

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

ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI:

S4

IGAMAKUHWEDA LOMKHIQIZO KANYE NESIMO SOMTHAMOSILINGANISO

DYNATOR 10 mg iphilisi elinongwengwezana

DYNATOR 20 mg iphilisi elinongwengwezana

DYNATOR 40 mg iphilisi elinongwengwezana

DYNATOR 80 mg iphilisi elinongwengwezana

Ngaphambi kokuba uqale ukusebenzisa iDYNATOR funda ngokucophelela lonke leli pheshana lolwazi.

Ligcine leli pheshana lolwazi. Kungenzeka ukuthi kudingeke ukuba uphinde futhi ulifunde.

Uma uneminye imibuzo engeziwe, buza udokotela wakho noma usokhemisi.

IDYNATOR iqondene nawe kuphela futhi inikezwe wena, ngakho-ke ungalokothi wabelane ngayo nabanye abantu. Kungenzeka bona ibalimaze, nakuba nabo benezimpawu ezifana nezakho.

1. OKUQUKETHWE YIDYNATOR:

Isithako sokwelapha esiyinhloko esiqukethwe lapha yi-*atorvastatin*.

DYNATOR 10 mg: Iphilisi ngalinye liqukethe i-*atorvastatin calcium* elingana ne-*atorvastatin* engama-10 mg.

DYNATOR 20 mg: Iphilisi ngalinye liqukethe i-*atorvastatin calcium* elingana ne-*atorvastatin* engama-20 mg.

DYNATOR 40 mg: Iphilisi ngalinye liqukethe i-*atorvastatin calcium* elingana ne-*atorvastatin* engama-40 mg.

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DYNATOR 80 mg: Iphilisi ngalinye liqukethe *i-atorvastatin calcium* elingana ne-*atorvastatin* engama-80 mg.

Ezinye izithako *yicrospovidone, magnesium stearate, microcrystalline cellulose, Opadry OYL – 28900 white, Sinespum C, sodium hydrogen carbonate, sodium lauryl sulphate.*

Iqukethe *i-w/w butylhydroxyanisole* engama-0,02 %, njengesilondolozimuthi.

Iqukethe ushukela.

DYNATOR 10 mg: Iqukethe ushukela wobisi, *ilactose monohydrate* engama-65,01 mg noshukela wezitshalo, *isucrose* engama-3,88 mg ephilisini ngalinye.

DYNATOR 20 mg: Iqukethe ushukela wobisi, *ilactose monohydrate* engama-130,02 mg noshukela wezitshalo, *isucrose* engama-7,77 mg ephilisini ngalinye.

DYNATOR 40 mg: Iqukethe ushukela wobisi, *ilactose monohydrate* engama-260,03 mg noshukela wezitshalo, *isucrose* engama-15,53 mg ephilisini ngalinye.

DYNATOR 80 mg: Iqukethe ushukela wobisi, *ilactose monohydrate* engama-520,05 mg noshukela wezitshalo, *isucrose* engama-31,07 mg ephilisini ngalinye.

2. IDYNATOR ISETSHENZISELWA LOKHU:

Kubantu abadala i**DYNATOR** isetshenziselwa:

- Ukwehlisa ikholesteroli egazini lakho. **IDYNATOR** unikezwa yona ngumhlinzeki wakho wosizo lwezempilo nokwelashwa uma ikholesteroli yakho ingehli ngokwanele ngokuzivocavoca kanye nokulandela uhlelo lokudla okunamafutha amancane kuphela.
- Ukuvimbela isifo senhliziyo ezigulini ezisengcupheni enkulu yokuhlaselwa yisifo senhliziyo njengalezo ezibhemayo, ezinomfutho wegazi ophakeme, ezinesifo sikashukela, ezine-HDL-C ephansi (okusho, amazinga aphantsi ekholesteroli enhle) noma lezo ezinamalungu omndeni aphethwe noma ake aphathwa yisifo senhliziyo.

