

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

**ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI**

**S5**

**ZYTOMIL 5 mg**, iphilisi elinongwengwezi

**ZYTOMIL 10 mg** iphilisi elinongwengwezi

**ZYTOMIL 15 mg** iphilisi elinongwengwezi

**ZYTOMIL 20 mg** iphilisi elinongwengwezi

*Escitalopram*

IZYTOMIL ayinawo ushukela.

**Ngaphambi kokuba uqale ukusebenzisa iZYTOMIL 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.
- IZYTOMIL 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 iZYTOMIL futhi isetshenziselwani?
2. Okumele ukwazi ngaphambi kokuba usebenzise iZYTOMIL
3. Indlela yokusebenzisa iZYTOMIL
4. Imithelela engathandeki okungenzeka ibe khona
5. Indlela yokugcina iZYTOMIL
6. Okuqukethwe ephaketheni lamaphilisi kanye nolunye ulwazi

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**1. Iyini iZYTOMIL futhi isetshenziselwani?**

IZYTOMIL ngumuthi wokwelapha ingcindezi yengqondo oyingxenye yeqoqwana lemithi engamaSSRI (*selective serotonin reuptake inhibitors*).

IZYTOMIL isetshenziselwa ukwelapha:

- Ingcindezi enkulu yengqondo
- Inkinga yokushaywa wuvalo nokufikelwa wukwesaba kungazelelwe okungenzeka kuhambisane ne-*agoraphobia* noma kungahambisani ne-*agoraphobia* (isibonelo, uvalo lokushiya indlu yakho, lokungena ezitolo, ukuba phakathi kwezixuku kanye nasezindaweni zomphakathi)
- Inkinga yokuba netwetwe nexhala ezimweni zomphakathi (*social phobia*)
- Inkinga ebeleselayo yokukhathazeka okunamandla futhi okweqile maqondana nezimo kanye nezindaba zansukuzonke
- Inkinga yemicabango engathandeki kanye nomuzwa owenza umuntu enze into ethile ngokuphindaphindekayo.

**2. Okumele ukwazi ngaphambi kokuba usebenzise iZYTOMIL**

**Ungalokothi usebenzise iZYTOMIL:**

- Uma umzimba wakho ungezwani nesithako i-*escitalopram* noma uma ungezwani nanoma yisiphi esinye isithako seZYTOMIL (bheka isigaba 6).
- Uma uneminyaka engaphansi kwe-18 ubudala (bheka isigatshana esithi Qaphela kakhulu uma usebenzisa iZYTOMIL).
- Uma usebenzisa nanoma yimiphi eminye imithi yengcindezi yengqondo enjengama*monoamine oxidase inhibitors* (MAOI). Kumele kudlule okungenani izinsuku eziyi-14 phakathi kokuyeka ukusebenzisa imithi enjalo kanye nokuqala ukwelashwa ngeZYTOMIL (bheka isigatshana esithi Ukusebenzisa eminye imithi ngesikhathi esifanayo neZYTOMIL).
- Uma usebenzisa amanye amaMAO inhibitors anjenge*selegiline* (esetshenziselwa ukwelapha isifo i*Parkinson's disease*), i*moclobemide* (esetshenziselwa ukwelapha ingcindezi yengqondo)

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kanye ne*linezolid* (eyi-antibhayothikhi).

- Uma usebenzisa i-antibhayothikhi *ilinezolid*, njengoba kungadingeka ukuthi kuguqulwe umthamosilinganiso wakho.
- Uma usebenzisa *ipimozide* (umuthi wokwelapha ukugula okuphathelene nokusebenza kwengqondo), njengoba lokhu kungaholela ekutheni uphathwe yizinkinga zenhliziyi.
- Uma wazalwa nenkinga yokushaya kwenhliziyi ngesigqi esingajwayelekile noma uma uke waba nesiwombe sokushaya kwenhliziyi ngesigqi esingajwayelekile (okuhlonzwe yi-ECG: ukuhlolwa okwenziwa ngenhloso yokubheka nokuhlola ukuthi inhliziyi yakho ayinazo yini izinkinga).
- Uma usebenzisa imithi yokwelapha izinkinga zesigqi senhliziyi noma imithi engaphazamisa isigqi senhliziyi (bheka isigatshana esithi Ukusebenzisa eminye imithi ngesikhathi esifanayo neZYTOMIL).
- Uma ukhulelwe noma usancelisa umntwana wakho (bheka isigatshana esithi Ukukhulelwa kanye nokuncelisa).
- Uma unesifo esibizwa nge*porphyria* (inkinga yegazi eyivelakancane ehambisana nezimpawu ezinjengezinhlungu esiswini nendawo ezungeze isisu, izinhlungu esifubeni sakho, emhlane noma emilenzeni, ukuhlanza noma ukushaya kwenhliziyi ngamandla).

