

**IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI
UHLA LWEZINHLOBO ZAMAPHILISI IDYNACEF**

ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI:

S4

DYNACEF 100 mg iphilisi elinongwengwezana

DYNACEF 200 mg iphilisi elinongwengwezana

Cefpodoxime

“Liqukethe ushukela”, *ilactose monohydrate*, ongama-9 mg kuDYNACEF 100 mg kanye nama-18 mg kuDYNACEF 200 mg.

Ngaphambi kokuba uqale ukusebenzisa iDYNACEF 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.
- IDYNACEF iqondene nawe kuphela futhi inikezwe wena, ngakho-ke ungalokothi wabelane ngayo nabanye abantu. Kungenzeka bona ibalimaze, nakuba nabo benezimpawu ezifana nezakho.

Okuqukethwe kuleli phashana lolwazi

1. Iyini iDYNACEF futhi isetshenziselwani?
2. Okumele ukwazi ngaphambi kokuba usebenzise iDYNACEF
3. Indlela yokusebenzisa iDYNACEF
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5. Indlela yokugcina iDYNACEF
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1. Iyini iDYNACEF futhi isetshenziselwani?

IDYNACEF iqukethe *icefpodoxime proxetil* futhi iyingxenye yeqoqwana lemithi engama-antibhayothikhi eyaziwa ngamacephalosporins.

Amaphilisi iDYNACEF asetshenziswa kubantu abadala ukwelapha izifo ezihlukahlukene ezibangwa ngamabhakhthiriya ezihlasela amathansela, umphimbo (*ipharyngitis*), amaphaphu (ibhronkhayithisi, inyumoniya) kanye nezimbotshana zamasayinasi.

2. Okumele ukwazi ngaphambi kokuba usebenzise iDYNACEF

Ungalokothi uthathe iDYNACEF:

- uma umzimba wakho ungezwani nezithako *icefpodoxime*, ama-antibhayothikhi *icephalosporin*, nephenisilini noma uma ungezwani nanoma yisiphi esinye isithako seDYNACEF (bheka isigaba 6)
- uma ukhulelwe noma usancelisa umntwana wakho

Izixwayiso kanye nezinto okumele uziqikelele

Qaphela kakhulu:

- uma umzimba wakho ungezwani nama-antibhayothikhi athile. Tshela udokotela wakho mayelana nazo zonke izigameko ezenzekile kuwena phambilini zokungezwani komzimba wakho nokuthile, ikakhulukazi imithi.
- uma umzimba wakho ungezwani nama-antibhayothikhi ephenisilini, njengoba kungenzeka akhule amathuba okuthi umzimba wakho ungezwani namacephalosporins (kubandakanya neDYNACEF) ngokunjalo.
- uma uhlaselwa wuhudo, ikakhulukazi uhudo olunamandla futhi/noma olubeleselayo olulokhu luqhubeke njalo, olukuphatha ngenkathi welashwa ngeDYNACEF noma lukuphathe emavikini okuqala kulandela ukwelashwa ngeDYNACEF. Lokhu kungaba

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wuphawu lwesifo esibucayi esibizwa nge*pseudomembranous colitis* (isifo sokuvuvukala kukapopopo esibangelwa ibhakhthiriya *iClostridium difficile*).

- uma unezinkinga zezinso (kungadingeka ukuthi kuguqulwe umthamosilinganiso onikezwa wona).
- uma ususebenzise iDYNACEF isikhathi esingaphezu kwezinsuku eziyi-10, udokotela wakho kungenzeka afune ukwenza ukuhlolwa kwegazi njalo futhi ngokuqhubekayo.
- uma uzokwenza ukuhlolwa kwegazi noma komchamo okuthile njengoba iDYNACEF kunokwenzeka iphazamise imiphumela.

Ukusetshenziswa kweminye imithi neDYNACEF

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

Imithi ethile kungenzeka iguqule indlela esebenza ngayo iDYNACEF emzimbeni kanti nayo ngokwayo ingaguqula ukusebenza kweminye imithi emzimbeni. Kulezi zimo, kungenzeka kudingeke ukuthi kuguqulwe umthamosilinganiso noma kumiswe ukwelashwa ngomunye waleyo mithi.

