

madopari®

levodofa + benserazidi

1. aRweriloba

1.1 Terapiul-farmakologiuri kuTvniloba

ATC kodi: N04BA.

madopari warmoadgens levodopasa da benserazidis kombinirebul parkinsonis daavadebis sawinaaRmdego preparats.

1.2 dozirebis forma

standartuli formebi:

madoparis kafsulebi 62, 5, 125, 250 mg-iani

madoparis jvaredindanayofebiani tabletebi-125, 250 mg

dispersuli formebi:

madoparis dispersuli tabletebi 62.5, 125 mg

kontrolirebuli gamonTavisuflebis formebi: madoparis HBS (hidrodinamikurad balansirebuli sistema) kafsulebi 125mg

1.3 miRebis gza -peroraluri.

1.4 Tvisobrivi da raodenobrivi Semadgenloba

madopari warmoadgens levodofasa da dekarosilazas

inhibitoris -benserazidis (benserazidis hidroqloridis)

kombinacias dozis TanafardobiT 4:1. arsebobs madoparis

Semdegi Semadgenlobebi:

Mmadopari '62.5' = levodofa 50 mg + benserazidi 12.5 mg
madopari '125' = levodofa 100 mg + benserazidi 25 mg
madopar '250' = levodofa 200 mg + benserazidi 50 mg

2. Terapiuli maxasiaTeblebi:

2.1 Terapiuli Cvenebebi : madopari naCvenebia parkinsonis daavadebis samkurnalod

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dispersiuli formis madopari mizanSewonilia pacientebSi disfagiiT (ylapvis gaZnelebiT) an im SemTxvevebSi, rodesac saWiroa moqmedebis adreuli dasawyisi, anu avdmyofebSi akineziiT dilis saaTebSi da dRis meore naxevarSi, aseve avadmyofebSi ~dagvianebis~ da ~gaTiSvis~ fenomeniT. madopari HDS naCvenebia avadmyofebSi levodopas moqmedebis nebismieri cvalebadobis tipiT (kerZod, ~dozis pikis diskinezia~ da ~dozis damTavrebis fenomeni~, magaliTad, umoZraoba RamiT).

2.2 dozireba da miRebis wesi:

madopariT mkurnaloba iwyeba TandaTanobiT, individualurad SerCeuli dozebiT. madoparis kafsulebs iReben mTlianad, dauReWavad. xolo tabletebi daqucmacdeba ylapvis gaadvilebisaTvis.

madoparis swrafad moqmedi tabletebi ixsnaba 25-50ml wyalSi. tabletebi ixsnaba srulad ramdenime wuTSi rZisferi xsnaris warmoqmniT. radganac swrafad warmoiqmneba naleqi, miRebis win aucilebelia xsnaris moreva. swrafad xsnadi madoparis miReba xdeba araugvianes 30 wuTisa gaxsnis Semdeg. madopari iniSneba 30 wuTiT adre Wamamde an Wamidan 1 saaTis Semdeg. madoparis miRebiT gamowveuli mosalodneli arasasurveili gastro-intestinaluri efeqtetbis Tavidan asacileblad,ZiriTadad mkurnalobis pirvel etapze, rekomendirebulia preparatTan erTad mcire zomis lukmis (mag. biskvitis) an siTxis miyoleba, aseve madoparis dozis TandaTanobiT gazrda.

dozirebis standartuli rejimi

madopariT standartuli rejimiT mkurnalobisas rekomendirebulia dozis TandaTanobiT gazrda, dozis individualuri titracia optimaluri Sedegis miRebamde. qvemoTmoyvanili dozirebis instruqciebi SesaZlebelia gamoyenebuli iqnas madopariT mkurnalobis rekomendaciad

sawyisi mkurnaloba

parkinsonis daavadebis adreul stadienze mkurnalobis dawyeba rekomendirebulia 62.5mg madoparis kafsulebiT an naxevari 125mg-iani tabletiT 3-4 jer dReSi. preparatis kargi amtanobis SemTxvevaSi, doza TandaTanobiT izrdeba avadmyofis reaqqiis mixedviT. Cveulebriv optimaluri efeqti miiRweva levodofa 300-800 mg+benserazidi 75-200 mg dReRamuri dRe-Ramuri dozis 3 jerad an metad miRebisas.

optimaluri efeqtis misaRebad saWiroa 4-6 kvira. dReRamuri dozis Semdgomi gazrda warmoebs 1 Tvis intervaliT.