**Izixwayiso kanye nezinto okumele uziqikelele**

**Qaphela kakhulu uma usebenzisa iZYTOMIL:**

- IZYTOMIL akumele isetshenziswe ezinganeni namabhungu namatshitshi aneminyaka engaphansi kwe-18 ubudala (bheka isigatshana esithi Ungalokothi usebenzise iZYTOMIL). Makhulu amathuba okuthi iziguli ezineminyaka engaphansi kwe-18 ubudala ziphathwe yimithelela engathandeki enjengokuzama ukuzibulala, imicabango yokuzibulala kanye nobutha (ikakhulukazi ukuziphatha ngendlela enobudlova, ukuziphatha ngendlela ephikisayo kanye nolaka) uma zisebenzisa iZYTOMIL. Alukho ucwaningo olwenziwe kubantu abanale

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minyaka yobudala ukucubungula imithelela yokuphepha yesikhathi eside eqondene nokukhula kanye nokuthuthuka kweZYTOMIL.

- Uma unengcindezi yengqondo kanye/noma izinkinga zetwetwe nexhala, kwesinye isikhathi kungenzeka ube nemicabango yokuzilimaza noma yokuzibulala. Lokhu kungenzeka kudlondlobale lapho usaqala ukusebenzisa imithi yengcindezi yengqondo, njengoba kuthatha isikhathi ukuthi le mithi isebenze (ngokuvamile okungaba ngamaviki alinganiselwa kwamabili kodwa kwesinye isikhathi kuyaye kube ngaphezulu kwalokho).
- Uma esikhathini esedlule uke waba nemicabango yokuzibulala noma yokuzilimaza.
- Udokotela wakho uzokubhekisisa ngokucophelela ukwelashwa kwakho kanye nenqubekela phambili yakho emavikini okuqala ambalwa. Uma noma nini unanoma yimiphi imicabango yokuzilimaza noma yokuzibulala, xhumana nodokotela wakho ngokushesha noma uphuthume esibhedlela.
- Kungenzeka ukuthole kuwusizo ukutshela isihlobo noma umngani wakho omkhulu ukuthi wena unengcindezi yengqondo noma inkinga yetwetwe nexhala, futhi ubacele ukuthi bafunde leli pheshana lolwazi. Ungabacela ukuthi baktshela ukuthi ngabe bacabanga ukuthi ingcindezi yakho yengqondo noma inkinga yakho yetwetwe nexhala iya ngokuya ibhebhethaka yini noma cha, noma baktshela uma bekhathazekile ngokuguquka kwendlela oziphatha ngayo.
- Uma unezinkinga zenzliziyo noma uma uke waba nezinkinga zenzliziyo noma uma kamuva nje uke wahlaselwa yisifo senhliziyo.
- Uma uzoyeka ukudla amaphilisi. Ungalokothi uyeke ukusebenzisa iZYTOMIL ungakaqali ngokukhuluma nodokotela wakho. Uma uyeka esithubeni nje ukudla amaphilisi akho iZYTOMIL, kungenzeka uphathwe yimithelela engathandeki ebangelwa wukuyeka kwakho ukusebenzisa amaphilisi (bheka isigatshana esithi Uma uyeka ukusebenzisa iZYTOMIL).
- Uma ungumuntu osekhulile ngokweminyaka yobudala (iminyaka engaphezu kwama-65 ubudala).
- Uma unenkinga yesibindi noma yezinso ezingasebenzi kahle.

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- Uma uhlaselwa wukudlikiza komzimba ngendlela engalawuleki (isifo sokuwa) ngenkathi welashwa ngeZYTOMIL, noma uma unomlando wokuphathwa yisifo sokuwa futhi uma kunokukhula kweziwombe zokuhlaselwa wukudlikiza komzimba ngendlela engalawuleki kungenzeka kudingeke ukuthi uyekiswe kancane kancane ukudla amaphilisi.
- Uma uthola inqubokwelapha lapho ubuchopho bakho bushiswa kancane ngogesi (*electroconvulsive treatment*) ngenhloso yokwelapha inkinga yengcindezi yengqondo ekuphethwe.
- Uma uneziwombe *zermania* (ukuziphatha ngendlela ebonisa ukukhuthala ngokweqile noma imicabango egijima ngokweqile).
- Uma njengamanje uvele usunayo inkinga yokushaya kwenhliziyo kancane.
- Uma ungumuntu onesifo sikashukela (ushukela ophakeme egazini) njengoba kungenzeka kudingeke ukuthi uguqulwe umthamosilinganiso wakho womuthi wesifo sikashukela.
- Uma idlondlobala inkinga yakho yetwetwe nexhala ngenkathi welashwa. Ezinye iziguli ezinenkinga yokushaywa wuvalo nokufikelwa wukwesaba kungazelelwe kungenzeka zibe nokuphakama kwezimpawu zetwetwe nexhala ekuqaleni kokwelashwa ngeZYTOMIL. Lezi zimpawu zivamise ukunyamalala kungakapheli amaviki amabili okwelashwa okuqhubekayo. Udokotela wakho uzokunikeza umthamosilinganiso ophansi lapho usaqala ukwelashwa ukuze anciphise amathuba okuthi uhlaselwe kakhudlwana yitwetwe nexhala.
- Uma uphathwa wumuzwa wokungahlaliseki/wokungabi nasinqe, ngokuvamile emavikini okuqala ambalwa okwelashwa (bheka isigatshana esithi Imithelela engathandeki okungenzeka ibe khona).
- Uma unamazinga aphansi *esodium* egazini ngenxa yesifo sohudo esinamandla kanye nokuhlanza noma ngenxa yokusebenzisa amaphilisi amanzi (*diuretics*).
- Uma usebenzisa eminye imithi efanayo yokwelapha ukugula kwengqondo, imithi yokwelapha ukuvuvukala nezinhlungu (*NSAIDs*) noma *i-aspirin* futhi uma unomlando wezinkinga eziphathelene nokopha njengoba iZYTOMIL kungenzeka ikhuphule ubungozi bokuthi wophe.