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- Ukuvimbela izigameko ezingadala umonakalo enhliziyweni ezigulini esezivele zinaso kakade isifo senhliziyo noma ikholesteroli ephakeme.
- **IDYNATOR** iyasetshenziswa futhi ngokuhlanganyela neminye imithi ukwehlisa ikholesteroli yakho.

IDYNATOR iyasetshenziswa ezinganeni ezineminyaka eyi-10 kuya kweyi-17 ukwehlisa ikholesteroli egazini.

3. NGAPHAMBI KOKUBA USEBENZISE IDYNATOR:

Ungalokothi usebenzise iDYNATOR:

- uma umzimba wakho ungezwani ne-*atorvastatin* noma uma ungezwani nanoma yisiphi esinye isithako se**DYNATOR** (bheka ingxenye ethi **LOKHO OKUQUKETHWE YIDYNATOR**).
- Uma unesifo sesibindi esinamandla futhi esikuxinayo noma esiyisimbelambela kubandakanya ne*cirrhosis*.
- Uma uke wathola noma yimiphi imiphumela yokuhlolwa kwegazi ebonisa okuthile okungajwayelekile futhi okungachazeki ukuthi kubangelwa yini mayelana nokusebenza kwesibindi.
- Uma ukhulelwe noma usancelisa umntwana wakho (bheka isigatshana esithi **Ukukhulelwa kanye nokuncelisa**)
- Uma usebenzisa *irifampicin* (ukwelapha isifo sofuba noma i*TB*), noma *diltiazem* (ukwelapha izinkinga eziphathelele nokungashayi kwenhliziyo ngesigqi esifanele) noma uma unomkhuba wokuphuza *igrapefruit* eningi kakhulu.
- Uma uneporphyrin (isifo sofuzo esiyivelakancane esinomthelela kumbala wegazi esibonakala ngezimpawu ezinjengomchamo omnyama kanye nokuzwela kakhulu kwesikhumba elangeni).

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Qaphela kakhulu uma usebenzisa iDYNATOR:

- Uma unomlando wokuphathwa yisifo sesibindi, njengoba **iDYNATOR** ingaphazamisa amazinga ezikhuthazalushintsho (ama-*enzyme*) esibindini sakho.
- Uma uphuza utshwala kakhulu.
- Uma unenkinga ebuya iphindelela noma engachazeki ukuthi ibangelwa yini yobuthakathaka bemisipha yomzimba, iminjunju noma izinhlungu (ikakhulukazi emahlombe, ethangeni noma engxenyeni yomhlane esezansi (esinqeni)) noma uma wena noma ilungu lomndeni nika naba nezinkinga zemisipha yomzimba.
- Uma esikhathini esedlule uke waba nezinkinga zemisipha yomzimba ngenkathi welashwa ngemithi eyehlisa amafutha (isibonelo, imithi engama '*statin*' noma ama '*fibrate*').
- Uma singasebenzi kahle isibindi sakho noma izinso.
- Uma uthelekile ngokugula okunamandla.
- Uma unomfutho wegazi ophansi.
- Uma usalulama ekuhlinzweni okukhulu noma ukulimala.
- Uma uphethwe wukudlikiza komzimba okungalawuleki (amafithi/ukudlikizela).
- Uma usanda kufakelwa isitho somzimba futhi usebenzisa umuthi wokuvimbela ukwalana komzimba nesitho lesi esifakwe kuwena.
- Ngaphambi kwanoma yikuphi ukuhlinzwa (kubandakanya nokuhlinzwa okuphathelene namazinyo), tshela udokotela wakho noma udokotela wamazinyo ophethe ukuthi wena usebenzisa **iDYNATOR**.
- Uma usebenzisa imithi ebizwa ngama *protease inhibitors* (esetshenziselwa ukwelapha isandulelangculazi kanye nesifo sokuvuvukala kwesibindi) njengoba le mithi kungenzeka iphazamise indlela esebenza ngayo **iDYNATOR**.
- Uma esikhathini esedlule uke wahlaselwa yisifo sohlangothi esihambisana nokopha kwegazi lingene ebuchosheni, noma uma unamaconsana oketshezi ebuchosheni adalwe yizigameko

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zokuhlaselwa yisifo sohlangothi esikhathini esedlule, njengoba imithamosilinganiso ephakeme ye**DYNATOR** (80 mg) kungenzeka ikhuphule ubungozi bokuhlaselwa yisifo sohlangothi.

