

**IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI
DYNACEF SUSPENSION**

ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI

S4

DYNACEF SUSPENSION (impushana yokwenza umuthi owuketshezi ophuzwayo)

Cefpodoxime proxetil

IDYNACEF SUSPENSION iqukethe ushukela (isucrose, okusho ushukela wezitshalo, ongama-2464,67 mg kumthamo ngamunye ongama-5 mL). Iqukethe i-*aspartame* engama-20 mg/5 ml.

Ngaphambi kokuba uqale ukusebenzisa iDYNACEF SUSPENSION 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.
- IDYNACEF SUSPENSION 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 iDYNACEF SUSPENSION futhi isetshenziselwani?
2. Okumele ukwazi ngaphambi kokuba usebenzise iDYNACEF SUSPENSION
3. Indlela yokusebenzisa iDYNACEF SUSPENSION
4. Imithelela engathandeki okungenzeka ibe khona
5. Indlela yokugcina iDYNACEF SUSPENSION
6. Okuqukethwe ephaketheni lomuthi kanye nolunye ulwazi

1. Iyini iDYNACEF SUSPENSION futhi isetshenziselwani?

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IDYNACEF SUSPENSION iyingxenye yeqoqwana lemithi engama-antibhayothikhi eyaziwa ngamacephalosporins.

IDYNACEF SUSPENSION isetshenziselwa ukwelapha:

- Ukutheleleka ngokugula endlebeni
- Isifo samathansela, ukutheleleka ngokugula emphinjeni (*ipharyngitis*)
- Inyumoniya

2. Okumele ukwazi ngaphambi kokuba usebenzise iDYNACEF SUSPENSION

Ungalokothi usebenzise iDYNACEF SUSPENSION:

- uma umzimba wengane yakho ungezwani namanye ama-antibhayothikhi ohlobo lwecephalosporin, iphenisilini, nanoma yimaphi amanye ama-antibhayothikhi ayingxenye yeqoqwana lama-antibhayothikhi ohlobo lwebeta-lactam noma ezinye izithako zeDYNACEF SUSPENSION (bheka isigaba 6)
- IDYNACEF SUSPENSION akumele inikezwe izingane ezinesifo *iphenylketonuria* (okuyisifo sofuzo esiyivelakancane esidala ukuthi ama-amino acid abizwa ngephenylalanine anqwabelane emzimbeni wakho) njengoba le ngxubemakhambi iqukethe i-aspartame
- uma ingane yakho ingaphansi konyaka owodwa ubudala.

Izixwayiso kanye nezinto okumele uziqikelele

Qaphela kakhulu uma usebenzisa iDYNA SUSPENSION:

- IDYNACEF SUSPENSION kumele isetshenziswe ngokucophelela okukhulu ezigulini ezinemizimba evamise ukungezwani nemithi ethile. Tshela udokotela wakho mayelana nazo zonke izigameko okunokwenzeka ukuthi zenzekile enganeni yakho ngaphambilini zokungezwani komzimba wayo nokuthile, ikakhulukazi imithi.
- kumele uqaphele uma ingane yakho inomzimba ongezwani nama-antibhayothikhi ephenisilini njengoba emakhulu amathuba okuthi ngokunjalo futhi umzimba wayo ungezwani

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namacephalospirins (kubandakanya neDYNACEF SUSPENSION)

- uma ingane yakho iphethwe noma yake yaphathwa yisifo esibizwa nge*colitis* (ukuvuvukala kukapopopo okuhambisana nobuhlungu esiswini nendawo ezungezile, uhudo kanye nemfiva) noma uma ingane yakho iphathwa yisifo sohudo ngenkathi isebenzisa iDYNACEF SUSPENSION. Lokhu kungenzeka kube yinkomba yesifo sokuvuvukala kukapopopo (*colitis*). Bonisana nodokotela wakho ngokushesha.
- uma ingane yakho inezinkinga zezinso (kungadingeka ukuthi uguqulwe umthamosilinganiso enikezwa wona).
- uma ingane yakho izokwenza ukuhlolwa kwegazi noma komchamo okuthile, njengoba iDYNACEF SUSPENSION kunokwenzeka iphazamise imiphumela.
- uma ingane yakho iphathwa yizimpawu ezinjengokudlikiza komzimba okungalawuleki, ukudideka, izinkinga zokuhlala iphapheme futhi ibone konke okwenzekayo noma uma ineminyakazo exakile futhi engajwayelekile (okwenzeka ikakhulukazi ezinganeni ezinezinkinga zezinso noma kulezo eziphuziswe imithi engaphezulu kwaleyo eziyidingayo), xhumana nodokotela wakho noma umhlinzeki wosizo lwezempilo nokwelashwa ngokushesha