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- Uma ukhulelwe futhi udokotela ekuyalele ukuthi usebenzise iZYTOMIL enyangeni eyandulela usuku lwakho lokubeletha, kunobungozi bokuthi wophe ngokweqile emuva kokubeletha.
- Uma usebenzisa umuthi wokuvimbela ukuguquka kwegazi libe ngamahlule (isibonelo, *iwarfarin*) noma uma ungumuntu owopha kalula njengoba iZYTOMIL kungenzeka ikhuphule ubungozi bokopha.
- Uma usebenzisa imithi yokwelapha izinhlungu (isibonelo, *itramadol*), noma yokwelapha ikhanda elinkenkethayo ikakhulukazi ohlangothini olulodwa lwekhanda (isibonelo, *isumatriptan*) njengoba kungenzeka ube sengcupheni yokuphathwa *yiserotonin syndrome* (isifo esihambisana nezimpawu ezinjengokuyaluza ungabi nasinqe futhi ube nenhliziyo encane noma ungahlaliseki/ungabi nasinqe, izinhlamvu zamehlo ezinwebekile kanye nokujuluka kakhulu).
- Uma usebenzisa imithi equkethe *ilithium* noma *itryptophan* njengoba kungenzeka akhuphuke amandla okusebenza kweZYTOMIL (bheka isigatshana esithi Ukusebenzisa eminye imithi ngesikhathi esifanayo neZYTOMIL).
- Uma uphethwe *yiglaucoma* (inkinga yamehlo engaholela ekulimaleni kwenzwa yehlo ethumela imiyalezo ebuchosheni (*optic nerve*)).
- IZYTOMIL akumele isetshenziswe kanyekanye namamonoamine oxidase inhibitors, i-*imipramine*, eminye imithi ekhuphula amazinga eserotonin, *imoclobemide*, utshwala, *iwarfarin* noma *icimetidine* (bheka isigatshana esithi Ukusebenzisa eminye imithi ngesikhathi esifanayo neZYTOMIL kanye nesigatshana esithi Ukuphuza iZYTOMIL kanye nokudla nophuzo).
- Uma usebenzisa i *St. John's Wort* (umuthi oyikhambi) njengoba lokhu kungaholela ekutheni uphathwe yimithelela engathandeki (bheka isigatshana esithi Ukusebenzisa eminye imithi ngesikhathi esifanayo neZYTOMIL).
- Uma uneminyaka engama-50 noma ngaphezulu ubudala. Ezigulini ezineminyaka engama-50 noma ngaphezulu ubudala ezisebenzisa iZYTOMIL sekuke kwabonakala ukukhuphuka kobungozi bokuphuka kwamathambo.

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**Ukusetshenziswa kweminye imithi neZYTOMIL**

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 nanoma yimiphi eminye imithi yokwelapha ingcindezi yengqondo (isibonelo, *amamonoamine oxidase inhibitors*, *i-imipramine*, eminye imithi engamaserotonergic (umuthi onomthelela ekukhishweni kweserotonin, uhlobo lwehomoni), *ilinezolid* kanye *nemoclobemide* ungakabonisani nodokotela wakho ngoba le mithi kungenzeka iguqule indlela esebenza ngayo iZYTOMIL (bheka isigatshana esithi Ungalokothi usebenzise iZYTOMIL).
- Ungalokothi uthathe iZYTOMIL uma usebenzisa imithi engaphazamisa isigqi senhliziyo enjenge*pimozide* (bheka isigatshana esithi Ungalokothi usebenzise iZYTOMIL).

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

- *Iselegiline* (esetshenziselwa ukwelapha isifo *iParkinson's disease*) ikhuphula ubungozi bokuphathwa yimithelela engathandeki.
- Imithi eyelula noma ephazamisa isigqi senhliziyo (*amaphenothiazide derivatives*, *ipimozide*, *ihaloperidol*), *amatricyclic antidepressants*, imithi ethile yokubulala amagciwane futhi enqanda ukukhula kokhunta (*antimicrobial medicines*) (*isparfloxacin*, *imoxifloxacin*, *i-erythromycin IV*, *ipentamidine*, imithi yokwelapha umalaleveva ikakhulukazi *ihalofantrine*), imithi ethile yokwelapha ama-aleji (*imizolastine*), njengoba kungenzeka iphazamise indlela esebenza ngayo iZYTOMIL (bheka isigatshana esithi Ungalokothi usebenzise iZYTOMIL).
- Imithi yokwelapha isilungulela noma izilonda esiswini enjenge*cimetidine* iguqule indlela egayeka ngayo *i-escitalopram*, futhi kungenzeka kudingeke ukuthi uguqulwe umthamosilinganiso weZYTOMIL.
- *Isumatriptan* kanye nemithi efanayo (esetshenziselwa ukwelapha ikhanda elinkenkethayo ikakhulukazi ohlangothini olulodwa) kanye *netramadol* (esetshenziselwa ukudambisa