- Uma unenkinga yokungasebenzi kahle kwamaphaphu, njengoba kungenzeka ukuthi **iDYNATOR** ikwenze kube kubi kakhulu lokhu (bheka isigatshana esithi **IMITHELELA ENGATHANDEKI**).
- Uma unesifo sikashukela noma usengcupheni yokuphathwa yisifo sikashukela, njengoba udokotela wakho kungenzeka afune ukukubona njalo futhi ngokuqhubekayo ukuze ahlole ushukela egazini lakho.
- Uma usebenzisa umuthi ongamaconsi amehlo oyi-antibhayothikhi noma usebenzisa umuthi wokugcoba oqukethe *ifusidic acid*.

Udokotela wakho kungadingeka ukuthi enze ukuhlolwa ukuze aqaphe isimo sakho ngaphambi kokwelashwa kanye/noma nangenkathi welashwa.

Ukuphuza iDYNATOR nokudla kanye nophuzo:

Ukuphuza utshwala kakhulu kungenzeka kuguqule indlela **iDYNATOR** ekuphatha ngayo emzimbeni. Akumele uphuze utshwala nsukuzonke noma uphuze iziphuzo ezingaphezu kwesisodwa noma ezimbili nganoma yisiphi isikhathi. Ngaphambi kokuba akunikeze imithi ozoyisebenzisa ukwehlisa ikholesteroli yakho, udokotela wakho kungenzeka azame ukulawula ikholesteroli yakho ngokuthi akunikeze umyalelo wokuthi udle kuphela izinhlobo ezithile zokudla. Lezo zinhlobo zokudla kuzoba wukudla okunomthamo ophansi wamafutha, ikakhulukazi uhlobo lwamafutha oluphenduka lube yisinqumela, kanye nekholesteroli etholakala emikhiqizweni yezilwane esizidlayo. **IDYNATOR** izosebenza kuphela uma umuntu elulandela ngendlela efanele uhlelo lokudla okuthiwa makalulandele.

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Ungalokothi uphuze ujusi we*grapefruit* ngenkathi usebenzisa **iDYNATOR**, njengoba kungenzeka lokhu kuholele emazingeni aphakeme e**DYNATOR** egazini lakho.

IDYNATOR ungayiphuza nokudla noma uyiphuze ngaphandle kokudla.

Ukukhulelwa kanye nokuncelisa:

Ungalokothi usebenzise **iDYNATOR** uma ukhulelwe, noma uma uhlela ukukhulelwa noma uma usancelisa umntwana wakho. Ngenkathi usebenzisa **iDYNATOR** kumele uqinisekise ukuthi usebenzisa izivimbela ezanele, futhi ungakhulelwa.

Uma ukhulelwe noma usancelisa umntwana wakho, bonisana nodokotela wakho, usokhemisi noma omunye ungoti wosizo lwezempilo nokwelashwa ngaphambi kokuba usebenzise **iDYNATOR**.

Uma uhlela ukukhulelwa, kumele udlulise okungenani inyanga eyodwa emuva kokuyeka ukwelashwa nge**DYNATOR**.

Ukushayela kanye nokusebenzisa imishini:

Ungalokothi usebenzise imishini noma ushaye imoto kuze kufike isikhathi lapho sewazi ukuthi **iDYNATOR** ikuphatha kanjani emzimbeni, njengoba kungenzeka ukuthi lawa maphilisi akubangele isicanucanu, ikhanda elibuhlungu kanye nesiyezi.

