

**IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI
UHLA LWEZINHLOBO ZAMAPHILISI IDYNA SERTRALINE**

ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI

S5

Amaphilisi anongwengwezana i**IDYNA SERTRALINE 50 mg**

Amaphilisi anongwengwezana i**IDYNA SERTRALINE 100 mg**

Sertraline

IDYNA SERTRALINE ayinawo ushukela.

Ngaphambi kokuba uqale ukusebenzisa iDYNA SERTRALINE 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.
- IDYNA SERTRALINE 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 iDYNA SERTRALINE futhi isetshenziselwani?
2. Okumele ukwazi ngaphambi kokuba usebenzise iDYNA SERTRALINE
3. Indlela yokusebenzisa iDYNA SERTRALINE
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1. Iyini iDYNA SERTRALINE futhi isetshenziselwani?

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Isertraline ingomunye weqoqwana lemithi ebizwa ngama *Selective Serotonin Re-uptake Inhibitors (SSRIs)*; le mithi isetshenziselwa ukwelapha ingcindezi yengqondo kanye/noma izinkinga zengqondo ezibonakala ngetwetwe nexhala.

IDYNA SERTRALINE isetshenziselwa ukwelapha:

- Ingcindezi yengqondo kanye nomuzwa wovalo nokwethuka, kubantu abadala, ofika ngokushesha futhi kungazelelwe
- Inkinga yemizwa nemicabango engathandeki ebeleselayo futhi okuhambisana nemizwa yokubheka noma ukwenza into ngokuphindaphindiwe futhi okungalawuleki, phecelezi, i-*obsessive compulsive disorder (OCD)* kubantu abadala kanye nasezinganeni (ezineminyaka eyi-13 kuya kweyi-17 ubudala)

Lesi yisifo esibonakala ngemicabango engathandeki, kodwa elokhu ibelesele njalo kanye/noma ukwenza izinto ezingenangqondo ozizwa uphoqelekile ukuthi uzenze ngokuphindaphindekayo.

2. Okumele ukwazi ngaphambi kokuba usebenzise iDYNA SERTRALINE

Ungalokothi usebenzise iDYNA SERTRALINE:

- Uma umzimba wakho ungezwani nesithako isertraline noma uma ungezwani nanoma yisiphi esinye isithako samaphilisi iDYNA SERTRALINE (bheka isigaba 6).
- Uma usebenzisa eminye imithi yokwelapha ingcindezi yengqondo ebizwa ngama *monoamine oxidase inhibitors (MAOIs)*, isibonelo, *iselegiline*, *moclobemide* kanye *nelinezolid*, noma uma uke wayisebenzisa le mithi noma nini kula maviki amabili adlule. Udokotela wakho uzokweluleka ukuthi kumele uqale kanjani ukusebenzisa iDYNA SERTRALINE lapho usuyekile ukusebenzisa amaMAOI. Akumele uqale ukusebenzisa amaMAOIs kuze kuphele okungenani isikhathi esiyizinsuku eziyisikhombisa emuva kokuyeka ukwelashwa ngeDYNA SERTRALINE.
- Uma ukhulelwe noma usancelisa umntwana wakho (bheka isigatshana esithi Ukukhulelwa, ukuncelisa kanye nokuba sesimweni sokuzala nokuthola abantwana).
- Uma usebenzisa umuthi obizwa nge *pimozide* (wokwelapha inkinga yokungasebenzi kahle kwengqondo), njengoba iDYNA SERTRALINE kungenzeka idale inkinga embi kakhulu yokushaya kwenhliziyo ngesigqi esingahambelani kahle uma isetshenziswa kanyekanye nalo

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muti, okuyinto engambulala nokumbulala umuntu.

- Uma uxinwe kakhulu yinkinga yokuphazamiseka kokusebenza kwesibindi noma isifo sesibindi esinamandla.
- Uma unesifo esibizwa nge*porphyria* (inkinga yezikhuthazalushintsho ebonakala ngezimpawu ezinjengezinhlungu esiswini nendawo ezungeze isisu, izinhlungu esifubeni, emhlane noma emilenzeni yakho, ukuhlanza noma ukushaya kwenhliziyo ngamandla).
- IDYNA SERTRALINE akumele inikezwe izingane noma amabhungu namatshitshi aneminyaka engaphansi kwe-18 ubudala, ngaphandle kwezingane ezineminyaka ephakathi kwe-13 ne-17 ubudala ezelashelwa inkinga yemizwa nemicabango engathandeki ebeleselayo futhi okuhambisana nemizwa yokubheka noma ukwenza into ngokuphindaphindiwe futhi okungalawuleki (OCD) (bheka isigatshana esithi Qaphela kakhulu uma usebenzisa iDYNA SERTRALINE).