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izihlungu ezinamandla). Le mithi kungenzeka ikhuphule ubungozi bokuphathwa yimithelela engathandeki (bheka isigatshana esithi Qaphela kakhulu uma usebenzisa iZYTOMIL).

- *Lithium* (esetshenziselwa ukwelapha *imanic-depressive disorder*) kanye ne*tryptophan* (esetshenziswa ngumzimba ukukhiqiza *isero-tonin* elekelela ekulawuleni isimo sakho sengqondo nomphefumulo kanye nokulala).
- *Amaneuroleptics* (imithi esetshenziselwa ukwelapha *ischizophrenia* kanye nezinye izinkinga zengqondo ezinamandla, isibonelo, ama*phenothiazines*, *thioxanthenes* kanye namabutyrophenones), *imefloquine* (umuthi wokwelapha umalaleveva), *ibupro-pion* (umuthi wokwelapha ingcindezi yengqondo) kanye ne*tramadol* (umuthi osetshenziselwa ukwelapha izihlungu ezincane kanye nalezo ezinamandla kakhulu) kanye nemithi yokwelapha ingcindezi yengqondo (ama*tricyclics*, ama*SSRIs*) ngenxa yobungozi obunokwenzeka bokwehla komkhawulo wokudlikiza komzimba ngendlela engalawuleki.
- *lflecainide*, *propafenone*, kanye ne*metoprolol* (esetshenziswa ezifweni zenhliziyo); *idesipramine*, *clomipramine*, kanye ne*nortriptyline* (imithi yokwelapha ingcindezi yengqondo); kanye ne*risperidone*, *thioridazine*, kanye ne*haloperidol* (imithi yokwelapha ukugula okuphathelene nokusebenza kwengqondo). Umthamosilinganiso weZYTOMIL kungenzeka kudingeke ukuthi uguqulwe.
- I*St. John's Wort* (*Hypericum perforatum*) – ikhambi elisetshenziselwa ingcindezi yengqondo (bheka isigatshana esithi Qaphela kakhulu uma usebenzisa iZYTOMIL).
- Ungalokothi uphuze utshwala ngenkathi usebenzisa iZYTOMIL.
- Imithi eyehlisa amazinga *epotassium* noma *emagnesium* egazini njengoba kungenzeka iholele ekutheni uphathwe yimithelela engathandeki.
- *Ipimozide*, umuthi wokwelapha ukugula okuphathelene nokusebenza kwengqondo, njengoba kungenzeka uphazamise isigqi senhliziyo (bheka isigatshana esithi Ungalokothi usebenzise iZYTOMIL).
- I-*aspirin* kanye namanon-steroidal anti-inflammatory drugs (imithi esetshenziselwa ukudambisa izihlungu noma ukuvimbela ukushuba kwegazi liphenduke amahlule)



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kungenzeka kukhuphule ubungozi bokopha.

- *Iwarfarin* (umuthi osetshenziselwa ukuvimbela ukushuba kwegazi liphenduke amahlule).

Udokotela wakho kungenzeka ahlole isikhathi esithathwa yigazi lakho ngaphambi kokuthi lijiye ngenkathi uqala kanye nangenkathi uyeka ukusebenzisa iZYTOMIL ukuze aqinisekise ukuthi umthamosilinganiso wakho womuthi ovimbela ukushuba kwegazi usengumthamosilinganiso owanele.

**Ukuphuza iZYTOMIL nokudla kanye nophuzo:**

IZYTOMIL ungayiphuza nokudla noma uyiphuze ngaphandle kokudla.

Gwema ukuphuza utshwala ngenkathi usebenzisa iZYTOMIL (bheka isigatshana esithi Ukusebenzisa eminye imithi ngesikhathi esifanayo neZYTOMIL).

**Ukukhulelwa, ukuncelisa kanye nokuba sesimweni sokuzala nokuthola abantwana**

Uma ukhulelwe noma uncelisa umntwana wakho, bonisana nodokotela wakho, usokhemisi noma omunye ungoti wosizo lwezempilo nokwelashwa ngaphambi kokuba usebenzise iZYTOMIL ukuze uthole ukwelulekwa.

Uma usebenzisa iZYTOMIL sekusondele isikhathi sokuthi ubelethe kungenzeka bukhuphuke ubungozi bokuthi wophe kakhulu esithweni sakho sangasese kancane nje emuva kokubeletha, ikakhulukazi uma unomlando wokuphathwa yizinkinga eziphathelene nokopha. Udokotela wakho noma umbelethisi kumele aziswe ukuthi wena usebenzisa iZYTOMIL ukuze akweluleke.

