifazane abakhulelwe noma abesifazane abahlela ukukhulelwa futhi akumele isetshenziswe ngabesifazane abancelisayo (bheka isigatshana esithi Ungalokothi usebenzise iSIMVACOR)

Kumele usebenzise isivimbelanzalo esisebenza kahle ngenkathi welashwa ngeSIMVACOR.

Xoxisana nodokotela wakho ngokushesha uma ubona sengathi usukhulelwe ngenkathi usebenzisa iSIMVACOR.

Ukushayela kanye nokusebenzisa imishini

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ISIMVACOR ingabangela ikhanda elibuhlungu kanye nesiyezi. Ungalokothi ushayele imoto noma usebenzise noma yimuphi umshini kuze kufike isikhathi lapho usubonile ukuthi iSIMVACOR ikuphatha kanjani.

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

ISIMVACOR iqukethe ushukela wobisi (*lactose*).

3. Isetshenziswa kanjani iSIMVACOR

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

Ngaphambi kokuba akunikeze imithi ozoyisebenzisa ukwelapha isifo sakho, udokotela wakho kungenzeka azame ukulawula isifo sakho ngokuthi akuhlelele uhlelo lokudla oluqondene nawe ozolulandela. Uhlelo lokudla olunjalo kungenzeka kube wuhlelo lokudla olunomthamo ophansi wamafutha, ushukela kanye/noma ikholesteroli. Abantu abaningi bayakwazi ukulawula isifo sabo ngokuthi balandele ngokucophelela imiyalelo kadokotela wabo yokuthi babe nohlelo lokudla olufanelekile abalulandelayo futhi bazivocavoce.

Umuntu unikezwa imithi kuphela uma kudingeka usizo olwengeziwe, futhi imithi isebenza kahle kuphela uma elulandela ngendlela efanele uhlelo lokudla nokuzivocavoca.

Khumbula ukuthi iSIMVACOR ngeke iselaphe isifo sakho kodwa yona iyalekelela ekutheni silawuleke. Ngakho-ke, kumele uqhubeke nokusebenzeisa iSIMVACOR njengoba uyaleliwe, ukuze ugcine amazinga ekholesteroli yakho ephansi.

Iphilisi kumele uligwinye lonke liphelele, ulehlise ngamanzi.

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Ungawagayi noma uwahlafune lawa maphilisi. ISIMVACOR ungayiphuza nokudla noma uyiphuze ngaphandle kokudla.

Kubantu abadala

Ukwelapha ikholesteroli ephakeme

Umthamosilinganiso ojwayelekile womuntu omdala uma esaqala ukusebenzisa iSIMVACOR ngama-10 mg kusihlwa, futhi lokhu kuzoya ngokwesimo esiqondene nawe.

Ukwelapha isifo senhliziyo

Umthamosilinganiso ojwayelekile womuntu omdala yiphilisi elilodwa leSIMVACOR elingama-20 mg kusihlwa.

Ukuguqulwa Komthamosilinganiso Ukuze Uhambisane Nesimo Sakho

Umthamosilinganiso kungenzeka awukhuphule udokotela wakho ufinyelele kwiSIMVACOR engama-80 mg ephuzwa njengomthamosilinganiso owodwa kusihlwa nsukuzonke.

Uma udokotela ekuyalele ukuthi usebenzise iSIMVACOR kanyekanye nomunye umuthi wokwehlisa ikholesteroli oqukethe nanoma iyiphi *ibile acid sequestrant*, kumele iSIMVACOR uyiphuze okungenani kusasele ihora elilodwa ngaphambi kokuphuza *icholestyramine* noma uyiphuze sekudlule amahora amane emuva kokuphuza *icholestyramine*.

Ezigulini ezisebenzisa lo muthi kanyekanye *ne ciclosporin*, *amafibrates* noma *iniacin* kunconywa ukuthi umthamosilinganiso ophela wansukuzonke weSIMVACOR ube ngama-10 mg.