Imithi okungenzeka iguqule ukusebenza kweDYNACEF yilena elandelayo:

- imithi esetshenziselwa ukwelapha izilonda esiswini njenge*ranitidine* kanye nemithi yokuqeda i-asidi esiswini, phecelezi ama-*antacids* (esetshenziselwa ukwelapha inkinga edalwa ukungagayeki kahle kokudla esiswini) kungenzeka ibambezele indlela esebenza ngayo iDYNACEF
- *iprobenecid* (esetshenziselwa ukwelapha isifo igawuthi) kungenzeka ikhuphule amazinga eDYNACEF egazini futhi okungakhuphula amathuba okuhlaselwa imithelela

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engathandeki

- ama-antibhayothikhi e-*aminoglycoside* (isibonelo, *igentamicin*) (asetshenziselwa ukwelapha ukutheleleka ngamagciwane abanga izifo) kungenzeka abe nomthelela kwindlela ezisebenza ngayo izinso zakho
- ama-*diuretics* athile (phecelezi ama-*water tablets* isibonelo *ifurosemide*) asetshenziselwa ukukhuphula umthamo womchamo owuchamayo, kungenzeka abe nomthelela ekusebenzeni kwezinsu zakho
- ama-*anticoagulants* njenge-*warfarin* (asetshenziselwa ukuvimbela ukushuba kwegazi kanye namahlule) kungenzeka akhuphule ubungozi bokopha
- amaphilisi okuvimbela inzalo (okungamaphilisi okuvimbela inzalo aphuzwayo) kungenzeka angasebenzi kahle

Ukuphuza iDYNACEF nokudla kanye nophuzo:

IDYNACEF kumele iphuzwe emuva kokudla.

Ukukhulelwa kanye nokuncelisa

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 iDYNACEF.

Akuqinisekiswa ukuphepha kwamaphilisi kwabesifazane abakhulelwe.

Kumele ungancelisi noma-ke ungayisebenzisi iDYNACEF uma ungumama osancelisa umntwana wakhe. Lokhu kungenxa yokuthi kunomthamo omncane weDYNACEF okungenzeka ungene obisini lukamama. Lokhu kuyinto engaba nobungozi kumntwana wakho.

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Ukushayela kanye nokusebenzisa imishini

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

IDYNACEF 100 mg kanye ne-200 mg iqukethe uhlobo lukashukela wobisi olubizwa nge*lactose*.

Uma uke watshelwa ngudokotela wakho ukuthi umzimba wakho uyahluleka ukubekezelela izinhlobo ezithile zikashukela, xhumana nodokotela wakho ngaphambi kokusebenzisa la maphilisi okwelapha.

IDYNACEF iqukethe ushukela wobisi ongaba nomthelela ekulawulekeni koshukela egazini lakho uma ungumuntu onesifo sikashukela.

3. Isetshenziswa kanjani iDYNACEF

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

Kumele njalo iDYNACEF uyiphuze ncimishi ngendlela akuyalele ngayo udokotela wakho.

Kumele ubuze udokotela wakho noma usokhemisi uma ungaqinisekile.

Umthamosilinganiso weDYNACEF uzokwehluka ngokwesiguli nesiguli ngasinye ngisho izimpawu zezinye iziguli zifana nezakho.

Umthamosilinganiso kungenzeka uncike kulezi zimo ezilandelayo:

- isizathu sokusetshenziswa komuthi
- ezinye izifo ezikuphethe
- ekutheni ikhona yini eminye imithi oyisebenzisayo

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Uma unenkinga yesifo sezinso, uzothola umthamosilinganiso ophansi kunalowo ojwayelekile onikezwa umuntu omdala. Udokotela wakho uzothatha isinqumo maqondana nomthamosilinganiso ofanelekile azokunikeza wona emuva kokuba esekuxilongile futhi wabukisisa isimo sakho.