Izixwayiso kanye nezinto okumele uziqikelele

Qaphela kakhulu uma usebenzisa iDYNA SERTRALINE:

- Uma kuneminye imithi oyisebenzisayo yokwelapha inkinga yokuphazamiseka kwesimo sengqondo nomphefumulo, njengoba ungaba sengcupheni yokuphathwa yi*serotonergic syndrome* (isifo esibonakala ngezimpawu ezinjengokuyaluza ungabi nasinqe futhi ubenhliziyo encane noma ungahlaliseki, izinhlamvu zamehlo ezinwebekile, kanye nokujuluka kakhulu).
- Uma usebenzisa eminye imithi efanayo yokwelapha isifo sengqondo, njengoba lokhu kungaholela ekutheni uphathwe yi*Neuroleptic Malignant Syndrome*, okuyisifo esingambulala nokumbulala umuntu esibonakala ngezimpawu ezinjengemisipha yomzimba eqinile kanye nemfiva.
- Uma usebenzisa eminye imithi equkethe i*tryptophan* (ikhambi eliyisondlamzimba lokwelapha ingcindezi yengqondo), i*fenfluramine* (esetshenziselwa ukulawula inkinga yokukhuluphala ngokweqile), amanye ama-*5-HT agonists* (okuyimithi esetshenziselwa ukwelapha ingcindezi yengqondo) noma i*St John's Wort* (ikhambi eliyisondlamzimba lokwelapha ingcindezi yengqondo).

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- Uma uke watshelwa ukuthi umzimba wakho unenkinga yokushaya kwenhliziyo ngesigqi esingahambelani kahle ebizwa nge*prolonged QT interval* (emuva kokuhlolwa kwendlela eshaya ngayo inhliziyo yakho (*ECG*)).
- Uma uke waba neziwombe zokuphathwa yi*hypomania* noma *mania* (ukukhuthala ngokweqile futhi ngendlela engajwayelekile noma imicabango elandelana ngokushesha, elokhu ibelesele njalo).
- Uma uke waphathwa yisifo *manic depressive illness* (isifo *se bipolar*) noma *ischizophrenia*.
- Uma unesifo sokuwa (isithuthwane) noma isifo sokudlikiza komzimba ngendlela engalawuleki (amafithi).
- Uma unengcindezi yengqondo kanye/noma inkinga yetwetwe nexhala, kwesinye isikhathi ungazithola ufikelwa yimicabango yokuzilimaza noma yokuzibulala. Lokhu kungenzeka kukhule uma usaqala ukusebenzisa imithi yokwelapha ingcindezi yengqondo enjengeDYNA SERTRALINE, njengoba kuthatha isikhathi ukuthi le mithi isebenze (ngokuvamileyo kuye kube ngamaviki abalelwa kwamabili kodwa kwesinye isikhathi kuba yisikhathi esingaphezulu kwalokho).
- Uma ngaphambilini uke waba nemicabango yokuzibulala noma yokuzilimaza.
- Uma noma nini unanoma yimiphi imicabango yokuzilimaza noma yokuzibulala, xhumana nodokotela wakho ngokushesha noma uphuthume esibhedlela. Emavikini ambalwa okuqala udokotela wakho uzokuqapha futhi akubhekisise ngokucophelela ukwelashwa kwakho kanye nenqubekelaphambili yakho.
- Uma usebenzisa umuthi wokuvimbela ukushuba nokuguquka kwegazi libe ngamahlule, noma uma ungumuntu ovamise ukopha kalula, njengoba iDYNA SERTRALINE kungenzeka ikhuphule ubungozi bokopha.
- Uma ukhulelwe futhi udokotela wakho ekuyalele ukuthi usebenzise iDYNA SERTRALINE ngenyanga eyandulela ukubeletha kwakho, kunobungozi bokuthi wophe ngokweqile emuva kokubeletha.
- Uma usebenzisa amaphilisi amanzi (anjengemithi ethile esetshenziselwa ukwelapha inkinga

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yomfutho wegazi ophakeme) tshela udokotela wakho, njengoba le mithi kungenzeka iguqule izinga lesodium egazini lakho.