Ukusetshenziswa kweminye imithi neDYNACEF SUSPENSION

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

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

IDYNACEF SUSPENSION isebenza kangcono uma iphuzwa nokudla.

Imithi okungenzeka iguqule ukusebenza kweDYNACEF SUSPENSION yilena elandelayo:

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- imithi esetshenziselwa ukwelapha izilonda esiswini njenge*ranitidine* noma *icimetidine* kanye nemithi yokuqeda i-esidi esiswini, phecelezi ama-*antacids* (esetshenziselwa ukwelapha inkinga edalwa wukungagayeki kahle kokudla esiswini enjenge-*aluminium hydroxide*, *sodium bicarbonate*) kungenzeka ibambezele indlela esebenza ngayo iDYNACEF SUSPENSION
- *ipentagastrin* (umuthi osetshenziselwa ukukhuthaza ukukhishwa kwe-esidi esiswini) kungenzeka ikhulise amandla okusebenza eDYNACEF SUSPENSION
- *iprobenecid* (esetshenziselwa ukwelapha isifo igawuthi) kungenzeka ikhuphule amazinga eDYNACEF SUSPENSION egazini futhi okungakhuphula amathuba okuhlaselwa yimithelela engathandeki
- ama-*anticoagulants* anjenge*warfarin* (asetshenziselwa ukuvimbela ukushuba kwegazi liphenduke amahlule) kungenzeka akhuphule ubungozi bokopha
- qinisekisa ukuthi udokotela wakho uyazi ukuthi ingane yakho isebenzisa iDYNACEF SUSPENSION uma kuzodingeka ukuthi enze noma yikuphi ukuhlolwa (okungaba okwegazi, okomchamo noma okokuhlonza isifo esithile), njengoba lo muthi kungenzeka uphazamise imiphumela yokuhlolwa
- ama-*diuretics* athile (phecelezi ama*water tablets* isibonelo *ifurosemide*) asetshenziselwa ukukhuphula umthamo womchamo owuchamayo, kungenzeka abe nomthelela ekusebenzeni kwezinsu zakho
- ama-antibhayothikhi i-*aminoglycoside* (isibonelo, *gentamicin*) (asetshenziselwa ukwelapha ukutheleleka ngamagciwane abanga izifo) kungenzeka abe nomthelela kwindlela ezisebenza ngayo izinsu zakho
- njengoba ama-*anti-coagulants* kungenzeka akhuphule ubungozi bokopha, udokotela wakho kungenzeka afune ukubhekisisa njalo futhi ngokuqhubekayo isilinganiso esiphakeme sesikhathi esithathwa yigazi ukuthi liphenduke libe ngamahlule ngenkathi ingane yakho isebenzisa iDYNACEF SUSPENSION.

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Ukuphuza iDYNACEF SUSPENSION nokudla kanye nophuzo:

IDYNACEF SUSPENSION kumele iphuzwe emuva kokudla.

Ukukhulelwa, ukuncelisa kanye nokuba sesimweni sokuzala nokuthola abantwana

Lokhu akuqondene nezingane.

Ukushayela kanye nokusebenzisa imishini:

Lokhu akuqondene nezingane.

Ulwazi olubalulekile mayelana nezinye zezithako zeDYNACEF SUSPENSION:

IDYNACEF SUSPENSION iqukethe i-*aspartame* (20 mg/5 mL), kanye noshukela wezitshalo.

IDYNACEF SUSPENSION akumele isetshenziswe yiziguli ezinesifo i-*phenylketonuria* njengoba omunye wemikhiqizo yayo yezinqubo zamakhemikhali ezeseka impilo (*metabolic products*) kuyi-*phenylalanine* (bheka isigatshana esithi Ungalokothi usebenzise iDYNACEF SUSPENSION).