Udokotela wakho uzokutshela ukuthi kuzothatha isikhathi eside kangakanani ukwelashwa kwakho ngeSIMVACOR.

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

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Uma uphuze iSIMVACOR 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.

Uma kwenzeka ukhohlwa ukuphuza iSIMVACOR

Uma kwenzekile wakhohlwa ukuphuza umthamosilinganiso wamaphilisi, waphuze ngokushesha emuva kokukhumbula ukuthi kumele uwaphuze.

Uma sekusondele isikhathi sokuphuza umthamosilinganiso wakho olandelayo, ungabe usawuphuza lowo mthamosilinganiso okhohliwe ukuwuphuza futhi uqhubeke uphuze iphilisi ngesikhathi esijwayelekile. Ungalokothi uphuze imithamosilinganiso yamaphilisi ephindwe kabili noma umthamosilinganiso oweqile ngenhloso yokuvala isikhala semithamosilinganiso okhohliwe ukuyiphuza.

Uma uyeka ukusebenzisa iSIMVACOR

Khuluma nodokotela wakho noma usokhemisi ngoba kungenzeka iphinde futhi ikhuphuke ikholesteroli yakho.

4. Imithelela engathandeki okungenzeka ibe khona

ISIMVACOR kungenzeka ibe nemithelela engathandeki.

Akuyona yonke imithelela engathandeki ebikiwe yeSIMVACOR equkethwe kuleli pheshana lolwazi.

Uma siba sibi isimo sakho sempilo jikelele, noma uma uzwa umthelela ongemnandi futhi ongathandeki emzimbeni ngenkathi usebenzisa iSIMVACOR, bonisana nomhlinzeki wakho wosizo lwezempilo nokwelashwa ukuze uthole ukwelulekwa.

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

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- 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 neSIMVACOR oyisebenzile. 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:

- imisipha yomzimba ebuhlungu kakhulu lapho ithintwa noma icindezelwa, ubuthakathaka, izinhlungu kanye nokuqina emahlombe kanye nasesinqeni.
- *Lupus-Like Syndrome: Drug-induced lupus erythematosus (DIL)* yisifo esiyingxenywe yeqoqwana lezifo lapho amasosha omzimba ehlasela amathishu nezitho zomzimba esichazwa ngokuthi *ylupus-like syndrome* esikuphatha ngesikhathi lapho usebenzise uhlobo oluthile lomuthi futhi esipholayo emuva kokuyeka ukusebenzisa lowo muthi
- ukuvuvukala kwemigudu yegazi okuhambisana nezimpawu ezibandakanya imfiva, ukukhathala kakhulu, ukwehla/ukuncipha emzimbeni kanye nobuhlungu bemisipha noma amajoyinti omzimba.
- ukuhuzuka okungajwayelekile
- izinhlungu noma ukuvuvukala emajoyinti omzimba
- ukubheduka kwamaqhutshana kanye nokuvuvukala kwesikhumba, umqubuko, amahives, ukuzwela kwesikhumba ekukhanyeni, imfiva, ukufikelwa wukushisa okukhulu esikhunjeni nasebusweni
- ubuhlungu bamajoyinti omzimba, i-*arthritis*
- iphika kanye nokuzizwa ungaphilile emzimbeni wonke