Ulwazi olubalulekile mayelana nezinye zezithako zeDYNATOR:

IDYNATOR iqukethe ushukela wobisi. Iziguli ezinezifo zofuzo eziyivelakancane zokuhluleka komzimba ukugaya ushukela wobisi noma olunye uhlobo lukashukela olubizwa nge*galactose* akumele zisebenzise **iDYNATOR**.

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

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iDYNATOR.

IDYNATOR iqukethe ushukela wobisi kanye noshukela wezitshalo ongaba nomthelela ekulawulekeni koshukela egazini lakho uma ungumuntu onesifo sikashukela.

Ukusebenzisa eminye imithi kanyekanye neDYNATOR:

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

(Lokhu kubandakanya nemithi eyizondlamzimba kanye nemithi yesintu.)

IDYNATOR kungenzeka iguqule indlela esebenza ngayo imithi elandelayo:

- *Irifampicin* (esetshenziselwa ukwelapha i *TB*) kungenzeka iphazamise indlela esebenza ngayo **iDYNATOR**.
- Imithi ethile engama-*calcium channel blockers* esetshenziselwa ukwelapha izinhlungu esifubeni (*angina*) noma umfutho wegazi ophakeme, isibonelo, i-*amlodipine*, ne*diltiazem* kungenzeka iphazamise indlela esebenza ngayo **iDYNATOR** futhi kuzodingeka ukuthi sibhekisiswe njalo futhi ngokuqhubekayo isimo sakho.
- *Iciclosporin* (umuthi osetshenziswa emuva kokufakelwa isitho somzimba) noma *idelavirdine* (umshanguzo wesandulelangculazi). Kungenzeka ukuthi kudingeke ukuthi uncishiswe umthamosilinganiso wakho we**DYNATOR** futhi kudingeke nokuthi sibhekisiswe njalo futhi ngokuqhubekayo isimo sakho.
- *I-itraconazole*, *ketoconazole*, *fluconazole*, *voriconazole*, *clotrimazole* noma *iposaconazole* (yokwelapha izifo ezibangelwa wukhunta (*antifungal*)). Kungenzeka kudingeke ukuthi uncishiswe umthamosilinganiso wakho we**DYNATOR** futhi kudingeke nokuthi sibhekisiswe njalo futhi ngokuqhubekayo isimo sakho.

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- I-*erythromycin*, *telithromycin* ne*clarithromycin* (ama-antibhayothikhi) kungenzeka ikhuphule amandla okusebenza kwe**DYNATOR**.
- Imithi esetshenziselwa ukwelapha iHIV (njenge-*indinavir*, *ritonavir*, *lopinavir*, *atazanavir*, *darunavir*, *saquinavir*, *tipranavir*, *efavirenz* noma inhlanganisela yokwelapha ngale mithi) kungenzeka iphazamise indlela esebenza ngayo i**DYNATOR**.
- I*niacin* (uVithamini B3) esetshenziselwa ukwelapha ikholesteroli ephakeme kungenzeka ikhuphule ubungozi bokuphathwa yimithelela engathandeki yezinkinga zemisipha yomzimba (bheka isigatshana esithi **IMITHELELA ENGATHANDEKI**).
- Eminye imithi esetshenziselwa ukunciphisa amazinga ekholesteroli (njenge*gemfibrozil*, amanye ama*fibrates*, *colestipol*, *ezetimibe*) kungenzeka ikhuphule ubungozi bokuphathwa yimithelela engathandeki yohlaka lwamathambo noma imisipha yomzimba (bheka isigatshana esithi **IMITHELELA ENGATHANDEKI**).
- I*fusidic acid* (eyi-antibhayothikhi) njengoba kungalungile ukusebenzisa i**DYNATOR** ngesikhathi esifanayo nalo muthi futhi kungadingeka ukuthi kuyekwe ukwelashwa nge**DYNATOR** (bheka isigatshana esithi **Qaphela kakhulu uma usebenzisa iDYNATOR**).
- Imithi esetshenziselwa ukulawula isigqi sokushaya kwenhlinziyo yakho ukuze sihambelane kahle, isibonelo, *digoxin*, *verapamil*, *amiodarone*, *ranolazine* kungenzeka iguqule indlela esebenza ngayo i**DYNATOR** futhi kuzodingeka ukuthi sibhekisiswe njalo futhi ngokuqhubekayo isimo sakho.
- I*cimetidine* (esetshenziselwa isilungulela noma izilonda esiswini) ayinawo umthelela ku**DYNATOR**.
- Imithi yokuqeda i-esidi esiswini (imithi yokwelapha inkinga yokungagayeki kahle kokudla equkethe i-*aluminium* noma i*magnesium*) kungenzeka iguqule indlela esebenza ngayo i**DYNATOR**.
- I*warfarin* (umuthi ovimbela ukuguquka kwegazi libe ngamahlule) njengoba udokotela wakho