IDYNACEF SUSPENSION akumele inikezwe iziguli ezinomlando wokuhluleka kwemizimba yazo ukugaya ushukela wezitshalo noma isifo sofuzo sokuhluleka komzimba ukugaya izinhlobo ezithile zikashukela, phecelezi, i-*hereditary sucrose-isomaltase deficiency*.

3. Isetshenziswa kanjani iDYNACEF SUSPENSION

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

Izingane:

Umthamosilinganiso ojwayelekile ngama-8 mg/kg/day onikezwa njengemithamosilinganiso emibili

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njalo emuva kwamahora ayi-12, ophuzwa nokudla. Udokotela uzowuguqula ngendlela efanele umthamosilinganiso ukuze uhambelane nesisindo sengane.

Lokhu okulandelayo kungasetshenziswa njengomhlahlandlela womthamosilinganiso:

- Ezinganeni ezinesisindo esiphakathi kwama-10 kg nama-15 kg umthamosilinganiso ngama-5 mL njalo emuva kwamahora ayi-12.
- Ezinganeni ezinesisindo esingama-15 kg noma ngaphezulu umthamosilinganiso ngama-10 mL njalo emuva kwamahora ayi-12.

Lixukuze ibhodlela ngaphambi kokulisebenzisa. Maqondana nemiyalelo yokuxuba umuthi, bheka isigaba 6.

Izinkinga zezinso:

Uma ingane yakho inenkinga yesifo sezinso, izothola umthamosilinganiso ongaphansi kwalowo ojwayelekile. Udokotela wakho uzothatha isinqumo maqondana nomthamosilinganiso ofanelekile, ngokubuka isimo sayo.

IDYNACEF SUSPENSION akumele inikezwe izingane ezinesifo *iphenylketonuria*, njengoba le ngxubemakhambi iqukethe i-*aspartame* (bheka isigatshana esithi Ungalokothi usebenzise iDYNACEF SUSPENSION).

IDYNACEF SUSPENSION akumele inikezwe izingane ezingaphansi konyaka ubudala njengoba okwamanje kungakaqinisekiswa ukuphepha kwayo ezinganeni ezingako.

Udokotela wakho uzokutshela ukuthi kuzothatha isikhathi eside kangakanani ukwelashwa kwengane yakho ngeDYNACEF SUSPENSION. Uma ubona sengathi iDYNACEF SUSPENSION inamandla ngokweqile noma sengathi ayinawo neze amandla, tshela udokotela wakho noma usokhemisi.

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Uma ingane iphuziswe iDYNACEF SUSPENSION engaphezulu kwaleyo okumele iyiphuze, kumele wenze lokhu:

Uma kwenzekile ingane yakho yaphuza umthamosilinganiso oweqile, bonana nodokotela wakho noma usokhemisi. Uma uhluleka ukuthola omunye walaba, xhumana nesibhedlela esiseduze nawe noma isikhungo esilawula ubuthi/ushevu.

Ngenkathi uyobonana nodokotela, phatha leli pheshana lolwazi kanye nanoma yisiphi isiceke somuthi osele ukuze azi ukuthi yimiphi imithi ephuzwe yingane yakho.

Izimpawu zomthamosilinganiso oweqile kungenzeka zibandakanye lokhu:

- noma yiziphi izimpawu kulezo ezichazwe ngaphansi kweMithelela Engathandeki kubandakanya ubuthi ohlelweni lwezinzwa zomzimba olubandakanya ubuchopho nomfunkulu (*spinal cord*) (okubonakala ngezimpawu ezibandakanya itwetwe nexhala, isiyenzi, umlomo ondikindiki, inzululwane, ukukhala kwemisindo noma izihlonono ezindlebeni kanye nokudlikizela) kanye nezinkinga eziphathelene nokusebenza kobuchopho (ezibonakala ngezimpawu ezinjengokukhohlwa, ukuguquka kwendlela oziphatha ngayo nocabanga ngayo futhi owenza ngayo izinto, ukudlikiza komzimba ngendlela engalawuleki kanye nokudikiza kwemisipha yomzimba)

Uma kwenzeka ukhohlwa ukuphuza iDYNACEF SUSPENSION

Uma kwenzekile wakhohlwa ukuphuzisa ingane yakho iDYNACEF SUSPENSION, yiphuzise ngokushesha emuva kokukhumbula, ngalo usuku lolo. Uma ungayiphuzisanga ingane yakho umuthi ngosuku lolo, yiphuzise umthamosilinganiso ojwayelekile ngosuku olulandelayo. Ungalokothi uphuzise ingane yakho imithamosilinganiso ephindwe kabili ngenhloso yokuvala isikhala semithamosilinganiso okhohliwe ukuyiphuzisa yona.