SemamarCunebeli Teropia

madoparis saSualo SemamarCunebeli doza Seadgens 125mg-s 3-6 jer dReSi. miRebis jeradoba (aranakleb 3-sa) da maTi ganawileba DdRis ganmavlobaSi unda iZleodes maqsimalur efeqts. efeqtis optimizaciisaTvis SesaZlebelia Cveulebrivi madoparis Secvla dispergirebul an HHDS madopariT.

2.2.1 dozireba gansakuTrebul SemTxvevaSi

avadmyofebma, romlebic iReben parkinsonis daavadebis sawinaaRmdego sxva preparatebs, SeiZleba miiRon madoparic. mxolod madopariT mkurnalobis gagrZelebisas da misi Terapiuli efeqtis gamovlenisas SeiZleba gaxdes saWiro sxva preparatebis dozis Semcireba an maTi moxsnis aucilebloba.

Tu avadmyofs dRis ganmavlobaSi aReniSneba preparatis moqmedebis meryeoba ~CarTva-gamorTva~ fenomenis saxiT, rekomendebulia preparatis mcire dozebis xSiri miReba, an upiratesad _ madopari hds-s daniSvna.

es preparati iniSneba meore dRidan, dilidan. preparatis doza da miRebis sqema rCeba igive, rac Cveulebrivi madoparis daniSvnis dros.

2-3 dRis Semdeg preparatis doza izrdeba 50%-iT. aucilebelia avadmyofebis gafrTxileba imis Sesaxeb, rom maTi mdgomareoba SeiZleba gauaresdes. madopari hds moqmedebis mogvianebiT. klinikuri efeqti aRiniSneba ufro swrafad, Tu daniSneba madopari hds-i Cveulebriv kafsulebTan erTad an swrafad moqmed tabletebTan. es gansakuTrebiT sasargebloa pirveli dilis dozis dros, romelic ufro didia, vidre Semdgomi dozebi. madopari hds-s individualuri dozis SerCeva xdeba TandaTanobiT, xolo intervali Secvlil dozebs Soris Seadgens 2-3 dRes. avadmyofebSi Ramis simptomatikiT dadebiTi efeqti aRiniSneba madopari hds-s saRamos dozis gazrdiT 250mg-mde Zilis win.

madopari hds-s gamoxatuli efeqtis dros (diskinezia) mizanSewonilia intervalis gazrda dozebs Soris, vidre Semcirdes erTjeradi doza. Tu madopari hds-i araefekturia, rekomendebulia mkurnaloba gagrZeldes Cveulebrivi an swrafad moqmedi madopariT.

mosalodneli arasasurveli fsiqiatრიული simpomebis gamo rekomendirebulia pacintebze mkacri kontroli.

2.3 winaaRmdegCvenebebi:

momatebuli mgrZnobeloba preparatis mimarT;

ar SeiZleba madoparis daniSvna mao-s araseleqtiur inhibitorebTan. rac Seexeba mao-B-s seleqtiur inhibitorebs, magaliTad, selegilins da mao-A seleqtiur inhibitorebs, magaliTad, moklobeds, isini winaaRmdegnaCvenebebi ar aris.

mao-A-s da mao-B-s inhibitorebis kombinireba equivalenturia mao-s araseleqtiuri daTrgunvisa, amitom aseTi kombinaciis daniSvna erTdroulad madoparTan miuRebelia.