- Uma uyeka esithubeni nje ukusebenzisa amaphilisi akho iDYNA SERTRALINE, kungenzeka uphathwe yimithelela engathandeki ebangelwa wukuyeka kwakho ngaphambi kwesikhathi ukwelashwa ngalawa maphilisi (bheka isigatshana esithi IMITHELELA ENGATHANDEKI OKUNGENZEKA IBE KHONA). Ungalokothi uyeke ukusebenzisa iDYNA SERTRALINE ungakakhulumi nodokotela wakho.
- Uma kwenzeka uphathwa wumuzwa wokungahlaliseki kahle nokungabi nasinqe, ngokuvamile okwenzeka emavikini okuqala ambalwa okwelashwa (bheka isigatshana esithi IMITHELELA ENGATHANDEKI OKUNGENZEKA IBE KHONA).
- Uma unezinkinga zezinso noma isibindi.
- Uma unesifo sikashukela, njengoba kungenzeka kudingeke ukuthi uguqule umthamosilinganiso womuthi wakho.
- Uma kwenziwa inqubokwelapha kuwena ebizwa nge-*electro-convulsive therapy* (yokukhuthaza ukusebenza kobuchopho ngokubushisa kancane ngogesi ngenhloso yokwelapha ingcindezi yengqondo).
- Uma uphuza ujusi we*grapefruit*, lokho kungaphazamisa indlela esebenza ngayo iDYNA SERTRALINE.
- Uma kudingeka ukuthi uyokwenza ukuhlolwa komchamo noma kwegazi, njengoba kungenzeka ukuthi iDYNA SERTRALINE iphazamise imiphumela (kungenzeka uthole umphumela wokuhlolwa komchamo ophaphalazayo obonisa ukuthi wena usebenzise okuthile okungavumelekile kodwa empeleni kube kungenjalo).
- Uma uphethwe yi*glaucoma* (isifo samehlo esingaholela ekulimaleni kwezinzwa ezithumela imiyalezo esuka emehlweni iye ebuchosheni).
- Uma unenkinga yesisindo somzimba esiphansi.
- Uma usanda kuphathwa yisifo senhliziyo noma uke wahlaselwa yizinkinga zokungasebenzi kahle kwenhliziyo.

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Izingane kanye namabhungu namatshitshi

- IDYNA SERTRALINE akumele inikezwe izingane noma amabhungu namatshitshi aneminyaka engaphansi kwe-18 ubudala futhi kumele isetshenziswe kuphela ukwelapha izingane kanye namabhungu namatshitshi aneminyaka eyi-13 kuya kweyi-17 ubudala, anenkinga yemizwa nemicabango engathandeki ebeleselayo futhi okuhambisana nemizwa yokubheka noma ukwenza into ngokuphindaphindiwe futhi okungalawuleki (OCD). Uma welashelwa lesi sifo, udokotela wakho uzofuna ukusiqapha futhi asibhekisise ngokuqhubekayo isimo sakho.

Ukusetshenziswa kweminye imithi neDYNA SERTRALINE

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

Ungalokothi usebenzise iDYNA SERTRALINE kanyekanye nemithi elandelayo:

- Imithi ebizwa ngamamonoamine oxidase inhibitors (MAOIs) kubandakanya *nemoclobemide*, *linezolid* (eyi-antibhayothikhi), *iselegiline* (esetshenziselwa ukwelapha isifo iParkinson's disease) kanye *nemethylene blue* (esetshenziselwa ukwelapha izinkinga ezithile eziphathelene negazi) (bheka isigatshana esithi Ungalokothi usebenzise iDYNA SERTRALINE).
- *Ipimozide* (esetshenziselwa ukwelapha *ischizophrenia*) njengoba iDYNA SERTRALINE kungenzeka ibangele izinkinga ezinamandla zokushaya kwenhliziyo ngesigqi esingahambelani kahle uma isetshenziswa ngokuhlanganyela nale mithi.

Tshela udokotela wakho uma kukhona noma yimuphi owusebenzisayo kule mithi elandelayo:

- *Idiazepam* (esetshenziswa okwesikhashana ukwelapha izimpawu ezihlobene nenkinga yetwetwe nexhala).
- *Itoebutamide* (esetshenziswa ekwelapheni inkinga kashukela ophakeme egazini noma isifo sikashukela).