Akumele usebenzise iZYTOMIL uma ukhulelwe noma uncelisa (bheka isigatshana esithi Ungalokothi usebenzise iZYTOMIL).

**Ukushayela kanye nokusebenzisa imishini:**

IZYTOMIL kungenzeka ikuphazamise ungakwazi ukushayela kahle imoto nokusebenzisa umshini. Qaphela kakhulu uma uzizwa unesiyezi, ukhathele noma wozela ngenkathi usebenzisa iZYTOMIL.

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

**3. Isetshenziswa kanjani iZYTOMIL**

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

**Ingcindezi enkulu yengqondo:**

Umthamosilinganiso ojwayelekile weZYTOMIL ngama-10 mg ophuzwa njengomthamosilinganiso owodwa nsukuzonke. Umthamosilinganiso kungenzeka awukhuphule udokotela wakho ufinyelele kumthamosilinganiso ophelele ongama-20 mg ngosuku, okuzoncika ekutheni umzimba wakho ubonisa umehluko ongakanani emuva kokuqalisa ukwelashwa.

**Izinkinga zokushaywa wuvalo nokufikelwa wukwesaba kungazelelwe okungenzeka  
kuhambisane ne-*agoraphobia* noma kungahambisani ne-*agoraphobia*:**

Umthamosilinganiso weZYTOMIL okumele uwuphuze uma usaqala ukwelashwa ngama-5 mg ophuzwa njengomthamosilinganiso owodwa nsukuzonke evikini lokuqala, ngaphambi kokuthi umthamosilinganiso ukhushulwe ube ngama-10 mg ngosuku. Umthamosilinganiso kungenzeka aphinde futhi awukhuphule udokotela wakho ufinyelele kumthamosilinganiso ophelele ongama-20 mg ngosuku, okuzoncika ekutheni umzimba wakho ubonisa umehluko ongakanani emuva kokuqalisa ukwelashwa.

**Inkinga yokuba netwetwe nexhala ezimweni zomphakathi (*social phobia*):**

Umthamosilinganiso ojwayelekile weZYTOMIL ngama-10 mg ophuzwa njengomthamosilinganiso owodwa nsukuzonke. Udokotela wakho kungenzeka awukhuphule umthamosilinganiso ufinyelele kumthamosilinganiso ophelele ongama-20 mg, okuzoncika ekutheni umzimba wakho ubonisa umehluko ongakanani emuva kokuqalisa ukwelashwa.

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**Inkinga ebeleselayo yokukhathazeka okunamandla futhi okweqile maqondana nezimo kanye nezindaba zansukuzonke:**

Umthamosilinganiso ojwayelekile weZYTOMIL ngama-10 mg ophuzwa njengomthamosilinganiso owodwa nsukuzonke. Umthamosilinganiso kungenzeka awukhuphule udokotela wakho ufinyelele kumthamosilinganiso ophela ongama-20 mg ngosuku, okuzoncika ekutheni umzimba wakho ubonisa umehluko ongakanani emuva kokuqalisa ukwelashwa.

**Inkinga yemicabango engathandeki kanye nomuzwa owenza umuntu enze into ethile ngokuphindaphindekayo (OCD):**

Umthamosilinganiso ojwayelekile weZYTOMIL ngama-10 mg ophuzwa njengomthamosilinganiso owodwa nsukuzonke. Umthamosilinganiso kungenzeka awukhuphule udokotela wakho ufinyelele kumthamosilinganiso ophela ongama-20 mg nsukuzonke, okuzoncika ekutheni umzimba wakho ubonisa umehluko ongakanani emuva kokuqalisa ukwelashwa.

**Izingane kanye namabhungu namatshitshi (aneminyaka engaphansi kwe-18 ubudala):**

IZYTOMIL akumele inikezwe izingane noma amabhungu namatshitshi aneminyaka engaphansi kwe-18 ubudala (bheka isigatshana esithi Ungalokothi usebenzise iZYTOMIL).

Udokotela wakho uzokutshela ukuthi kuzothatha isikhathi eside kangakanani ukwelashwa kwakho ngeZYTOMIL. Ungalokothi uyeke ukudla amaphilisi akho ngaphambi kwesikhathi ngoba kungenzeka uphathwe yimithelela engathandeki.

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

**Uma uphuze iZYTOMIL 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.

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Ngenkathi uyobonisana nodokotela, phatha leli pheshana lolwazi kanye nanoma yimaphi amaphilisi akho asele ukuze azi ukuthi yimaphi amaphilisi owasebenzisile. Uma kwenzekile waphuza umthamosilinganiso oweqile, udokotela wakho uzokwelapha izimpawu zomthamosilinganiso oweqile.

**Izimpawu zomthamosilinganiso oweqile kungenzeka zibandakanye lokhu:**

- ukukhathala okuphakamayo, ubuthakathaka, ubuthongo obunamandla, isiyezi, ukuthuthumela, isicanucanu, ukuphathwa wubuthongo, ukozela futhi kukhuphuke nezinga lokushaya kwenhliziyo.