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- *iperipheral neuropathy* (ubuthakathaka, ubundikindiki kanye nobuhlungu obubangelwa wukulimala kwezinzwa, okuvamise ukwenzeka ezingalweni, ezandleni, emilenzeni kanye nasezinyaweni)
- *i-interstitial lung disease* (iqoqwana lezinkinga zamaphaphu ezidala ukulimala nokuvela kwezibazi emaphashini)
- ukuvuvukala kwamanyikwe okuvamise ukuhambisana nezinhlungu ezinamandla esiswini nendawo ezungeze isisu
- ukuvuvukala kwesibindi (isifo *ihepatitis*, ijondisi) okuhambisana nezimpawu ezilandelayo: ukuguquka kwesikhumba namehlo kube nombala ophuzi, ukuluma, umchamo onombala omnyama noma indle enombala ophaphathekile, ukuzizwa ukhathele noma ubuthakathaka, ukuphelelwa wuthando lokudla, ukuhluleka kwesibindi ukusebenza
- *imyalgia* (ubuhlungu nokunkenketha kwemisipha yomzimba okungaba wubuhlungu obuncane kuya kubuhlungu obunamandla kakhulu)
- amajaqamba
- *imyopathy* (isifo lapho imicu yemisipha ingasebenzi kahle)
- *imyositis* (ukuvuvukala kwemisipha yomzimba, izimpawu zibandakanya ubuthakathaka, ukuvuvukala kanye nobuhlungu)
- *irhabdomyolysis* ebonakala ngophawu olunjengobuhlungu bemisipha yomzimba obuhambisana nokuphakama kwe*creatine phosphokinase* kanye ne*myoglobinuria* okuholela ekutheni izinso zihluleke ukusebenza
- ukugqabuka kwemisipha yomzimba
- *itendinopathy* (isifo lapho kuvuvukala amathishu ahlanganisa umsipha nethambo), kwesinye isikhathi eba yimbi kakhulu ngenxa yenkinga edalwa wukugqabuka kwemisipha
- *i-immune-mediated necrotising myopathy* (IMNM) (isifo samasosha omzimba esibangela ukufa kwezinhlayiya zemisipha yomzimba)
- ukukhula komthamo wama*serum transaminases* (*alanine aminotransferase*, *aspartate aminotransferase*, *γ-glutamyl transpeptidase*), umthamo ophakeme we-*alkaline phosphatase*,

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okudala ukuvuvukala noma ukulimala kwesibindi

- ukuphakama kwamazinga *eserum CK* (lokhu kungasho ukuthi unokulimala kwemisipha yomzimba noma isifo semisipha yomzimba, esinjenge*muscular dystrophy* noma *irhabdomyolysis*)

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

Tshela udokotela wakho uma ubona okunye kwalokhu okulandelayo:

Imithelela engathandeki engavamile ukwenzeka:

- *i-anemiya* (inkinga lapho igazi lingenazo izingqalampilo zegazi ezimhlophe eziphilile ezanele).
- ukuphakama kwamazinga kashukela egazini.
- inkinga yokungalali kahle, ukukhohlwa kanye nokudideka.
- ikhanda elibuhlungu kanye/noma isiyenzi, ukuzizwa ukhathele noma ubuthakathaka kakhulu, umuzwa wokunambitha oguqukile, umuzwa onsonsothayo ama'*pins and needles*'.
- amehlo afiphele, inkinga yokuphazamiseka kokusebenza kwamehlo.
- ubuhlungu esiswini nendawo ezungeze isisu kanye nokudonseka kwemisipha yesisu, ukuqunjelwa, isifo sohudo, ukugcwala komoya esiswini, isicanucanu, ukuhlanza, inkinga yokungagayeki kahle kokudla.
- ukuqubuka kwesikhumba, *i-alopecia* (ukuqothuka kwezinswele kungazelelwe, ngokavamile okudala izibhadu eziqothukile eziyindilinga), ama-*lichenoid drug eruptions* (amaqhutshana nezibhadu ezinombala osabukhwebezane, ngokavamile okulinganayo ngokwesimo nokwakheka futhi okusabalele).
- *igynaecomastia* (ukuvuvukala kwamathishu ezibele zowesilisa okubangelwa yinkinga yokushoda kwamahomoni noma ukuba khona komthamo omningi ngokweqile wamahomoni emzimbeni).
- *i-asthenia* (umzimba obuthakathaka ngendlela engagwayelekile noma ukungabi namandla).

Le mithethelela elandelayo ibikiwe kodwa akwaziwa ukuthi ivamise kangakanani ukwenzeka:

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- *ineutropenia* (isibalo esiphansi ngokungajwayelekile futhi ngokweqile sohlobo lwezingqalampilo zegazi ezimhlophe) (*neutrophils*)
- ingcindezi yengqondo
- ukungavuki kwenduku kowesilisa
- ukuzimuka (ukukhuluphala).