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- *Iwarfarin* (esetshenziselwa ukwenza igazi lingashubi liphenduke amahlule) noma eminye imithi evimbela ukuguquka kwegazi libe ngamahlule, njengoba ukusetshenziswa kweDYNA SERTRALINE kungaholela ekutheni wophe.
- *Ifenfluramine* (esetshenziselwa ukwelapha ukukhuluphala ngokweqile).
- *Ifentanyl* (esetshenziselwa ukulalisa umuntu ozohlinzwa ukuze angabuzwa ubuhlungu ngenkathi ehlinzwa) kanye ne*tramadol* noma *ipethidine* (yokuqeda izinhlungu).
- *Tryptophan* (isondlamzimba esiyi-*amino acid*), namanye ama-SSRI's, noma i*St John's Wort* (isihlahla esisetshenziselwa ukwelapha ingcindezi yengqondo) njengoba ukusebenzisa le mithi kanyekanye neDYNA SERTRALINE kungaholela ekutheni uphathwe yisifo esibizwa nge"*serotonin syndrome*" esinezimpawu ezinjengamafithi (isithuthwane), ukuthuthumela, ukungahlaliseki kahle noma ukungabi nasinqe kanye nenhliziyo encane/ukucasuka kalula.
- *Phenytoin*, *phenobarbital*, *carbamazepine* (esetshenziselwa ukwelapha nokuvimbela ukudlikizela komzimba ngendlela engalawuleki kumuntu ophethwe yisifo sokuwa) kungenzeka inciphise amandla okusebenza kweDYNA SERTRALINE.
- Kumele futhi ucophelele lapho uyeka ukusebenzisa umuthi othile wokwelapha ingcindezi yengqondo ushintshela komunye, ikakhulukazi uma ushintshela emithini esebenza isikhathi eside emzimbeni enjenge*fluoxetine*.
- *Scimetidine* (umuthi wokwelapha isilungulela kanye nezilonda esiswini) kungenzeka iwakhuphule amandla okusebenza kweDYNA SERTRALINE.
- *Lithium* (esetshenziselwa ukwelapha ingcindezi yengqondo) njengoba iDYNA SERTRALINE kungenzeka ikhuphule amandla okusebenza alo muthi.
- *Sumatriptan* (umuthi osetshenziselwa ukwelapha ikhanda elinkenkethayo, ikakhulukazi elinkenketha ohlangothini olulodwa lwekhanda).
- Imithi yokwelapha isifo sikashukela, njengoba kuzodingeka ukuthi aqashelwe futhi abhekisiswe ngokuqhubekayo amazinga kashukela egazini.
- *Aspirin*, *ibuprofen* noma eminye imithi ebizwa ngamaNSAIDs (*non-steroidal anti-inflammatory medicines*) esetshenziselwa ukwelapha izinhlungu nokuvuvukala.

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- *Amadiuretics* (amaphilisi amanzi) kungenzeka aholele emazingeni aphansi esodium egazini, ikakhulukazi kubantu asebekhulile ngokweminyaka.
- Imithi esetshenziselwa ukwelapha ukutheleleka okubangelwa wukhunta (*fungal infections*) (enjenge*ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole, clarithromycin, telithromycin, nefazodone, aprepitant, erythromycin, verapamil* kanye *nediltiazem*) kungenzeka ikhuphule amandla okusebenza kweDYNA SERTRALINE.
- Imithi yokwelapha i-esidi eningi ngokweqile esiswini (*omeprazole, lansoprazole, pantoprazole, rabeprazole*).
- *Ifluoxetine, fluvoxamine* (esetshenziselwa ukwelapha ingcindezi yengqondo) njengoba kungenzeka ikhuphule amandla okusebenza kweDYNA SERTRALINE.
- *Iritonavir* (esetshenziselwa ukwelapha iHIV) kungenzeka ikhuphule amandla okusebenza kweDYNA SERTRALINE.

Ukuphuza iDYNA SERTRALINE nokudla kanye nophuzo

IDYNA SERTRALINE ungayiphuza nokudla noma uyiphuze ngaphandle kokudla. Kugweme ukuphuza ujusi we*grapefruit*.

Kumele ubugweme utshwala ngenkathi usebenzisa iDYNA SERTRALINE.

Ukukhulelwa, ukuncelisa kanye nokuba sesimweni sokuzala nokuthola abantwana

Uma ukhulelwe noma usancelisa umntwana wakho, bonisana nodokotela wakho, usokhemisi noma omunye umhlinzeki wosizo lwezempilo nokwelashwa ukuze uthole ukwelulekwa ngaphambi kokuba usebenzise iDYNA SERTRALINE.

Akuqinisekiswa ukusetshenziswa kweDYNA SERTRALINE ngokuphepha kumuntu okhulelwe noma oncelisayo. Ungalokothi usebenzise iDYNA SERTRALINE uma ukhulelwe noma usancelisa umntwana wakho (bheka isigatshana esithi Ungalokothi usebenzise iDYNA SERTRALINE). Uma usebenzisa iDYNA SERTRALINE ngasekupheleni kokukhulelwa kwakho, kungenzeka bukhuphuke ubungozi bokopha esithweni sakho sangasese kancane nje emuva kokubeletha, ikakhulukazi uma esikhathini esedlule uke waphathwa yizinkinga eziphathelele nokopha.

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Udokotela wakho noma umbelethisi kumele aziswe ukuthi wena usebenzisa iDYNA SERTRALINE ukuze akweluleke (bheka isigatshana esithi Izixwayiso kanye nezinto okumele uziqikelele).