madopari ar iniSneba avadmyofebSi endokrinuli organoebis, RviZlis, Tirkmelebis, gul-sisxlZarRvTa sistemis funqciis darRveviT, fsiqური daavadebebis dros fsiqozuri komponentiT da daxurulkuTxovani glaukomiT.

preparati ar iniSneba avadmyofebSi 25 wlamde (unda iyos dasrulebuli Zvlovani ConCxis ganviTareba).

madopari ar iniSneba orsulebSi an qalebSi reproduqciul asakSi, romlebic ar iyeneben kontracepciis sando meTodebs. Tu madoparis miRebis fonze ganviTarda orsuloba, preparatis miReba unda Sewydes.

2.4 gafrTxileba da gafrTxilebis zomebi:

2.4.1 zogadi sifrTxilis zomebi: avadmyofebSi momatebuli mgrZnobelobiT Sesazlebelia Sesabamisi reaqciebis ganvitareba.

avadmyofebSi RiakuTxovani glaukomiT rekomendebulia Tvalis Sida wnevis regularuli kontroli, radganac levodofas SeuZlia Tvalis Sida wnevis gazrda.

depresia parkinsonis daavadebis klinikur suraTis Semadgeneli nawilia da Sesazloa gamovlindes madopariT mkurnalobisas.

levodofas miRebisas zogadi anesteziis dros (garda halotaniT anesteziisa), rekomendirebulia misi gagrzeleba operaciande. halotaniT anesteziisas madoparis miReba wydeba qirurgiul Carevamde 12-48 saatIT adre, vinaidan madopari halotaniT narkozis dros iwvevs arteriuli wnevis cvalebadobas da aritmias. operaciis Semdeg xdeba mkurnalobis ardgena operaciande periodis donemde.

madoparis mkvetri moxсна dauSvebelia. aman SeiZleba gamoiwvios ~avTvisebiani neirolefsiuri sindromi~ (temperaturis momateba, kunTebis rigidoba, aseve Sesazlebelia fsiqiuri cvlilebebi da kreatinfosokinazas momateba sisxlis Sratsi), rac SeiZleba saxifaTo iyos sicocxlisavis. misi ganvitarebisas avadmyofi imyofeba eqimis meTvalyureobis qveS (aucileblobis SemTxvevaSi hospitalizacia) da utardeba saTanado simptomuri mkurnaloba, rac gulisx mobs madoparis ganmeorebit daniSvnas avadmyofis mdgomareobis Sesabamisi Sefasebis Semdeg.

levodofas miRebas Tan axlavs somnolencia da uecari CaZinebis epizodebi. uecari CaZinebis epizodebi gamafrTxilebeli wina simptomebis gareSe Cveulebrivi dRiuri aqtivobisas Zalian iSviaTia. levodofas miRebisas pacientebi gavrTxilebuli unda iyvnen amis Sesaxeb da erCioT yuradRebis gavarjiSeba saWis marTvis da manqana-danadgarebTan muSaobisas. somnolenciis an/da uecari CaZinebis epizodebis arsebobis SemTxvevaSi ar SeiZleba saWis marTva da manqana-danadgarebTan muSaoba. winaaRmdeg SemTxvevaSi, unda Semcirdes levodofas doza. (ix. 2.4.3)

dofaminerguli preparatebi: parkinsonism daavadebis samkurnalod gamoyenebuli dofaminerguli preparatebisaTvis damaxasiaTebelia paTologiuri azartuloba, libidosa da seqsualobis mateba. Ramdenadac madopari ar warmoadgens dofaminis agonists, ar aris cnobili mizezobrivi kavSiri zemoTaRniSnul simptomebsa da madoparis miRebas Soris, Tumca ramdenadac madopari dofaminerguli preparatia, misi daniSvnisas rekomendirebulia sifrTxile.