**Uma kwenzeka ukhohlwa ukuphuza iZYTOMIL:**

Wuphuze ngokushesha umthamosilinganiso ongawuphuzanga. Kodwa uma sekusondele isikhathi sokuphuza umthamosilinganiso olandelayo, qhubeka uphuze umthamosilinganiso olandelayo ngesikhathi esijwayelekile. **Ungalokothi uphuze imithamosilinganiso ephindwe kabili ngenhloso yokuvala isikhala semithamosilinganiso okhohliwe ukuyiphuza.**

**Uma uyeka ukusebenzisa iZYTOMIL**

Ungalokothi uyeke esithubeni nje ukusebenzisa umuthi wakho ngoba lokhu kungaholela ekutheni uphathwe yimithelela engathandeki. Udokotela wakho uzoyalela ukuthi uncishiswe kancane kancane umthamosilinganiso.

Imithelela engathandeki evamise ukubikwa yisiyezi, ukunsonsotha (*amapins and needles*), ubundikindiki, izinkinga zokuphazamiseka kokulala (kubandakanya ukuqwashwa kanye namaphupho amabi), ukuyaluza ungabi nasinqe futhi ube nenhliziyo encane noma itwetwe nexhala, isicanucanu kanye/noma ukuhlanza, ukuthuthumela (ukuqhaqhaazela), ukudideka, ukujuluka, ikhanda elibuhlungu, isifo sohudo, ububhakubhaku benhliziyo (inhliziyi eshaya ngamandla), ukungazinzi kahle ngokwemizwa nomphefumulo, ukucasuka kalula kanye nezinkinga zokungaboni kahle emehlweni. Lezi zigameko ziye zibe yizigameko ezingenawo amandla noma ezimaphakathi ngokwamandla kodwa kwezinye iziguli kungenzeka zibe namandla kakhulu.

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**4. Imithelela engathandeki okungenzeka ibe khona**

IZYTOMIL kungenzeka ibe nemithelela engathandeki.

Akuyona yonke imithelela engathandeki ebikiwe yeZYTOMIL equkethwe kuleli pheshana lolwazi.

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

Uma kwenzeka noma yikuphi kulokhu okulandelayo, yeka ukusebenzisa iZYTOMIL 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

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

- Ukuhuzuka kalula noma ngokweqile, ukopha emanxebeni angajulile noma ukopha isikhathi eside emanxebeni okusikeka, emakhaleni, ezinsinini noma igazi emchameni noma endleni
- Ubuhlungu obuyisimbelambela kanye/noma ukuthuthumela
- Ukuzizwa unomuzwa wokuthakasa noma ukujabula kakhulu, ukukholelwa entweni engekho/engelona iqiniso, ukukhuthala ngokweqile, ubutha, imicabango yokuzibulala (ukucabanga ukuzibulala) kanye nokuziphatha ngendlela ebonisa isifiso sokuzibulala, ukubona izinto ezingekho (imibono nemisindo engajwayelekile)

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- Ukudlikiza komzimba ngendlela engalawuleki (amafithi), ukuqhaqhazela, ukushaya kwenhliziyo ngamandla noma ukushaya kwenhliziyo kancane, ukujuluka kakhulu kunokwejwayelekile, ukudideka, ukuguquguquka kwesimo sengqondo nomphefumulo, imfiva, ukuqhaqhazela okungalawuleki, iminyakazo yamehlo engalawuleki futhi ezenzekelayo, ukufinyela nokudluthuleka okufushane kweqoqwana lemisipha yomzimba, ubunzima bokunyakaza/bokuhamba, ukusebenza kwamalunga omzimba ngendlela exakile futhi engahambelani kahle noma ibhalansi yomzimba exakile futhi engajwayelekile (okwaziwa ngokuthi *yiserotonin syndrome*, ngenxa *yiserotonin* eningi ngokweqile ebuchosheni)
- Ukushaya kwenhliziyo ngokushesha futhi ngesigqi esingahambelani kahle, ukuquleka okungenzeka kube yizimpawu zesifo esingambulala nokumbulala umuntu esaziwa ngokuthi *yitorsades de pointes*, izinhlungu esifubeni
- Ukopha emgudwini wokudla, okunezimpawu ezingabandakanya ukuhlanza igazi elibomvu, ukuhlanza igazi elimnyama, indle enegazi noma indle emnyama
- Ukujika kwesikhumba noma izingxenye ezimhlophe zamehlo kube nombala ophuzi (ijondisi)
- Ubunzima bokuchama, ukungakwazi ukukhipha umchamo ngokuphelele esinyeni.