Udokotela wakho uzokutshela ukuthi kuzothatha isikhathi eside kangakanani ukwelashwa kwakho ngeDYNACEF. Ungalokothi uyeke ukudla amaphilisi akho ngaphambi kwesikhathi ngoba isifo kungenzeka siphinde sibuye futhi noma sidlondlobale kakhulu.

Uma ubona sengathi iDYNACEF inamandla ngokweqile noma-ke sengathi ayinawo neze amandla, tshela udokotela wakho noma usokhemisi.

Uma uphuze iDYNACEF engaphezulu kwaleyo okumele uyiphuze:

Izimpawu zomthamosilinganiso wamaphilisi oweqile kungenzeka zibandakanye lokhu:

Ukudlikiza komzimba ngendlela engalawuleki/amafithi kanye nokungasebenzi kahle kobuchopho (ikakhulukazi ezigulini ezinesifo sezinso). Lezi zimpawu zizonyamalala uma esenciphile amazinga omuthi emzimbeni wakho.

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

Uma kwenzeka ukhohlwa ukuphuza umthamosilinganiso weDYNACEF

Uma kwenzeka ukhohlwa ukuphuza umthamosilinganiso weDYNACEF, waphuze ngokushesha amaphilisi akho emuva kokukhumbula ukuthi kumele uwaphuze, bese emuva kwalokho uqhubeka nokuphuza iDYNACEF ngesikhathi esijwayelekile. Ungalokothi uphuze

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imithamosilinganiso yamaphilisi ephindwe kabili ngenhloso yokuvala isikhala semithamosilinganiso okhohliwe ukuyiphuza.

Uma uyeka ukusebenzisa iDYNACEF

Kusemqoka ukuthi uqhubeke nokuphuza amaphilisi akho ngisho usuzizwa usungcono emzimbeni emuva kwezinsuku ezimbadlwana. Lokhu kungenxa yokuthi uma uwayeka kungenzeka ukuthi sibuye isifo esikuphethwe noma-ke sidlondlobale kakhulu.

4. Imithelela engathandeki okungenzeka ibe khona

IDYNACEF kungenzeka ibe nemithelela engathandeki emzimbeni.

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

Uma kwenzeka noma yikuphi kulokhu okulandelayo, yeka ukusebenzisa iDYNACEF 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, ukuthuthumela komzimba (okungaba inhliziyo eshaya ngamandla, ukuphefumula ngendlela engajwayelekile noma izandla ezijulukile)
- ukuluma kakhulu kwesikhumba (okuhambisana nokumila kwamaqhubu amakhulu emzimbeni)

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- isifo esibucayi sokutheleleka ngamagciwane kolwelwesana lomgudu wendle, esibonakala ngohudo, imfiva kanye nezinhlungu esiswini

Konke lokhu kuyimithelela engathandeki ebucayi kakhulu futhi enobungozi. Uma unayo le mithethelela, kusho ukuthi kunokwenzeka ukuthi umzimba wakho awuzwananga neze neDYNACEF. 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:

- izimpawu ezinjengezomkhuhlane ezihambisana nokuqubuka okubuhlungu okusabalalayo okunombala obomvu noma osabukhwebezane (*purplish*) kanye namabhamuza (*Stevens-Johnson syndrome*)
- ukuqubuka okubi kakhulu okunamabhamuza lapho ungewengezi lwesikhumba kungenzeka luxebuke lushiye izingxenywe ezinkulu zenyama engambozekile emzimbeni, okuhambisana nokuzizwa ungaphilile neze emzimbeni wonke, nemfiva, nokuzwa amakhaza kanye nemisipha nezicubu zomzimba ezibuhlungu (okubizwa phecelezi nge *Toxic epidermal necrolysis*)
- unokuqubuka kwesikhumba noma izilonda esikhunjeni, okuyindilinga enombala ophinki/obomvu ephaphathekile phakathi nendawo okungenzeka kulume, kube nezimpephelezi noma kugcwale uketshezi ngaphakathi – ikakhulukazi ezintendeni zesandla noma ngaphansi kwezinyawo zakho (okuyi-aleji yesikhumba ebucayi kakhulu ebizwa nge-*erythema multiforme*)
- ukudlikiza komzimba ngendlela engalawuleki (amafithi), ukuquleka, ukudlikizela, itwetwe nexhala, uzizwe unesiyezi futhi uzwe sengathi uzoquleka