2.4.2. preparatis borotad moxamareba da wamaldamokidebuleba.

parkinsonis daavadebis mqone pacientebis mcire qvejgufSi ariniSneba cnobierebisa da qcevis darRvevebi, ramac Sesazlebelia gamoiwvios pacientebis mier preparatis daniSnulze meti doziT miReba

2.4.3. saWis marTva da da manqana -danadgarebTn muSaoba.

Pacientebis unda aexsnaT, rom levodofas miRebisas somnolenciis an/da uecari CaZinebis epizodebis arsebobis SemTxvevaSi ar SeiZleba saWis marTva da manqana-danadgarebTan muSaoba zemoTaRniSnuli gvediTi movlenebis gaqrobamde da winaaRmdeg SemTxvevaSi isini safrTxes Seuqmnian sxvasac da sakuTar Tvasac. (ix.2.4.1.)

2.4.4 Laboratoriuli analizebis cvlilebebi: madopariT mkurnalobisas rekomendirebulia RviZlis funqciisa da sisxlis saerTo analizis kontroli. diabetes dros rekomendirebulia glikemiis xSiri kontroli da antiglikemiuri preparatebis dozis koreqcia glikemiis donis Sesabamisad.

2.4.5 urTierTqmedeba sxva preparatebTan da urTierTqmedebis sxva formebi.

farmakokinetikuri urTierTqmedeba:

antiqolinerguli preparatis sami-heqsifenidilis madoparTan erTdrouli daniSvnisas mcirdeba levodopas Sewovis siCqare da ara xarisxi. misi erTdrouli daniSvna madopar hds-Tan ar moqmedebs levodopas farmakokinetikaze.

antacidebis erTdrouli daniSvna madopar hds-Tan amcirebs levodopas Sewovis xarisxs 32%-iT.

rkinis sulfati amcirebs levodopas maqsimalur koncentracias plazmaSi 30-50%-iT, es cvlilebebi zogierT avadmyofebSi klinikurad mniSvnelovania.

metoklopramidi zrdis levodopas Sewovis siCqares. levodopa ar amyarebs farmakokinetur urTierTqmedebas bromkriptinTan, amantadinTan, selegilinTan da domperidonTan.

farmakodinamikuri urTierTqmedeba

neirolefsiuri saSualebebi, opiatebi da antihipertenziuli saSualebebi, romlebic Seicaven rezerpins, Trgunaven madoparis moqmedebas.

Tu madopari iniSneba avadmyofebis, romlebic iReben mao-s Seuqcevad inhibitorebs, maTi miRebis Sewyvetidan madoparis miRebis dawyebamde unda gavides aranakleb 2 kvira. xolo mao-B-s seleqtiuri inhibitorebi (magaliTad, lazabemidi, selejilini), da mao-A-s seleqtiuri inhibitorebi (magaliTad, moklobemidi) SeiZleba dainiSnos madoparis mkurnalobis fonze. am dros xdeba levodopas dozis koreqtireba avadmyofis individualuri moTxovnilebis Sesabamisad. mao-A-s da mao-B-s inhibitorebis erTdrouli daniSvna eqivalenturia mao-s araseleqtiuri inhibitoris daniSvnisa, amitom aseTi kombinacia ar iniSneba madoparTan erTdroulad. (ix.2.3.)

madopari ar iniSneba erTdroulad simpatomimetur saSualebebTan (magaliTad, adrenalini, noradrenalini, izoproterenoli an amfetamini, romlebic iwveven simpatikuri nervuli sistemis stimulirebas), radganac levodopa iwvevs maTi moqmedebis potencirebas. Tu maTi erTdrouli daniSvna aucilebelia, unda ganxorcieldes gul-sisxI ZarRvTa sistemis funqciis monitoringi, xolo aucileblobisas _ simpatomimaturebis dozis Semcireba.