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ezofuna ukuthi asibhekisise njalo futhi ngokuqhubekayo isimo sakho.

- *Icholestyramine* (umuthi wokwelapha ikholesteroli ephakeme noma isifo sohudo).
- Izivimbela eziphuzwa ngomlomo, njengoba **iDYNATOR** kungenzeka inciphise amandla okusebenza kwamanye amaphilisi okuvimbela inzalo.
- Eminye imithi eyaziwayo ukuthi iyayiguqula indlela esebenza ngayo **iDYNATOR** ibandakanya *istiripentol* (umuthi wokuqeda ukudlikizela komzimba uma unesifo sokuwa), *iphenazone* (isidambisizinhlungu), *icolchicine* (esetshenziselwa ukwelapha isifo igawuthi (*gout*)), *iboceprevir* noma *itelaprevir* (esetshenziselwa ukwelapha isifo sesibindi esinjenge*hepatitis C*), *inefazondone* noma *St John's Wort* (okuyimithi esetshenziselwa ukwelapha ingcindezi yengqondo), futhi kungenzeka kudingeke ukuthi uguqulwe umthamosilinganiso noma kudingeke ukuthi isiguli sibhekiswe ngokucophelela njalo futhi ngokuqhubekayo.

4. ISETSHENZISWA KANJANI IDYNATOR:

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

Umthamosilinganiso uzokwehluka ngokwesiguli nesiguli.

IDYNATOR ungayiphuza nokudla noma uyiphuze ngaphandle kokudla.

Ngaphambi kokuqalisa ukwelashwa, udokotela wakho uzokufaka ngaphansi kohlelo lokudla kuphela ukudla okunekholesterol ephansi, okumele ululandele ngenkathi welashwa nge**DYNATOR**.

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Umthamosilinganiso womuntu omdala:

Umthamosilinganiso ojwayelekile uma usaqala ukwelashwa ngama-10 mg ongawuphuza noma ngasiphi isikhathi sosuku futhi uwuphuze nokudla noma ngaphandle kokudla.

Udokotela wakho kungenzeka awukhuphule umthamosilinganiso wakho uyofinyelela kumthamosilinganiso ophelele ongama-80 mg nsukuzonke, njalo emuva kwamaviki amane.

Umthamosilinganiso uzoya ngokwesimo sakho kanye nokuthi bukhona yini ubungcono obubonakalayo emzimbeni wakho ngenkathi uthola ukwelashwa.

Izingane (ezineminyaka eyi-10 kuya kweyi-17 ubudala):

Umthamosilinganiso ojwayelekile uma usaqala ukwelashwa ngama-10 mg ongawuphuza noma ngasiphi isikhathi sosuku.

Udokotela wakho kungenzeka awukhuphule umthamosilinganiso wakho uyofinyelela kumthamosilinganiso ophelele ongama-20 mg nsukuzonke, njalo emuva kwamaviki amane.

