

**IPHESHANA ELIQUKETHE ULWAZI OLUQONDENE NESIGULI
DYNA-LAMOTRIGINE 25/50/100/200 mg**

ISIMO SESHEDULI YOKUPHEPHA NOBUNGOZI BOMUTHI:

S3

IGAMAKUHWEDA LOMKHIQIZO KANYE NESIMO SOMTHAMOSILINGANISO

DYNA-LAMOTRIGINE 25 mg, amaphilisi

DYNA-LAMOTRIGINE 50 mg, amaphilisi

DYNA-LAMOTRIGINE 100 mg, amaphilisi

DYNA-LAMOTRIGINE 200 mg, amaphilisi

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

1. OKUQUKETHWE YI-DYNA-LAMOTRIGINE:

Isithako sokwelapha esiyinhloko esiqukethwe lapha yi*lamotrigine*.

Ezinye izithako yi-*ethanol absolute, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate*.

IDYNA-LAMOTRIGINE iqukethe ushukela (*ilactose monohydrate*) ngokomthamo olandelayo:

DYNA-LAMOTRIGINE 25 mg (24,70 mg)

DYNA-LAMOTRIGINE 50 mg (49,40 mg)

DYNA-LAMOTRIGINE 100 mg (98,80 mg)

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DYNA-LAMOTRIGINE 200 mg (197,60 mg)

2. IDYNA-LAMOTRIGINE ISETSHENZISELWA UKWELAPHA LOKHU:

- Amaphilisi iDYNA-LAMOTRIGINE asetshenziselwa ukwelapha izinhlobo ezihlukahlukene zesithuthwane (isifo sokuwa), kubandakanya ukudlikiza komzimba okungalawuleki nokuquleka okuhlobene nengxubezimpawu yesifo i*Lennox-Gastaut syndrome*.
- Amaphilisi iDYNA-LAMOTRIGINE asetshenziselwa ukwelapha isifo sengcindezi yengqondo esiyinjikanamizwa, phecelezi, *bipolar disorder (imanic depression)*, futhi amaphilisi aqondiswe ikakhulukazi, kulezo zikhathi zengcindezi yengqondo eyenzeka ku*bipolar disorder*.

3. NGAPHAMBI KOKUBA UTHATHE IDYNA-LAMOTRIGINE:

Ungalokothi uthathe iDYNA-LAMOTRIGINE:

- uma umzimba wakho ungezwani nesithako i*lamotrigine* noma ungezwani nanoma yisiphi esinye isithako seDYNA-LAMOTRIGINE (bheka ingxenye ethi LOKHO OKUQUKETHWE YIDYNA-LAMOTRIGINE).

Qaphela kakhulu uma usebenzisa iDYNA-LAMOTRIGINE:

- tshela udokotela wakho ngokushesha uma umzimba wakho uba nokuqubuka kwesikhumba noma uba nanoma iyiphi inkombasifo noma uphawu olubonisa ukuthi umzimba wakho awuzwani namaphilisi akho, isibonelo, imfiva, ubuso obuvuvukele, izimpawu ezinjengezomkhuhlane, izinhlungu, ubuhlungu noma ukuvuvukala endaweni ezungeze isibindi engxenye engasenhla kwesisu, izindlala ezivuvukele, isikhumba esiphuzi noma amehlo aphuzi, ukopha okungajwayelekile, noma izinkinga zokungasebenzi kahle kohlelo lwezinzwa emzimbeni ezinjengokudlikiza komzimba okungalawuleki nokuquleka, inkinga yokuhamba, ubunzima bokubona noma okunye ukuphazamiseka kokusebenza kwamehlo. Udokotela wakho uzokuxilonga emzimbeni, enze ukuhlolwa kwegazi kanye nezinye izinhlobo zokuhlolwa ukuze

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athole ukuthi awunayo yini *hemophagocytic lymphohistiocytosis* (HLH), okusho ukuphazamiseka kohlelo lwamasosha omzimba okubucayi kakhulu okungabangelwa yiDYNA-LAMOTRIGINE.