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, usokhemisi noma umhlengikazi. Futhi ungayibika imithelela engathandeki kwabakwaSAHPRA ngohleloxhumano lwe-inthanethi ukubazisa ngokuphatheka kabi okubangelwa wumuthi othile, ngokulandela lelinki elandelayo: <https://www.sahpra.org.za/Publications/Index/8>.

Ngokubika imithelela engathandeki, ungalekelela ekuhlinzekweni kolwazi oluthe xaxa maqondana nokuphepha kweSIMVACOR. Futhi ungathumela i-imeyili ngqo enkampanini, pharmacovigilance@pharmadynamics.co.za, ngenhloso yokuqinisekisa ukuphepha komkhiqizo.

5. Indlela yokugcina iSIMVACOR

Yonke imithi kumele uyigcine endaweni ezingafinyeleli kuyona izingane.

Yigcine endaweni eyomile 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).

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6. Okuqukethwe ephaketheni lamaphilisi kanye nolunye ulwazi

Okuqukethwe yiSIMVACOR

Isithako sokwelapha esiyinhloko esiqukethwe lapha yi *simvastatin*.

SIMVACOR 10 mg: Iphilisi ngalinye elinongwengwezana liqukethe *simvastatin* engama-10 mg.

SIMVACOR 20 mg: Iphilisi ngalinye elinongwengwezana liqukethe *simvastatin* engama-20 mg.

SIMVACOR 40 mg: Iphilisi ngalinye elinongwengwezana liqukethe *simvastatin* engama-40 mg.

Ezinye izithako yilezi:

7. Ezisengxenyeni engaphakathi yephilisi:

Ascorbic acid, butylhydroxyanisole, citric acid anhydrous, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, starch pre-gelatinised.

Ezikungwengwezana lwengxenye engaphandle yephilisi:

Hypromellose, propylene glycol, talc kanye necolourant titanium dioxide

8. Indlela ebukeka ngayo iSIMVACOR kanye nalokho okuqukethwe ephaketheni layo

SIMVACOR 10 mg: Iyiphilisi elimhlophe, eliyindingilizi (elingama-6 mm ububanzi) eliqumbile kancane nhlangothi zombili, elinonqenqema olutshekile, elinongwengwezana.

SIMVACOR 20 mg: Iyiphilisi elimhlophe, eliyindingilizi (elingama-8 mm ububanzi) eliqumbile kancane nhlangothi zombili, elinonqenqema olutshekile, elinongwengwezana.

SIMVACOR 40 mg: Iyiphilisi elimhlophe, eliyindingilizi (elingama-11 mm ububanzi) eliqumbile kancane nhlangothi zombili, elinonqenqema olutshekile, ohlangothini olulodwa elinomugqa onqamula phakathi, elinongwengwezana.

Amaphilisi iSIMVACOR atholakala kumaphakeshana ayizigcinamaphilisi ezakhiwe ngongwengwezana lwe *PVC/PE/PVDC* olushisisiwe ukuze kwakhekhe isimo salo kanye nefoyela le-*aluminium* elivala ngci (*heat sealing aluminium foil*).

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9. Umnikazi Wesitifiketi Sokubhaliswa

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Inamba yocingo: +27 21 707 7000

10. Leli pheshana lolwazi lagcina ukubuyekezwa mhla ziyisi-

06 kuNtulikazi 2022

11. Inamba yokubhaliswa

SIMVACOR 10 mg: RSA S4 A35/7.5/0237

SIMVACOR 20 mg: RSA S4 A35/7.5/0238

SIMVACOR 40 mg: RSA S4 A39/7.5/0132

SIMVACOR 10 mg: NAM NS2 04/7.5/1660

BOT S2 1202043

SIMVACOR 20 mg: NAM NS2 04/7.5/1659

BOT S2 1202044

MOZ 2885

SIMVACOR 40 mg: NAM NS2 07/7.5/0166

MOZ 2886