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

Uma uphuze iDYNATOR engaphezulu kwaleyo okumele uyiphuze:

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

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

Uma kwenzeka ukhohlwa ukuphuza umthamosilinganiso weDYNATOR:

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Uma kwenzekile wakhohlwa ukuphuza amaphilisi, waphuze ngokushesha amaphilisi akho emuva kokukhumbula ukuthi kumele uwaphuze. Ungalokothi uphuze **iDYNATOR** uma sekuphele amahora angaphezu kwe-12 kusukela esikhathini obekumele uphuze ngaso umthamosilinganiso wakho odlule. Linda futhi uphuze umthamosilinganiso olandelayo ngesikhathi esijwayelekile esibekiwe. Ungalokothi uphuze imithamosilinganiso yamaphilisi ephindwe kabili ngenhloso yokuvula isikhala semithamosilinganiso okhohliwe ukuyiphuza.

Imithelela ongahlangabezana nayo uma uyeka ukwelashwa ngeDYNATOR:

Kusemqoka ukuthi uqhubeke ulandele uhlelo lokwelashwa. Ungalokothi uyeke ukusebenzisa **iDYNATOR** ngaphandle uma udokotela wakho ekutshela ukuthi ukwenze lokho.

5. IMITHELELA ENGATHANDEKI OKUNGENZEKA IBE KHONA:

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

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

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

Konke lokhu kuyimithelela engathandeki ebucayi kakhulu futhi enobungozi. Uma unayo, kusho

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ukuthi kunokwenzeka ukuthi umzimba wakho awuzwananga neze ne**DYNATOR**. 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 ezinamandla engxenyeni yesisu engasenhla noma emhlane, isicanucanu kanye nokuhlaza njengoba lokhu kungenzeka kube wuphawu lokuba khona kwamatshe enyongweni yakho noma isifo samanyikwe esibizwa nge*pancreatitis*.
- Ubuthakathaka bemisipha, ubuhlungu obuzwakala endaweni ethile lapho ithintwa/icindezelwa noma izinhlungu, noma ubunzima uma unyakazisa izingalo zakho noma izinyawo futhi ikakhulukazi, uma ngesikhathi esifanayo, uzizwa ungaphilile emzimbeni futhi unezingakushisa eliphakeme kungenzeka ukuthi lokhu kubangelwa wukuwohloka okungajwayelekile kwemisipha yomzimba.
- Umfutho wegazi ophansi (ukuzizwa unesiyezi), izinhlungu esifubeni, ukushaya kwenhliziyo ngesigqi esingahambelani kahle noma ngokushesha.
- Ukuhuzuka kalula (*thrombocytopenia*).
- Ubuthakathaka emzimbeni, ukukhathala okukhulu, ukwehla emzimbeni, ikhanda elibuhlungu (okuyizimpawu zesifo esibizwa nge*vasculitis*).
- *Hepatitis* (isifo sokuvuvukala kwesibindi esibonakala ngezimpawu ezinjengobuhlungu esiswini nendawo ezungeze isisu noma ukukhukhumala kwesisu, umchamo omnyama kanye nendle enombala ophaphathekile noma umbala wobumba, ukukhathala okukhulu, imfiva, ukuluma komzimba wonke, ukuphelelwa wuthando lokudla, isicanucanu kanye nokuhlaza) kanye nejondisi (isifo sokuguquka kwesikhumba namehlo kube nombala ophuzi).

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- Ukukhohlwa, ukuguquka kwesimo sengqondo nomphefumulo, ukungakwazi ukuthatha izinqumo noma ukugxilisa ingqondo.
- I *Stevens-Johnson syndrome* (isifo sesikhumba esingambulala nokumbulala umuntu esihambisana nezimpawu ezinjengomqubuko obomvu ngokusabukhwebezane kanye namabhamuza).
- Ukuvuvukala kunoma iyiphi ingxenye yomzimba.
- Izinguquko ekusebenzeni kwezinsu kanye nokuchama, kubandakanya umthamo womchamo, ukuvamisa komchamo kanye nombala womchamo, igazi emchameni.
- Ukuquleka (*isyncope*).
- Ushukela wegazi ophansi (*ihypoglycaemia*), ushukela wegazi ophakeme (*ihyperglycaemia*).
- Ukukhubazeka kobuso, ukukhuphuka kwezinga lokungenwa yizifo.