Uma uyeka ukusebenzisa iDYNACEF SUSPENSION

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Kusemqoka ukuthi uqhubeke nokuphuzisa ingane yakho umuthi ngisho seyiqala ukuzizwa isingcono emzimbeni ngemuva kwezinsuku ezimbadlwana.

4. Imithelela engathandeki okungenzeka ibe khona

IDYNACEF SUSPENSION kungenzeka ibe nemithelela engathandeki emzimbeni.

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

Uma kwenzeka noma yikuphi kulokhu okulandelayo, yeka ukusebenzisa iDYNACEF SUSPENSION 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 inhliziyi eshaya ngamandla, ukuphefumula ngendlela engajwayelekile noma izandla ezijulukile)
- ukuqubuka noma isikhumba esilumayo
- ukuquleka

Konke lokhu kuyimithelela engathandeki ebucayi kakhulu futhi enobungozi. Uma ingane yakho inayo le mithelela, kusho ukuthi kunokwenzeka ukuthi umzimba wayo awuzwananga neze neDYNACEF SUSPENSION eyiphuzile. Kungenzeka ukuthi ingane yakho idinge usizo lokwelashwa oluphuthumayo noma ukulaliswa esibhedlela.

Tshela udokotela wakho ngokushesha noma uphuthume emnyangweni wezimo eziphuthumayo esibhedlela esiseduze nawe uma ubona okunye kwalokhu okulandelayo:

- *Hepatitis* (ukuvuvukala kwesibindi) kanye nezinye izinkinga zesibindi kubandakanya nejondisi (izimpawu zayo zingabandakanya: isicanucanu, ukuhlanza, izinhlungu esiswini, ukuphelelwa

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wuthando lokudla, ukukhathala, ukujika kwesikhumba noma izingxenye ezimhlophe zamehlo kube nombala ophuzi, umchamo omnyama), ukulimala kwesibindi, ukwanda kwezikhuthazalushintsho (*enzymes*) zesibindi.

- Isifo esinamandla futhi esibucayi sokutheleleka ngamagciwane kontwentwesana lomgudu wendle, esibonakala ngohudo, imfiva kanye nezinhlungu esiswini nendawo ezungezile. Lokhu kungenzeka kube yisifo esibizwa nge-'*Pseudomembranous colitis*', indle enegazi.
- Ukuvela kwamabhamuza esikhunjeni, ukuxebuka noma ukopha kwanoma iyiphi ingxenye yesikhumba sakho okungenzeka kuhambisane nomqubuko noma kungabi nomqubuko (kubandakanya izindebe, amehlo, umlomo, ikhala, izitho zangasese, izandla noma izinyawo), izimpawu ezinjengezomkhuhlane (imfiva, ukuzwa amakhaza, noma imisipha yomzimba enkenkethayo) okuyizimpawu zenkinga ebucayi yokungezwani kwesikhumba nomuthi osetshenzisiwe (i*Steven Johnson Syndrome* noma i*toxic epidermal necrolysis* (ebizwa nge*TEM*)) okuyisifo esingambulala nokumbulala umuntu.
- Ukuqubuka esikhunjeni noma izilonda esikhunjeni eziyindilinga enombala ophinki/obomvu futhi esiphaphathekile phakathi nendawo okungenzeka silume, sibe nezimpephelezi noma sigcwale uketshezi ngaphakathi. Umqubuko okungenzeka uvele ikakhulukazi ezintendeni zesandla noma ngaphansi kwezinyawo zakho. Lokhu kungenzeka kube yizimpawu ze-aleji yesikhumba ebucayi kakhulu ebizwa nge-'*erythema multiforme*'.
- I*pancreatitis* (isifo sokuvuvukala kwamanyikwe) (izimpawu zaso zingabandakanya ubuhlungu engxenyeni yesisu engasenhla obusabalalayo buze buyofinyelela emhlane, isisu esikhukhumele futhi esinezindawo ezibuhlungu lapho usithinta; isicanucanu nokuhlansa, imfiva kanye nenhliziyo eshaya ngamandla).
- Uma ingane yakho ingenwa yizifo kalula kunokwejwayelekile. Lokhu kungabangelwa yinkinga ephathelene negazi futhi makhulu amathuba okuthi lokhu kwenzeke uma ingane yakho isiyisebenzise isikhathi eside iDYNACEF SUSPENSION.
- Ukutheleleka ngokuphindelela (ukusuleleka ngesifo sesibili ngaphezu kwesifo sokuqala esikhona esibangelwa ngamanye amabhakhthiriya noma okuthile okunamandla okuvimbela