- kumele uqaphele kakhulu uma unemicabango yokuzilimaza noma yokuzibulala.
- tshela udokotela wakho uma usuqala ukusebenzisa noma uma usuyeka ukusebenzisa izivimbelenzalo ezilawula izigqa zomzimba (amahomoni), ezinjengePhilisi Lokuvimbela Inzalo.
- ungalokothi uyeke esithubeni nje ukusebenzisa amaphilisi akho.

Ukuphuza iDYNA-LAMOTRIGINE nokudla kanye nophuzo:

Gwema ukuphuza utshwala. Ukudla akunawo umthelela ekusebenzeni kweDYNA-LAMOTRIGINE.

Ukukhulelwa kanye nokuncelisa:

Akuqinisekiswa ukuphepha kwamaphilisi kumuntu okhulelwe noncelisayo, ngakho-ke ungayisebenzisi iDYNA-LAMOTRIGINE uma ukhulelwe noma uncelisa.

Uma ukhulelwe noma uncelisa umntwana wakho, bonisana nomhlinzeki wakho wosizo lwezempilo nokwelashwa ukuze akweluleke ngaphambi kokuba uqale ukusebenzisa iDYNA-LAMOTRIGINE.

Ukushayela kanye nokusebenzisa imishini:

IDYNA-LAMOTRIGINE ingakwenza ube nesiyezi futhi yenze ukuthi ubone sengathi into eyodwa iphindaphindeke kabili. Kumele ulinde futhi ubheke ukuthi iDYNA-LAMOTRIGINE ikuphatha kanjani wena emzimbeni ngaphambi kokuba ushayele imoto noma usebenzise imishini.

Ulwazi olubalulekile mayelana nezinye zezithako zeDYNA-LAMOTRIGINE:

IDYNA-LAMOTRIGINE iqukethe uhlobo lukashukela wobisi olubizwa nge/*actose*. Iziguli ezinezifo zofuzo ezingavamile zokuhluleka komzimba ukugaya ushukela wobisi akumele ziyisebenzise iDYNA-LAMOTRIGINE.

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IDYNA-LAMOTRIGINE iqukethe ushukela wobisi ongaba nomthelela ekulawulekeni koshukela egazini lakho uma ungumuntu onesifo sikashukela.

Ukusebenzisa eminye imithi ngesikhathi esifanayo neDYNA-LAMOTRIGINE:

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

Kuyinto esemqoka kakhulu ukuthi umtshela umhlinzeki wakho wosizo lwezempilo nokwelashwa uma kukhona nanoma yimuphi owusebenzisayo kule mithi elandelayo:

- eminye imithi yokwelapha isithuthwane (*iphenytoin, carbamazepine, phenobarbitone* kanye ne *primidone*)
- isinqindamandlamagciwane kumbe i-antibhayothikhi (*irifampicin*)
- imishanguzo yokudodobalisa isandulelangculazi (*ilopinavir/ritonavir* kanye ne-*atazanavir/ritonavir*)
- *ivalproic acid*, esetshenziselwa ukwelapha isithuthwane (ukudlikiza komzimba okungalawuleki nokuquleka, okubizwa ngamafithi)
- amaphilisi okuvimbela inzalo aphuzwayo, njengePhilisi Eliyisivimbelinzalo, phecelezi, *Pill* (isibonelo, *i-ethinyloestradiol* kanye ne *levonorgestrel*).

4. ISETSHENZISWA KANJANI IDYNA-LAMOTRIGINE:

Ungalokothi wabelane nanomi yimuphi omunye umuntu ngemithi onikezwe yona ngumhlinzeki wakho wezempilo nokwelashwa ngoba iqondene nawe kuphela.