Ukushayela kanye nokusebenzisa imishini:

IDYNA SERTRALINE akulindelekile ukuthi ikwenze ungakwazi ukushayela kahle imoto nokusebenzisa imishini. Akulula ukubikezela njalo ukuthi iDYNA SERTRALINE izoba nomthelela ongakanani emisebenzini yakho yansukuzonke.

Kumele uqinisekise ukuthi awuyenzi imisebenzi eshiwo ngenhla kuze kufike isikhathi lapho usubonile ukuthi iDYNA SERTRALINE ikuphatha kanjani.

3. Isetsheziwa kanjani iDYNA SERTRALINE

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

Umthamosilinganiso weDYNA SERTRALINE uzokwehluka ngokwesiguli nesiguli futhi uzoncika ekutheni umuthi usetshenziselwani kanye nokuthi ikhona yini eminye imithi esetshenziswa ngesikhathi esifanayo. Udokotela wakho uzothatha isinqumo maqondana nomthamosilinganiso ofanelekile oqondene nesimo sakho. Iphilisi kumele uligwinye lonke liphelele, ulehlise ngengilazi yamanzi futhi kumele uliphuze ngesikhathi esifanayo nsukuzonke.

Izingane:

IDYNA SERTRALINE ayikulungele ukusetshenziswa ezinganeni, ngaphandle kwezingane ezineminyaka ephakathi kwe-13 ne-17 ubudala eziphethwe yisifo i-OCD.

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Udokotela wakho uzokutshela ukuthi kuzothatha isikhathi eside kangakanani ukwelashwa kwakho ngeDYNA SERTRALINE. Ungalokothi uyeke ukudla amaphilisi akho ngaphambi kwesikhathi ngoba kungenzeka uphathwe yimithelala engathandeki eyizimpawu zokuyeka ukusebenzisa lo muthi ngaphambi kwesikhathi (bheka isigatshana esithi Uma uyeka ukusebenzisa iDYNA SERTRALINE). Uma ubona sengathi iDYNA SERTRALINE inamandla ngokweqile noma sengathi ayinawo neze amandla, tshela udokotela wakho noma usokhemisi.

Uma uphuze iDYNA SERTRALINE 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.

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

Izimpawu zomthamosilinganiso oweqile kungenzeka zibandakanye lokhu:

ukozela, isicanucanu kanye nokuhlanza, ukushaya kwenhliziyo ngamandla, ukuthuthumela, ukuyalaza ungabi nasinqe futhi ube nenhliziyo encane, isiyenzi, futhi kungenzeka uquleke nakuba lokhu kuyinto eyivelakancane noma engajwayelekile.

Uma kwenzeka ukhohlwa ukuphuza iDYNA SERTRALINE:

Uma kwenzekile wakhohlwa ukuphuza amaphilisi, waphuze ngokushesha amaphilisi akho emuva kokukhumbula ukuthi kumele uwaphuze. Ungalokothi uphuze iDYNA SERTRALINE 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 ephindwe kabili ngenhloso yokuvala isikhala semithamosilinganiso okhohliwe ukuyiphuza.

Uma uyeka ukusebenzisa iDYNA SERTRALINE

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Ungalokothi uyeke ukusebenzisa iDYNA SERTRALINE ngaphandle uma udokotela wakho ekutshela ukuthi ukwenze lokho. Udokotela wakho uzofuna ukuwunciphisa kancane kancane umthamosilinganiso wakho weDYNA SERTRALINE esikhathini esingamaviki ambadlwana, ngaphambi kokuthi ekugcineni uyeke ukusebenzisa lo muthi. Uma uyeka esithubeni nje ukusebenzisa iDYNA SERTRALINE kungenzeka uphathwe yimithelela engathandeki enjengesiyezi, ubundikindiki, izinkinga zokungalali kahle, ukuyaluza ungabi nasinqe futhi ube nenhliziyo encane noma itwetwe nexhala, ikhanda elibuhlungu, ukuzizwa sengathi uyagula (isicanucanu), ukuhlaselwa wukugula (ukuhlanza) kanye nokuthuthumela.

4. Imithelela engathandeki okungenzeka ibe khona

IDYNA SERTRALINE kungenzeka ibe nemithelela engathandeki emzimbeni.

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

Uma kwenzeka noma yikuphi kulokhu okulandelayo, yeka ukusebenzisa iDYNA SERTRALINE 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
- ukuqubuka noma ukuluma
- ukuquleka

Konke lokhu kuyimithelela engathandeki ebucayi kakhulu futhi enobungozi. Uma unayo, kusho ukuthi kunokwenzeka ukuthi umzimba wakho awuzwananga neze neDYNA SERTRALINE.