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ukusebenza kweDYNACEF SUSPENSION), kubandakanya izifo ezibangelwa wukhunta (*fungal infections*) ezinjengenkwehu yomlomo (*oral thrush*) noma inkwehu yesitho sangasese sowesifazane (*vaginal thrush*).

- Ukuzwa amakhaza, ukukhathala, isikhumba esinombala ophaphatheke ngokungajwayelekile, iphika, inhliziyo eshaya ngamandla noma umchamo onombala omnyama. Lezi kungenzeka kube yizimpawu zohlobo olubucayi lwe-anemiya.
- Izinkinga eziphathelene negazi ezingakhulisa amathuba okuthi ingane yakho ingenwe yizifo, ikhathale kalula nje, noma ihuzuke njalo.
- Uma ingane yakho ihuzuka kalula kunokwejwayelekile, noma kwenzeka ihlaselwe wumqubuko obuhlungu wamachashazi abomvu ngokumnyama ngaphansi kwesikhumba, angasuki uma uwapitshiza (*purpura*). Lokhu kungabangelwa yinkinga ebucayi ephathelene negazi.
- Ukudlikiza komzimba ngendlela engalawuleki, ubuthi ohlelweni lwezinzwa zomzimba olubandakanya ubuchopho nomfunkulu (okubonakala ngezimpawu ezibandakanya itwetwe nexhala, isiyezi, umlomo ondikindiki, inzululwane, ukukhala kwemisindo noma izihlonono ezindlebeni kanye nokudlikizela).
- Ukuphuma komchamo omncane lapho uzama ukuchama noma kungaphumi lutho, ukwehla kokusebenza kwezinsiso (okunezimpawu ezinjengokuvuvukala okudalwa wukugcwala kwamanzi emzimbeni kanye nomfutho wegazi ophakeme).
- Ukungezwa ezindlebeni.

Konke lokhu kuyimithelela engathandeki ebucayi futhi enobungozi. Kungenzeka kudingeke ukuba ingane yakho ithole usizo lokwelashwa oluphuthumayo.

Tshela udokotela wakho uma ubona okunye kwalokhu okulandelayo:

Imithelela engathandeki evamile ukubonakala:

- ukuphelelwa wuthando lokudla
- isicanucanu, ukuhlanza, isifo sohudo, izinhlungu esiswini nendawo ezungezile

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- ikhanda elibuhlungu

Imithelela engathandeki engavamile ukwenzeka:

- imiphumela yokuhlolwa kwegazi kanye/noma umchamo ebonisa okungajwayelekile
- isiyezi, umuzwa onsonsothayo, oshisayo, oncinzayo (obizwa phecelezi ngamapins and needles), noma isikhumba esindikindiki, i-asthenia (ukukhathala noma ukuzizwa ubuthakathaka ngendlela engajwayelekile)
- isisu esiqumbile, ukugcwala komoya esiswini (umsuzo), inkinga yokungagayeki kahle kokudla
- ukukhala kwezihlonono ezindlebeni
- imiphumela yokuhlolwa kwesibindi ebonisa okungajwayelekile
- ukuqubuka esikhunjeni noma ezinye izinkinga zesikhumba
- ukukhathala okukhulu
- imiphumela yokuhlolwa kwegazi ephaphalazayo ebonisa ubukhona besifo sibe singekho (ukuhlolwa okubizwa ngedirect Coombs' test).