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

Tshela udokotela wakho uma ubona okunye kwalokhu okulandelayo:

Imithelela engathandeki evamile ukubonakala:

- Ukukhula noma ukuncipha kothando lokudla, ukukhuluphala
- Ukuzizwa unexhala, ukungahlaliseki/ukungabi nasinqe noma isidingo sokuthi ugcogcome, amaphupho axakile futhi angajwayelekile, ukwehla kwelukuluku lokulangazelela ucansi
- ukuphazamiseka kokulala, ukuphathwa wubuthongo, isiyenzi, ukozela, ukungakwazi ukulala, umuzwa wokunsonsotha, ukushisa, ukuncinza (*amapins and needles*), noma ubundikindiki
- Isifo sokuvuvukala kontwentwesana kanye nezimbobo zomoya emakhaleni (*sinusitis*), ukuzamula

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- Isicanucanu, ukuqunjelwa, isifo sohudo, umlomo owomile, ukuhlanza, inkinga yokungagayeki kahle kokudla
- Ukujuluka kakhulu kunokwejwayelekile
- Ubuhlungu emisipheni yomzimba noma emajoyintini omzimba
- Izinkinga eziphathelene nokuya ocansini (ukuthatha isikhathi eside ngaphambi kokuthi uthunde, inkinga yokungaqhanyelwa, ukwehla kwelukuluku lokulangazelela ucansi, futhi abesifazane kungenzeka babe nobunzima bokufinyelela kuvuthondaba)
- Ukukhathala kakhulu, izingakushisa lomzimba eliphakeme (imfiva).

Imithelela engathandeki engavamile ukwenzeka:

- Ukwehla/ukuncipha emzimbeni
- Ukugedla kwamazinyo okwenzeka njalo, okuzenzekelayo futhi okungalawuleki (okuvamise ukwenzeka ngenkathi ulele), ukuzizwa unomuzwa wokuthi uyaluze ungabi nasinqe futhi ube nenhliziyo encane, uvalo, ufikelwe wukwethuka kungazelelwe, uzizwe udidekile, uziphathe ngendlela enobudlova, ukudideka kwengqondo, ukuzizwa usesimweni lapho imicabango yakho kanye nemizwa kungeyona into eyiqiniso ekhona ngokwempela noma ekungeyona eyakho
- Ukuphazamiseka komuzwa wokunambitha, inkinga yokungalali kahle, ukuquleka
- Ukunwebeka kwenhlamvu yeso
- Ukukhala kwemisindo noma izihlonono ezindlebeni
- Ukushaya kwenhliziyo okusheshayo noma okunensayo kunokwejwayelekile
- Ukucinana emakhaleni (ukuvimbana), *ihay fever*, izimpawu ezinjengezomkhuhlane, ukopha emakhaleni
- Izinhlungu esiswini nendawo ezungeze isisu
- Ukuqothuka kwezinswele, ukuguquka kombala wesikhumba okungumphumela wokopha ngaphansi kwesikhumba ngokuvamile okubangelwa wukuhuzuka, ukuqubuka noma amaqhubu abomvu ezandleni, ezinyaweni, ebusweni noma ezithweni zangasese, ama*hives*, ukuluma kwesikhumba

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- Ukopha esibeletweni okungahlobene nokuya esikhathini, ukopha kakhulu ngokungajwayelekile noma ukopha isikhathi eside ngenkathi usesikhathini
- Ukugcwala nokunqwabelana kwamanzi emzimbeni.

Le mitholela elandelayo ibikiwe kodwa akwaziwa ukuthi ivamise kangakanani ukwenzeka:

- Ukopha kakhulu esithweni sangasese sowesifazane kancane nje emuva kokubeletha (*postpartum haemorrhage*), bheka isigaba sesi-2 ukuze uthole ulwazi oluthe xaxa
- Amazinga aphantsi esodium egazini (okungaholela ekutheni ube nokudideka, ukudlikiza komzimba ngendlela engalawuleki, ukukhathala kakhulu kanye namazinga aphantsi okuhlala uphapheme ubona konke okwenzekayo eduze kwakho), ukuphelelwa wuthando lokudla
- Ikhandela elibuhlungu, ubunzima bokugxilisa ingqondo, ukuzizwa ungaphathekile kahle, uzizwe ugula noma uzwe kunokuthile okungalungile emzimbeni okwenza ungakhululeki neze kahle, ubunzima bokulawula iminyakazo, ukudikiza noma iminyakazo exakile futhi engajwayelekile engalawuleki
- Ukubona ngendlela efiphele noma exakile futhi engajwayelekile
- Umfutho wegazi ophantsi (ukuzizwa unenzululwane noma isiyenzi lapho usukuma uma ngezinyawo)
- Ukugxiza amathe
- Ukuvuvukala kwesibindi
- Umzimba obuthakathaka ngendlela engajwayelekile noma ukungabi namandla
- Ukukhiqizeka ngokweqile futhi ngendlela engafanele kobisi lwebele, inkinga ebeleselayo yokuqhanyelwa okubuhlungu.

Uma ubona noma yimiphi eminye imitholela engathandeki engabhalwe kuleli pheshana lolwazi, tshela udokotela wakho noma usokhemisi.