Kungenzeka udinge usizo lokwelashwa oluphuthumayo noma ukulaliswa esibhedlela.

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

- isifo sokuguquka kwesikhumba namehlo kube nombala ophuzi, futhi esibizwa ngejondisi
- ukushaya kwenhliziyo ngesigqi esisheshayo futhi esingahambelani kahle noma ngesigqi esinensayo, izinhlungu esifubeni
- umfutho wegazi ophakeme noma umfutho wegazi ophansi (ukuzizwa unesiyezi lapho usukuma uma ngezinyawo)
- ukukhuphuka kwezinga lokungenwa yizifo
- ukungakwazi ukuchama, ukuhluleka ukulawula isinye, ukuphuma komchamo omningi noma omncane kunalokho okujwayelekile kuwena lapho uchama
- ukopha kwesikhumba, ihlo noma isisu okuxakile futhi okungajwayelekile
- ukuzizwa unexhala/ukhathazekile (okwenzeka ikakhulukazi ezinganeni)
- umuzwa wovalo nokwethuka ofika ngokushesha futhi kungazelelwe
- ukucabanga ukuzibulala (okubizwa phecelezi ngesuicidal ideation) kanye nokuziphatha ngendlela ebonisa isifiso sokuzibulala
- ukubona ngendlela efiphele noma inkinga yamehlo angaboni ngendlela ejwayelekile, izinhlamvu zamehlo ezinwebekile noma iglaucoma (ingcindezi ephakeme ehlweni)
- ukuzizwa udidekile
- ukubona izinto ezingekho (ukubona izinto eziyinqaba/ezingajwayelekile noma ukuzwa imisindo engajwayelekile)
- ukudlikiza komzimba ngendlela engalawuleki, ukuqhaqhazela, ukujuluka ngokweqile
- ukulimala kwesibindi noma ukuhluleka kwesibindi ukusebenza kahle, ukuvuvukala kwesibindi (ihepatitis), okubonakala ngezimpawu ezinjengokukhathala kakhulu, ukuphelelwa wuthando lokudla kanye nokunkenketha kwemisipha namajoyinti omzimba
- ukukhohlwa, uhluleka ukugxilisa kahle ingqondo, ukuquleka isikhathi eside ungaphaphami.

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

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Tshela udokotela wakho uma ubona okunye kwalokhu okulandelayo:

Imithelela engathandeki evamile ukubonakala:

- umphimbo obuhlungu
- ukukhula noma ukuncipha kothando lokudla, ukwehla/ukuncipha emzimbeni
- uvalo, ingcindezi yengqondo, ukuzibona njengomuntu osephusheni (umuzwa lapho imicabango yakho noma imizwa kubonakala sengathi yinto engekho futhi engenzeke ngokwempela noma okungeyona eyakho), ukuhluleka ukuhlala unganyakazi/ungagcogcomi, ukuncipha kwelukuluku lokulangazelela ucansi
- ikhanda elibuhlungu, ukuzizwa unesiyenzi noma uqhaqhaqha (ukuthuthumela), ukungalali kahle (ukuqwashwa/ukungafikelwa wubuthongo) noma ukuzizwa unobuthongo/wozela, umuzwa onsonsothayo noma oncinzayo (*pins and needles*), imisipha eqinile, umuzwa wokunambitha okubi okusansimbi emlonyeni
- ukukhala kwemisindo noma izihlonono ezindlebeni
- umuzwa osheshayo wokufikelwa wukushisa ebusweni, emqaleni noma esifubeni
- ukuzamula
- ukuzizwa ugula, isifo sohudo, ukuqunjelwa, ubuhlungu esiswini nendawo ezungeze isisu, ukugcwala ngokweqile komoya esiswini (umsuzo), umlomo owomile, inkinga yokungagayeki kahle kokudla, isifo sokuzizacisa, phecelezi i-*anorexia* (isifo esiphathelene nokungadli kahle, esibonakala ngokwehla kwemisindo somzimba, uvalo lokukhuluphala kanye nesifiso esinamandla sokuzaca), ukuhlaselwa wukugula
- ukuqubuka, ukujuluka kakhulu kunokwejwayelekile
- ubuhlungu emisipheni nasemajoyintini omzimba
- inkinga yokuthatha isikhathi eside ngaphambi kokuthi uthunde noma inkinga yohluleka ukuthunda/ukukhipha isidoda
- imfiva, ukuzizwa ukhathele noma ungaphilile neze emzimbeni wonke.