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- izinkinga zesibindi (izimpawu zesifo esibonakala ngesikhumba esinombala ophuzi kanye namehlo anombala ophuzi (ijondisi) kanye nezinhlungu engxenyeni yesisu engasenhla ngakwesokudla), indle ephaphathekile ngokombala, umchamo onombala omnyama
- izinkinga zezinso (ukuphuma komchamo omningi kunalokho okujwayelekile kuwena lapho uchama noma ukwenzeka kwalokhu njalo)

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:

- ukutheleleka okubangelwa wukhunta (*fungal infections*) okunjengenkwehu yomlomo noma inkwehu yesitho sangasese sowesifazane
- ukutheleleka ngokuphindelela (ukusuleleka ngesifo sesibili ngaphezu kwesifo sokuqala esikhona esibangelwa ngamanye amabhakhthiriya noma okuthile okunamandla okuvimbela ukusebenza kweDYNACEF)
- ukutheleleka ngezifo kalula kunokwejwayelekile. Lokhu kungabangelwa yinkinga ephathelene negazi. Kunokwenzeka lokhu uma sekunesikhathi eside usebenzisa lo muthi
- isifo sohudo, isicanucanu, ukuhlanza, izinhlungu esiswini
- ukuphelelwa wuthando lokudla

Imithelela engathandeki engavamile ukwenzeka:

- imiphumela yokuhlolwa kwegazi ebonisa okungajwayelekile kubandakanya ne-anemiya
- ikhanda elibuhlungu, ukuphathwa isiyenzi, umuzwa ohlabayo osanalithi obizwa ngamapins and needles, ubundikindiki, noma umuzwa onsonsothayo

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- *ihepatitis* (ukuvuvukala kwesibindi okuhambisana nezimpawu ezinjengesicanucanu, imfiva engenawo kakhulu amandla, izinhlungu esiswini nendawo ezungeze isisu), imiphumela yokuhlolwa kwesibindi ebonisa okungajwayelekile
- ukuvuvukala kwamanyikwe (ubuhlungu engxenyeni yesisu engasenhla obusabalalayo buze buyofinyelela emhlane, isisu esikhukhumele futhi esinezindawo ezibuhlungu lapho usithinta noma usicindezela, isicanucanu, ukuhlanza, imfiva kanye nenhliziyo eshaya ngamandla)
- inkinga yokungagayeki kahle kokudla, isisu esiqumbile, ukuqunjelwa (ukugcwala komoya esiswini), indle enegazi
- ukukhala kwezihlonono ezindlebeni, ukungezwa ezindlebeni
- ukukhathala okukhulu, ukuzizwa ungaphathekile kahle emzimbeni wonkana, ukugula, noma uzwe kunokuthile okungalungile emzimbeni okwenza ungakhululeki neze kahle

Le mitholela elandelayo ibikiwe kodwa-ke akwaziwa ukuthi ivamise kangakanani ukwenzeka:

- ukukhathala ngendlela engajwayelekile, ukungabi namandla noma ubuthakathaka emzimbeni

Uma ubona noma iyiphi eminye imitholela engathandeki engabhaliwe kuleli pheshana lolwazi, tshela udokotela wakho noma usokhemisi.

Ukubika imitholela engathandeki

Uma uphathwa yimitholela engathandeki, khuluma nodokotela wakho, usokhemisi noma umhlengikazi. Futhi ungayibika imitholela engathandeki kwabakwaSAHPRA ngohlelo xhumano lwe-inthanethi ukubazisa ngokuphatheka kabi okubangelwa wumuthi othile, ngokulandela lelinki elandelayo: <https://www.sahpra.org.za/Publications/Index/8>.