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:

- Ukungafikelwa wubuthongo/ukungalali
- Isifo sokuvuvukala kontwentwesana kanye nezimbotshana zomoya ekhaleni (okubizwa nge*sinusitis*), umphimbo obuhlungu, ukopha emakhaleni.
- Ikhanda elibuhlungu.
- Izinhlungu noma ukuvuvukala kumajoyinti amakhulu namancane noma emahlombe, amathambo abuhlungu, ubuhlungu noma ukuvuvukala kwemisipha ehlanganisa izicubu zomzimba namathambo, ukugqabuka/ukuklebhuka kwemisipha ehlanganisa izicubu zomzimba namathambo, intamo elukhuni futhi ebuhlungu.

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UHLA LWEZINHLOBO ZEPHILISI IDYNATOR**

Imithelela engathandeki engavamile ukwenzeka:

- Amaphupho amabi.
- Isifo sohudo, ukuqunjelwa, ukugcwala komoya esiswini (umsuzo).
- Ukuzimuka (ukukhuluphala), isifo sokuzizacisa, ukukhula kothando lokudla.
- Amehlo afiphele.
- Ukukhala kwezihlonono ezindlebeni (okubizwa phecelezi ngetinnitus), ukungezwa ezindlebeni.
- Ukuqubuka esikhunjeni noma ezinye izinkinga zesikhumba, ezinjengokufikelwa wumuzwa wokushisa okuhambisana nokuguquka kwesikhumba sibe bomvu ngokombala, umqubuko obangelwa wukungezwani nokudla/nomuthi othile (phecelezi amahives), ukuluma, isikhumba esomile, i-eczema, izinduna namabala kanye nokuqothuka kwezinwele, nezifo zesikhumba ezibucayi kakhulu ezidala amabhamuza nokuxebuka kwesikhumba, umonakalo kumathishu omzimba.
- Ukukhukhumala kwezibele kubantu besilisa.
- Izimpawu ezinjengezomkhuhlane (ukuzwa amakhaza, ukuphefumula kanzima, isiyazi, imfiva, ikhanda elibuhlungu, ubuhlungu bemisipha yomzimba namathambo, ukukhathala okukhulu kanye nokuqhaqazela), umzimba obuthakathaka ngendlela engajwayelekile, ukungabi namandla.

Imithelela engathandeki okungaziwa ukuthi ivamise kangakanani ukwenzeka:

- I-anemiya, ukuvuvukala kwezindlala.
- Iperipheral neuropathy (isifo sokulimala kwezinzwa ezingaphandle komfunkulu, okuphazamisa ukusebenza ngendlela ejwayelekile kwamalunga omzimba kanye neminyakazo kanye/noma okuphazamisa umuzwa wezitho ezingaphandle komzimba, kubandakanya izingalo zakho kanye nemilenze).
- Amajaqamba, igawuthi, isifo samathambo.
- Ingcindezi yengqondo, ukozela.

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- Isicanucanu, ukuhlanza, ubuhlungu esiswini nendawo ezungeze isisu, isilungulela, indle emnyama ngokusatiyela.
- Isifuba somoya, ibhronkhayithisi, iphika, isifo samaphaphu nemigudu yokuphefumula (isifo sesifuba), ukutheleleka kokugula emphinjeni, ukucinana emakhaleni.
- Umuzwa onsonsothayo ezandleni, ezinyaweni noma ezindebeni (“*pins and needles*”).
- Ukuncipha kokusebenza kwezinzwa zokuthinta (ubundikindiki).
- Ikhanda elinkenkethayo, isiyezi, ukulahlekelwa wumuzwa wokunambitha, ukuphazamiseka komuzwa wokunambitha.
- Isifo sokungaboni kahle kwehlo elilodwa, amehlo omile, ukuphazamiseka kokubona, *iglaucoma* (ukukhula kwengcindezi ehlweni edala ukulahleka kancane kancane kokubona), ukopha ehlweni.
- Ukuzwela kwesikhumba ekukhanyeni (okubizwa phecelezi nge*photosensitivity*).
- Izigaxa ebeleni, ukopha ngendlela engajwayelekile kowesifazane osesikhathini.
- Izinkinga eziphathelele nokuya kahle ocansini.
- Ukukhathala okukhulu, imfiva, ukuzizwa ungaphathekile kahle noma ungaphilile kahle emzimbeni wonke.
- Ukulimala ngengozi.