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Imithelela engathandeki engavamile ukwenzeka:

- amafinyila noma ukucinana emakhaleni
- *ineoplasm* (izimila zesikhumba ezingajwayelekile)
- imiphumela yokuhlolwa kwegazi, inhliziyo kanye nomchamo ebonisa okungajwayelekile
- izinga lokusebenza kwendlala yegilo elingaphansi kwelifanelekile (kungenzeka uzizwe unengcindezi yengqondo nomphefumulo, ukhathele futhi unenkinga yokukhohlwa)
- amazinga aphakeme noma aphantsi kashukela egazini, ikholesteroli ephakeme
- ulaka, ukuzizwa usesimweni sokuthakasa nokujabula okukhulu, ukungabi nentshisekelo, ukucabanga ngendlela exakile nengajwayelekile, umuzwa wokuzibona uyisisulu nokusola sengathi abantu bafuna ukukwenza isilo sengubo, ukuhluleka ukuphila ngaphandle komuthi othile, ukuhamba ulele
- ukuphakama noma ukwehla komuzwa wokuthinta, ukudikiza kwezicubu zomzimba, inkinga yokungakwazi ukukhuluma kahle, ukuhluleka kokusebenza kwemisipha namalunga omzimba ngendlela ehambelanayo, ikhanda elinkenkethayo, ikakhulukazi elinkenketha ohlangothini olulodwa lwekhanda (ikhanda elibuhlungu kakhulu)
- ukungakwazi ukukhiqiza izinyembezi, ukungaphatheki kahle emehlweni noma ubuhlungu emehlweni ngenxa yokuphathwa kabi wukukhanya
- indlebe ebuhlungu
- isifo sokuvuvukala kontwentwesana kanye nezimbobo zomoya emakhaleni, ibhronkhayithisi, ukukhwehlela, ukopha emakhaleni, ubunzima bokukhuluma obubangelwa yinkinga ephathelene nomlomo, ulimi, umphimbo noma imisipha yephimbo, ingwici
- ukugwinya kanzima, imizoko (*haemorrhoids*), amathe amaningi ngokweqile, indle enegazi noma emnyama ngokusatiyela, ulimi oluvuvukele, izilonda olimini kanye nasemlonyeni, izinkinga eziphathelene namazinyo
- ukuqothuka kwezinswele noma isimo sokwakheka kwezinswele esixakile nesingajwayelekile, isikhumba esinephunga, umjuluko okungenzeka ubangelwe wukushisa noma ongahambisani nokushisa, isikhumba esomile, ukuvuvukala ebusweni, amachashazi esikhunjani anombala

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osabukhwebezane, ukuqubuka, ukuluma, amabhamuza

- imisipha yomzimba ebuthakathaka, umhlane obuhlungu, ukudikiza kwemisipha yomzimba, izinkinga eziphathelene namathambo
- ukuchama kakhulu ebusuku noma emuva kokuvuka/kokuphaphama, umuzwa oshisayo lapho uchama
- inkinga yokuhluleka ukuya kahle ocansini noma ukuziphumela kobisi ngokwalo emabeleni, isitho sangasese sowesifazane esivuvukele noma isitho sangasese sowesilisa ongasokile esivuvukele, inkinga yokuqhanyelwa okubuhlungu, ukuya kowesifazane esikhathini okubuhlungu noma okuxakile futhi okungajwayelekile, ukuphuma koketshezi olungajwayelekile esithweni sangasese sowesifazane, ukushesha kwendoda ithunde lapho iya ocansini
- ukoma, ukuqhaqhazela okubangelwa wukuzwa amakhaza, *ihernia* (inkinga lapho ingxenye yesitho somzimba ivela futhi iqumba ibonakale ngaphandle komzimba, ngokuvamile okuba ngamathumbu), ukuncipha kwamandla omzimba okubekezelela umuthi, ukuvuvukala kwemilenze
- ukulimala

Le mithelela elandelayo ibikiwe kodwa akwaziwa ukuthi ivamise kangakanani ukwenzeka:

- ukopha kakhulu kwesitho sangasese sowesifazane kancane nje emuva kokubeletha (*postpartum haemorrhage*), bheka isihlokwana esithi Ukukhulelwa esigabeni sesi-2 ukuze uthole ulwazi oluthe xaxa
- amaphupho asabekayo kanye namaphupho amabi, ukugedla kwamazinyo
- ukungabi khona noma ukuncipha kweminyakazo yomzimba
- izinhlamvu zamehlo ezingalingani, inkinga yamehlo *i-optic neuritis* (izinhlungu ehlweni noma inkinga yokungayiboni kahle imibala), isilazi, phecelezi *icataract* (ungwengwezi olufiphaza amehlo okwenza umuntu angaboni kahle)
- *ipancreatitis* (isifo sokuvuvukala kwamanyikwe esibonakala ngobuhlungu besisu nendawo)