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

5. Indlela yokugcina iDYNACEF

Yonke imithi kumele uyigcine endaweni ezingafinyeleli kuyona izingane.

IDYNACEF 100 mg kanye ne-Dynacef 200 mg:

Amaphilisi wagcine ezingeni lokushisa elingama-25 °C noma ngaphansi kwalokho, uwavikele ekukhanyeni nomswakama.

Amaphilisi wagcine kwiphakeshana afike nalo.

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 yiDYNACEF

Isithako sokwelapha esiyinhloko esiqukethwe lapha yicefpodoxime.

DYNACEF 100 mg:

Iphilisi ngalinye elinongwengwezana liqukethe *icefpodoxime proxetil* elingana necef engama-100 mg. Iphilisi ngalinye elingama-100 mg liqukethe ushukela (*ilactose monohydrate* engama-9 mg ephilisini ngalinye).

DYNACEF 200 mg:

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Iphilisi ngalinye elinongwengwezana liqukethe *icefpodoxime proxetil* elingana ne*cefpodoxime* engama-200 mg. Iphilisi ngalinye elingama-200 mg liqukethe ushukela (*ilactose monohydrate* engama-18 mg ephilisini ngalinye).

7. Ezinye izithako:

IDynacef -100 mg kanye ne-200 mg:

Engxenyeni engaphakathi yephilisi kunalokhu:

Carmellose calcium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, sodium lauryl sulphate

Ungwengwezana olungaphandle:

Ungwengwezana olumhlophe (*Opadry White*) (olunikeza iphilisi umbala) 03A28718

olubandakanya lokhu:

Hypromellose (E464), titanium dioxide (E171) kanye netafc (E553b).

8. Indlela ebukeka ngayo iDYNACEF kanye nalokho okuqukethwe ephaketheni layo

DYNACEF 100 mg: Ingamaphilisi anongwengwezana olunombala omhlophe kuya kumbala omhlophe ngokusampunga noma ngokusaphuzi, ayindingilizi futhi aqumbile kancane nhlangothi zombili, ohlangothiini olulodwa anombhalo oqoshiwe ongunombolo "100" kanti ngakolunye uhlangothi akubhaliwe lutho.

DYNACEF 200 mg: Ingamaphilisi anongwengwezana olunombala omhlophe kuya kumbala omhlophe ngokusampunga noma ngokusaphuzi, ayindingilizi futhi aqumbile kancane nhlangothi zombili, ohlangothiini olulodwa anombhalo oqoshiwe ongunombolo "200" kanti ngakolunye uhlangothi akubhaliwe lutho.

IDYNACEF ipakishwe ngendlela elandelayo:

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DYNACEF 100 mg:

Itholakala kuqwenjana oluyisigcinimaphilisi olulodwa lwesiliva olwakhiwe nge-*aluminium*/isimbozo sefoyela le-*aluminium* oluqukethe amaphilisi ayi-10 akwibhokisana elinombhalo ngaphandle.

DYNACEF 200 mg: Itholakala kuqwenjana olulodwa noma ezimbili eziyizigcinamaphilisi zesiliva ezakhiwe nge-*aluminium*/ isimbozo sefoyela le-*aluminium* oluqukethe amaphilisi ayi-10 noma angama-20 akwibhokisana elinombhalo ngaphandle.

Akubona bonke osayizi bephakethe abathengiswayo ezindaweni okuthengiswa kuzona imithi.

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: + 27 21 707 7000

www.pharmadynamics.co.za

10. Leli pheshana lolwazi lagcina ukubuyezwa mhla zingama-

28 kuNdasa 2022

11. Inamba yokubhaliswa

DYNACEF 100 mg: A44/20.1.1/0012

DYNACEF 200 mg: 48/20.1.1/0583

**IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI
UHLA LWEZINHLOBO ZAMAPHILISI IDYNACEF**

DYNACEF 100 mg:

NAM: 12/20.1.1/0058

MOZ: J5227