Uma ubona noma iyiphi 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. Lokhu kubandakanya ngisho naleyo mithelela engathandeki okungenzeka ikuphathe kodwa engabhaliwe kuleli pheshana. Futhi ungayibika imithelela engathandeki kwabakwaSAHPRA ngohlelo xhumano 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 kweDYNACEF SUSPENSION. Futhi ungathumela i-imeyili ngqo enkampanini, pharmacovigilance@pharmadynamics.co.za, ngenhloso yokuqinisekisa ukuphepha komkhiqizo.

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5. Indlela yokugcina iDYNACEF SUSPENSION

Yonke imithi kumele uyigcine endaweni ezingafinyeleli kuyona izingane.

Ngaphambi kokuxutshwa komuthi:

Wugcine ezingeni lokushisa elingama-25°C noma ngaphansi kwalokho, uwuvikele ekukhanyeni nomswakama.

Ngemuva kokuxutshwa komuthi:

Wusebenzise zingakapheli izinsuku eziyi-10. Wugcine esiqandisini (2-8°C).

Wuxukuzisise ngaphambi kokuwusebenzisa.

Ligcine livalwe ngci ibhodlela. Lahla noma yisiphi isiceke somuthi esingasetshenzisiwe. Ungalokothi uwubandise kakhulu uze uqine ube yiqhwa.

Ungawusebenzisi umuthi emuva kosuku lokuphelelwa kwawo yisikhathi olubhalwe ebhodleleni 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 lomuthi kanye nolunye ulwazi

Okuqukethwe yiDYNACEF SUSPENSION

Umthamo ngamunye ongama-5 mL womuthi uqukethe *icefpodoxime proxetil* elingana *necefpodoxime* engama-40 mg.

Ezinye izithako yilezi:

Anhydrous citric acid, impushanambumbulu eyomile enokunambitheka okusabhanana yokuzenzela, *aspartame*, *hydroxypropyl cellulose*, isitashi sommbila, *microcrystalline cellulose & carboxymethyl cellulose sodium*, *silica colloidal anhydrous*, *sodium benzoate* (isilondolozimuthi esingama-0,2 % m/v), *Spectralol yellow iron oxide*, ushukela wezitshalo.

7. Imiyalelo kanye neNdelela Yokuxuba Umuthi:

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Khipha isivalo esikulufwayo ngokusicindezela ube usiphendula. Susa isivimbo esiyisimuncaketshezi ngokuthi uxebule ithebhu elenzelwe ukuthi siphume kalula isivimbo bese uyasilahla. Ngeza amanzi angama-27,0 mL kwimpushana eyomile ukwenza umuthi owuketshezi ongama-50 mL. Ngeza amanzi angama-54,0 mL, uwahlukanise ngokulinganayo (ama-27,0 mL amabili) kwimpushana eyomile ukwenza umuthi owuketshezi ongama-100 mL. Xukuzisisa njalo emuva kokwengeza okuthile ngakunye. Bheka isigaba 3. Indlela yokusebenzisa iDYNACEF SUSPENSION.

8. Indlela ebukeya ngayo iDYNACEF SUSPENSION kanye nalokho okuqukethwe ephaketheni layo

Impushana yokwenza umuthi owuketshezi.

Impushana: Iyimpushana ecishe ibe mhlophe kuya kumbala ophuzi ophaphathekile.

Ingxubemakhambi ewuketshezi: Inombala omhloshana kuya kumbala ophuzi ophaphathekile futhi igabe kakhulu ngephunga elimnandi lezithelo.

Isebhodleleni leHDPE elikhanyayo elinesivalo se*polypropylene* esimhlophe esingama-28 mm (esakhiwe ngendlela eyenza zingakwazi ukusivula izingane, esinesivimbo sefoyela ngaphansi esixebukayo), eliqukethe impushana yokuxuba umuthi ongafinyelela kuma-50 mL noma kuma-100 mL, elifakwe kwibhokisana elibhaliwe ngaphandle.

9. Umnikazi Wesitifiketi Sokubhaliswa

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10. Leli pheshana lolwazi lagcina ukubuyezwa mhla zi-

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3 kuMasingana 2023

11. Inamba yokubhaliswa

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