**Ukubika imitholela engathandeki**



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Uma uphathwa yimithelela engathandeki, khuluma nodokotela wakho noma usokhemisi. Lokhu kubandakanya ngisho naleyo mithethelela engathandeki okungenzeka ikuphathe kodwa engabhaliwe kuleli pheshana. Futhi ungayibika imithelela engathandeki kwabakwaSAHPRA ngokusebenzisa ifomu lokubika imithelela engathandeki ("**6.04 Adverse Drug Reporting Form**"), elitholakala kuwebhusayithi yabakwaSAHPRA: [www.sahpra.org.za](http://www.sahpra.org.za) ngaphansi "kwezinsizakalo ezitholakala nge-inthanethi" ("*online services*"). Ngokubika imithelela engathandeki, ungalekelela ekuhlinzekweni kolwazi oluthe xaxa maqondana nokuphepha kweZYTOMIL.

### **5. Indlela yokugcina iZYTOMIL**

Yonke imithi kumele uyigcine endaweni ezingafinyeleli kuyona izingane.

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

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

Wagcine evalwe ngci amabhodlela amaphilisi.

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 yiZYTOMIL**

ZYTOMIL 5 mg: Iphilisi ngalinye elinongwengwezi liqukethe i-*escitalopram oxalate* elingana ne-*escitalopram* engama-5 mg.

ZYTOMIL 10 mg: Iphilisi ngalinye elinongwengwezi liqukethe i-*escitalopram oxalate* elingana ne-*escitalopram* engama-10 mg.

ZYTOMIL 15 mg: Iphilisi ngalinye elinongwengwezi liqukethe i-*escitalopram oxalate* elingana ne-*escitalopram* engama-15 mg.

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ZYTOMIL 20 mg: Iphilisi ngalinye elinongwengwezi iqukethe i-*escitalopram oxalate* elingana ne-*escitalopram* engama-20 mg.

**7. Ezinye izithako yilezi:**

*Colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl methyl-cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, talc, titanium dioxide.*

**8. Indlela ebukeya ngayo iZYTOMIL kanye nalokho okuqukethwe ephaketheni layo**

ZYTOMIL 5 mg: Iyiphilisi elimhlophe, elimise okweqanda, elinongwengwezi oluvikela iphilisi lingancibilikaliswa yi-esidi esiswini, eliqoshwe umbhalo onohlamvu “E” kanye no“C” ohlangothini olulodwa kanti ngakolunye uhlangothi akubhaliwe lutho.

ZYTOMIL 10 mg: Iyiphilisi elimhlophe, elimise okweqanda, elinongwengwezi oluvikela iphilisi lingancibilikaliswa yi-esidi esiswini, eliqoshwe umbhalo onohlamvu “E” kanye no“C” ohlukaniswe ngumugqa onqamula phakathi ohlangothini olulodwa kanti ngakolunye uhlangothi kubhalwe inamba “10”.

ZYTOMIL 15 mg: Iyiphilisi elimhlophe, elimise okweqanda, elinongwengwezi oluvikela iphilisi lingancibilikaliswa yi-esidi esiswini, eliqoshwe umbhalo onohlamvu “E” kanye no“C” ohlangothini olulodwa kanti ngakolunye uhlangothi akubhaliwe lutho.

ZYTOMIL 20 mg: Iyiphilisi elimhlophe, elimise okweqanda, elinongwengwezi oluvikela iphilisi lingancibilikaliswa yi-esidi esiswini, eliqoshwe umbhalo onohlamvu “E” kanye no“C” ohlukaniswe ngumugqa onqamula phakathi ohlangothini olulodwa kanti ngakolunye uhlangothi kubhalwe inamba “20”.

IZYTOMIL igcinwe kwizingqwenjana ezingumsweswana eziyizigcinamaphilisi ezakhiwe ngefoyela le-*aluminium* eliqinile elinombala osiliva / iPVC/PVDC noma iPVC/PE/PVDC ecacile, eziqukethe amaphilisi ama-3 X 10 kuqwenjana ngalunye, angaphakathi kwebhokisana likakhadibhodi.

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IZYTOMIL ifakwe futhi emabhodleleni eHDPE amhlophe anepolyester *pharmcoil*

enesimuncaketshezi kanye nesivalo esimhlophe esikulufwayo sohlobo lwePP aqukethe amaphilisi angama-30 ngaphakathi.

**9. Umnikazi Wesitifiketi Sokubhaliswa**

Pharma Dynamics (Pty) Ltd

1<sup>st</sup> Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Inamba yocingo: 021 707 7000

**10. Leli pheshana lolwazi lagcina ukubuyezwa mhla ziyi-**

14 kuNhlangulana 2021

**11. Izinamba zokubhaliswa**

ZYTOMIL 5 mg: A42/1.2/0911

ZYTOMIL 10 mg: A42/1.2/0912

ZYTOMIL 15 mg: A42/1.2/0913

ZYTOMIL 20 mg: A42/1.2/0914

**NAMIBIA:**

ZYTOMIL 10 mg: NAM NS3 10/1.2/0479

ZYTOMIL 20 mg: NAM NS3 10/1.2/0481

**MOZAMBIQUE:**

ZYTOMIL 10: N5935

ZYTOMIL 20: N5936