Kumele njalo iDYNA-LAMOTRIGINE uyiphuze ncimishi ngendlela akuyalele ngayo udokotela wakho. Kumele ubuze udokotela wakho noma usokhemisi uma ungaqinisekile.

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Udokotela wakho uzokunikeza amaphilisi anomthamosilinganiso ophansi ngenkathi usaqala ukuwasebenzisa bese ewukhuphula kancane kancane uze uyofinyelela kumthamosilinganiso okulungele futhi okusebenzelayo.

Amaphilisi wagwinye namanzi amancane.

Udokotela wakho uzokutshela ukuthi kuzothatha isikhathi eside kangakanani ukwelashwa kwakho ngeDYNA-LAMOTRIGINE. Ungalokothi uyeke esithubeni nje ukusebenzisa amaphilisi akho.

Udokotela wakho uzokutshela ukuthi uzokuyekisa kanjani ukudla amaphilisi.

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

Uma uphuze i-DYNA-LAMOTRIGINE engaphezulu kwaleyo okumele uyiphuze:

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

Izinkombasifo kanye nezimpawu zokweqiswa komthamosilinganiso wamaphilisi zibandakanya, ukunyakaza kwamehlo ngendlela esheshayo futhi okuzenzekelayo nokungalawuleki, ukuhluleka ukulawula ngokuphelele iminyakazo yomzimba, ukuhluleka ukuqaphela nokubona izimo ezikuzungezile nalokho okwenzekayo, ukufinyela kwemisipha yomzimba okunamandla amakhulu.

Uma kwenzeka ukhohlwa ukuphuza umthamosilinganiso weDYNA-LAMOTRIGINE:

Ungalokothi uphuze imithamosilinganiso yamaphilisi ephindwe kabili ngenhloso yokuvala isikhala semithamosilinganiso yamaphilisi okhohliwe ukuwaphuza. Qhubeka uphuze iphilisi elilandelayo ngesikhathi esijwayelekile. Uma unenkinga yokukhumbula ukuthi kumele uyiphuze nini imithi yakho, cela usokhemisi wakho akuphe amacebo azokusiza ukuthi ukhumbule.

5. IMITHELELA ENGATHANDEKI OKUNGENZEKA IBE KHONA:

IDYNA-LAMOTRIGINE kungenzeka ibe nemithelela engathandeki emzimbeni.

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

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

- izimpawu zokuphazamiseka kakhulu kohlelo lwamasosha omzimba *hemophagocytic lymphohistiocytosis* (HLH), okubonakala ngemfiva, ukuhluleka ukusebenza kwezitho zomzimba eziningi, izinhlungu, ubuhlungu noma ukuvuvukala phezu kwendawo ezungeze isibindi engxenyeni engasenhla kwesisu, izindlala ezivuvukele, ukuqubuka kwesikhumba, isikhumba esiphuzi noma amehlo aphuzi, ukopha okungajwayelekile, noma izinkinga zokungasebenzi kahle kohlelo lwezinzwa emzimbeni ezinjengokudlikiza komzimba okungalawuleki nokuquleka, inkinga yokuhamba, ubunzima bokubona noma okunye ukuphazamiseka kokusebenza kwamehlo.
- *i-angioedema* (inkinga yokuphefumula, ukuvuvukala ebusweni, emlonyeni, ezandleni noma ezinyaweni).

Konke lokhu kuyimithelela engathandeki ebucayi kakhulu futhi enobungozi. Uma unayo le mithelela, kusho ukuthi kunokwenzeka ukuthi umzimba awuzwananga neze neDYNA-LAMOTRIGINE oyisebenzisile. 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:

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- izifo zegazi (ezizibonakalisa ngombala wesikhumba ophaphathekile, ubuthakathaka bezicubu zomzimba, ukugula nokuhlaselwa yizifo njalo, ukuzizwa ungaphilile neze emzimbeni wonke)
- ukopha ezindaweni eziningi, imihuzuko, imfiva
- *ipancytopenia* (ebonakala ngokuhlaselwa yizifo, izinkinga zokopha, inhliziyo eshaya ngamandla, isikhumba esiphaphathekile)
- *iseptic shock* (ebonakala ngezingakushisa lomzimba eliphakeme noma eliphansi kakhulu, umzimba ogodolayo, ukuphathwa isiyenzi uma ume ngezinyawo, ukushaya kwenhliziyo ngamandla)
- ukwanda kokuhlaselwa yizigameko zokudlikiza komzimba nokuquleka (amafithi)
- isifo sokuvuvukala kolwelwesi lobuchopho okungabangeliwe ngamagciwane, phecelezi, *non-bacterial meningitis* (esibonakala ngemfiva, umzimba ogodolayo, ikhanda elibuhlungu, ukuhlanza, ukuphelelwa wuthando lokudla)
- izinkinga zesibindi (ezibonakala ngesicanucanu, ukuphelelwa wuthando lokudla, ukukhathala okukhulu, isifo sohudo, ukujika kwesikhumba noma amehlo kube nombala ophuzi)
- *Stevens-Johnson syndrome* (isifo esibucayi futhi esinobungozi esibonakala ngokuvela kwamabhamuza esikhunjeni, emlonyeni, emehlweni kanye nasezithweni zangasese, ukuqubuka kwesikhumba).

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

Tshela udokotela wakho ngokushesha uma ubona okunye kwalokhu okulandelayo:

Imithelela engathandeki evamile ukubonakala:

- ulaka, ukucasuka kalula, ukudideka
- ikhanda elibuhlungu, ukungakwazi ukulala (ukungafikelwa ubuthongo), isiyenzi, ukozela, ukuthuthumela, ukuyaluza ungabi nasinqe futhi ube nenhliziyo encane

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- *iparaesthesia* (ukuhlaba, ukunwayizela, ukuluma, ukubaba noma ukubanda kwesikhumba), *i-ataxia* (ukuhluleka nokungakwazi ukulawula iminyakazo yomzimba)
- izinkinga zokubona kubandakanya ukubona ngendlela efiphele kanye nokubona sengathi into eyodwa iphindaphindeke kabili, ukunyakaza kwamehlo ngokushesha okungalawuleki futhi okuzenzekelayo
- ukuzizwa sengathi uyagula (isicanucanu) noma-ke ukuhlaselwa wukugula (ukuhlanza)
- ukuqubuka okukhulu kwesikhumba
- ubuhlungu bamalunga omzimba, ubuhlungu bemisipha kanye nobuthakathaka emzimbeni
- ukwehla emzimbeni, ukukhathala, ubuhlungu bomhlane, umlomo owomile.

Imithelela engathandeki engavamile ukwenzeka:

- ukugula okuphathelene nenkinga yezindlala (kungenzeka uphathwe yimfiva noma ujuluke ebusuku, uzizwe ukhathele kakhulu kunokujwayelekile, ube nesigaxa esibuhlungu esifudumele noma esibomvu ngaphansi kwesikhumba sakho)
- ukubona izinto ezingekho, ukudluthuleka okungalawuleki (inkwantshu ebusweni)
- itwetwe nexhala, ingcindezi yengqondo, ukukhohlwa, ukuyaluza ungabi nasinqe futhi ube nenhliziyo encane, ukukhuluma unambuluke futhi unkwankwaze kungazwakali kahle okushoyo
- uphenyane (isifo samehlo esithathelwanayo)
- *irhinitis* (ukucinana emakhaleni, amafinyila, ukuthimula), isilungulela, ukuhluleka ukuphefumula okwesikhashana ngenkathi ulele
- ukuqunjelwa, isifo sohudo, inkinga yokungagayeki kahle kokudla
- ukuqubuka esikhunjeni, ukuqothuka kwezinwele
- imfiva, ukuzizwa ungaphathekile kahle emzimbeni wonkana/ukuzizwa ugula (ubuthakathaka nokucobeka komzimba), ukuzwela kwamehlo ngokwedlulele uma ehlangana nokukhanya, izimpawu ezinjengezomkhulane.