Uma ubona noma iyiphi eminye imithelela engathandeki engabaliwe kuleli pheshana lolwazi, tshela udokotela wakho noma usokhemisi.

6. UKUGCINWA NOKUL AHLWA KWEDYNATOR:

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

Yivikele ekukhanyeni nomswakama.

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

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YIGCINE ENDAWENI EZINGAFINYELELI KUYONA IZINGANE.

Ungawasebenzisi amaphilisi emuva kosuku lokuphelelwa kwawo yisikhathi olubhalwe kwilebula noma esitsheni esiqukethe amaphilisi.

Yiphindisele emuva kusokhemisi wakho yonke imithi engasetshenziswanga. Ungalokothi ulahle imithi engasetshenziswanga ezinhlelweni zamapayipi okuchitha amanzi noma okuthutha indle (isibonelo, ezindlini zangasese).

7. UKWETHULWA KWEDYNATOR:

Amaphilisi i**DYNATOR** afakwe kwizingqwenjana ezingumsweswana eziyizigcinamaphilisi ezinombala osiliva, ezakhiwe nge-*aluminium* / i-*aluminium* eqinile eziqukethe amaphilisi ama-3 x 10 ngaphakathi kwebhokisana likakhadibhodi.

8. UKUHLONZWA KWEDYNATOR:

DYNATOR 10 mg:

Iyiphilisi elingumbhoshongo, eliqumbile nhlangothi zombili, elinongwengwezana olunombala omhlophe, ohlangothini olulodwa linomugqa onqamula phakathi kanti ngakolunye uhlangothi kubhalwe ikhodi ethi AT1.

DYNATOR 20 mg:

Iyiphilisi elingumbhoshongo, eliqumbile nhlangothi zombili, elinongwengwezana olunombala omhlophe, ohlangothini olulodwa linomugqa onqamula phakathi kanti ngakolunye uhlangothi kubhalwe ikhodi ethi AT2.

DYNATOR 40 mg:

Iyiphilisi elingumbhoshongo, eliqumbile nhlangothi zombili, elinongwengwezana olunombala omhlophe, ohlangothini olulodwa linomugqa onqamula phakathi kanti ngakolunye uhlangothi kubhalwe ikhodi ethi AT4.

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DYNATOR 80 mg:

Ingamaphilisi amise okukanxande, aqumbile nhlangothi zombili, anongwengwezana olunombala omhlophe, ohlangothini olulodwa anomugqa onqamula phakathi kanti ngakolunye uhlangothi kubhalwe ikhodi ethi AT8.

9. IZINAMBA ZOKUBHALISWA:

DYNATOR 10 mg: A43/7.5/0167

DYNATOR 20 mg: A43/7.5/0168

DYNATOR 40 mg: A43/7.5/0169

DYNATOR 80 mg: A43/7.5/0170

10. IGAMA, IKHELI LENKAMPANI KANYE NENAMBA YOCINGO YOMNIKAZI WESITIFIKETI

SOKUBHALISWA:

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake

Cape Town

7945

South Africa

Inamba yocingo: + 27 21 707 7000

11. USUKU LOKUSHICILELWA:

Usuku lokubhaliswa: 07 Zibandlela 2012

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

Usuku lokugunyazwa kwakamuva: 02 Nhlangukana 2017

NAMIBIA

DYNATOR 10 mg: NAM NS2 13/7.5/0111

DYNATOR 20 mg: NAM NS2 13/7.5/0112

DYNATOR 40 mg: NAM NS2 13/7.5/0113

DYNATOR 80 mg: NAM NS2 13/7.5/0114