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ezungeze isisu obuba bubu kakhulu emuva kokudla, izindawo ezibuhlungu esiswini lapho usithinta noma usicindezela, isicanucanu kanye nokuhlaza)

- Ukuzwela kwesikhumba ekukhanyeni
- amajaqamba, ukuphuka kwamathambo
- Ukukhukhumala kwezibele kubantu besilisa

Uma ubona noma yimiphi eminye imithelela engathandeki engabhalwe 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 ngokusebenzisa ifomu lokubika imithelela engathandeki ("**6.04 Adverse Drug Reporting Form**"), elitholakala ku-inthanethi ngaphansi kwemibhalo namaphepha ashicileliwe abakwaSAHPRA:

<https://www.sahpra.org.za/Publications/Index/8>". Ngokubika imithelela engathandeki, ungalekelela ekuhlinzekweni kolwazi oluthe xaxa maqondana nokuphepha kweDYNA SERTRALINE.

5. Indlela yokugcina iDYNA SERTRALINE

Yonke imithi kumele uyigcine endaweni ezingafinyeleli kuyona izingane.

Yigcine ezingeni lokushisa elingama-25 °C noma ngaphansi kwalokho. Yigcine endaweni epholile futhi eyomile.

Ungazikhiphi kwibhokisana lazo izingqwenjana eziyizigcinamaphilisi kuze kufike isikhathi lapho sekudingeka ukuba asetshenziswe.

Ungawasebenzisi amaphilisi 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 yiDYNA SERTRALINE

Isithako sokwelapha esiyinhloko esiqukethwe lapha yi*sertraline*.

DYNA SERTRALINE 50: Iphilisi ngalinye elinongwengwezana liqukethe *isertraline hydrochloride* elingana ne*sertraline* engama-50 mg.

DYNA SERTRALINE 100: Iphilisi ngalinye elinongwengwezana liqukethe *isertraline hydrochloride* elingana ne*sertraline* engama-100 mg.

Ezinye izithako yilezi:

Ezisengxenyeni engaphakathi yephilisi:

Dibasic calcium phosphate anhydrous, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose kanye nesodium starch glycollate.

Ezikungwengwezana lwengxenyeni engaphandle:

Opadry Blue (equkethe iFD&C Blue #2/indigo carmine aluminium lake, hypromellose, macrogol, polysorbate, titanium dioxide) njengesithako esinikeza iDYNA SERTRALINE 50 umbala kanye ne-Opadry Yellow (equkethe ihypromellose, iron oxide yellow, macrogol, polysorbate, titanium dioxide) njengesithako esinikeza iDYNA SERTRALINE 100 umbala.

Indlela ebukeka ngayo iDYNA SERTRALINE kanye nalokho okuqukethwe ephaketheni layo

IDYNA SERTRALINE 50 iyiphilisi elinongwengwezana elinombala oluhlaza okwesibhakabhaka, elinesakhiwo esisambhoshongo, eliqumbile nhlangothi zombili, ohlangothini olulodwa elinombhalo oqoshiwe othi 'SER', kanti ngakolunye uhlangothi, engxenyeni ngayinye yephilisi ehlukaniswe ngumugqa onqamula phakathi, libhalwe inamba '5' kanye nenamba '0'.

IDYNA SERTRALINE 100 iyiphilisi elinongwengwezana elinombala ophuzi, elinesakhiwo esisambhoshongo, eliqumbile nhlangothi zombili, ohlangothini olulodwa elinombhalo oqoshiwe othi 'SER', kanti ngakolunye uhlangothi libhalwe inamba '100'.

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Amaphilisi iDYNA SERTRALINE agcinwe kwizingqwenjana eziyizigcinamaphilisi eziyimisweswana ezimhlophe ezingakubonisi lokho okungaphakathi ezakhiwe ngePVC/PVDC kanye ne-aluminium eziqukethe amaphilisi angama-30. Izingqwenjana eziyizigcinamaphilisi zizofakwa kwibhokisana elinemibhalo edingekayo ngokusemthethweni ebonisa ulwazi neminingwane esemqoka yalokho okuqukethwe ngaphakathi.

Umnikazi Wesitifiketi Sokubhaliswa

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Leli pheshana lolwazi lagcina ukubuyezwa mhla zingama-

30 kuMandulo 2021

Inamba yokubhaliswa

DYNA SERTRALINE 50: A43/1.2/0339

DYNA SERTRALINE 100: A43/1.2/0340

NAMIBIA:

DYNA SERTRALINE 50: NS3 14/1.2/0627

DYNA SERTRALINE 100: NS3 14/1.2/0628