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Imithelela engathandeki okungaziwa ukuthi ivamise kangakanani ukwenzeka:

- amaphupho amabi
- ukukhwehlela okomile okungenaso isikhwehlela
- ukuphuka kwamathambo, ukukhula kancane noma ukuthuthuka kancane kunokujwayelekile (lokhu kuhambisana nokwelashwa isikhathi eside).

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

6. UKUGCINWA NOKUL AHLWA KWEDYNA-LAMOTRIGINE:

Amaphilisi wacine ephaketheni noma kwibhokisana afike nalo ezingeni lokushisa elingama-25 °C noma ngaphansi kwalokho.

Wavikele kumswakama nokukhanya.

Ungawakhiphi kuqwenjana oluyisigcinamaphilisi kuze kufike isikhathi lapho sekudingeka ukuba uwasebenzise.

Yonke imithi kumele uyigcine endaweni ezingafinyeleli kuyona izingane.

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).

7. UKWETHULWA KWEDYNA-LAMOTRIGINE:

IDYNA-LAMOTRIGINE 25 mg, 50 mg, 100 mg kanye ne-200 mg itholakala kumaphakeshana aqukethe izingqwenjana eziyizigcinamaphilisi akhiwe nge *PVC/Aluminium* anamaphilisi angama-60; okungamaphilisi ayi-10 kuqwenjana oluyisigcinamaphilisi ngalunye.

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8. UKUHLONZWA KWEDYNA-LAMOTRIGINE:

DYNA-LAMOTRIGINE 25 mg: Ingamaphilisi anombala ophuzi ngokuphaphathekile (*beige*),

ayindingiliza, ayisicaba, anezinhlamvu “MC” eziwugqinsi futhi anobubanzi obungama-6,0 mm

DYNA-LAMOTRIGINE 50 mg: Ingamaphilisi anomugqa owenza aqhephuleke kalula, anombala

ophuzi ngokuphaphathekile, ayindingiliza, ayisicaba futhi anobubanzi obungama-8,0 mm

DYNA-LAMOTRIGINE 100 mg: Ingamaphilisi anomugqa owenza aqhephuleke kalula, anombala

ophuzi ngokuphaphathekile, ayindingiliza, ayisicaba futhi anobubanzi obungama-9,5 mm

DYNA-LAMOTRIGINE 200 mg: Ingamaphilisi anomugqa owenza aqhephuleke kalula, anombala

ophuzi ngokuphaphathekile, ayindingiliza, ayisicaba futhi anobubanzi obungama-12,7 mm

9. IZINAMBA ZOKUBHALISWA:

DYNA-LAMOTRIGINE 25 mg: A40/2.5/0173

DYNA-LAMOTRIGINE 50 mg: A40/2.5/0169

DYNA-LAMOTRIGINE 100 mg: A40/2.5/0166

DYNA-LAMOTRIGINE 200 mg: A40/2.5/0167

10. IGAMA, IKHELI LENKAMPANI KANYE NENAMBA YOCINGO YOMNIKAZI

WESITIFIKETI SOKUBHALISWA:

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Inamba yocingo: + 27 21 707 7000

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11. USUKU LOKUSHICILELWA:

Usuku lokubhaliswa: 18 Mbaso 2008

Usuku lokugunyazwa kwakamuva: 03 Mbaso 2020

DYNA-LAMOTRIGINE 25 mg: NAM NS2 08/2.5/0177

DYNA-LAMOTRIGINE 50 mg: NAM NS2 08/2.5/0178

DYNA-LAMOTRIGINE 100 mg: NAM NS2 08/2.5/0179

DYNA-LAMOTRIGINE 200 mg: NAM NS2 08/2.5/0180