SesaZlebelia preparatis kombinireba parkinsonis daavadebis sawinaaRmdego sxva saSualebebTan (magaliTad, antiqolinerguli saSualebebi, amantadini,

dofaminis agonistebi), rac aZlierebs rogorc sasurvel, asve arasasurvel efeqtebs. SesaZlebelia madoparis an sxva preparatis dozis Semcireba. rodesac mkurnalobas umateben kateqol-o-meTiltransferazas inhibitors, SeiZleba Semcirdes madoparis doza. Tu mkurnaloba dawyebulia madopariT, antiqolinerguli preparatebi mkveTrad ar ixsnoba, vinaidan levodopa ar moqmedebs dauyovnebliv.

levodopam SeiZleba imoqmedos kateqolaminebis, kreatininis, Sardovanas da glukozis laboratoriuili monacemebis Sedegebze.

avadmyofebSi, romlebic iReben madopars, kumbsis sinjma SeiZleba mogvces cru dadebiTi Sedegebi.

preparatis erTdroulma miRebam ciliT mdidar sakvebTan erTad SeiZleba daarRvios levodopas Sewova kuW-nawlavis traqtidan.

halotaniT anesTeziisas madoparis miReba wydeba qirurgiul Carevamde 12-48 saaTiT adre, vinaidan madopari halotaniT narkozis dros iwvevs arteriuli wnevis cvalebadobas da ariTmias. sxva saanesTezio saSualebabis gamoyenebisas madoparis gamoyenebis Sesaxeb informacia ix. 2.4.1

2.5 gamoyeneba gansakuTrebul populaciebSi

2.5.1. orsulebi madopari winaaRmdegnaCvenebia orsulebSi da qalebSi reproduqciis periodSi, romlebic ar itareben kontracepciis adeqvatur zomebs. (ix. 2.3, 3.3.4, 3.3.5)

2.5.2. meZuZuri dedebi: cnobili ar aris gadadis Tu ara benserazidi dedis rZeSi, amitom madopariT mkurnalbis aucileblobis SemTxvevaSi ZuZuTi kveba unda Sewydes, vinaidan ar SeiZleba gamoiricxos bavSvis ConCxis araswori ganviTareba.

2.5.3. gamoyeneba pediatriaSi -ix. 2.3

2.5.4. Tirkmlis ukamrisoba: levodofa da benserazidi aqtirurad metabolizdeba da ucvleli saxiT levodofas 10 %-ze naklebi gamoiyofa SardiT. Msubuqi an saSualo xarisxis Tirkmlis ukmarisobis dros ar aris saWiro madoparis dozis Semcireba. Tirkmlis ukmarisobis dros levodofasa da benserazidis farmakokinetikuri monacemebi ar aris xelmisawvdomi. uremiiTa da dializze myof pacientebSi madopari kargad gadaitaneba.

2.5.5. RviZlis ukmarisoba: levodofa aromatuli aminomjavebis dekarboqsilazas monawileobiT, romelic lokalizebulia nawlavebSi, TirkmeSi, gulsa da RviZISic. ar arsebobs monacemebi RviZlis ukamrisobis dros levodofasa da benserazidis farmakokinetikis Sesaxeb.

2.6 arasasurveli efeqtebi:

2.6.1. postmarketingi

sixxlisa da limfuri sistemis darRvevebi: madoparis miRebisas iSviaTad vlindeba hemolizuri anemia, gardamavali leukopenia da Trombocitopenia. madopariT xangrZlivi miRebisas rekomendirebulia RviZlis funqciuri sinjebisa da sixxlis saerTo analizis perioduli kontroli.

Mmetaboluri da kvebis darRvevebi: anoreqsia

fsiaqiatრიული darRvevebi: parkinsonis daavadebisaTvis damaxasiaTebelia depresia, rogorc simptomi, Tumca igi Seileba gamowveuli iyos aseve madoparis miRebiT. deluzia da droebiTi dezorientacia mosalodnelia xandazmul da aRniSnuli paTologiis anamnezis mqone pacientebSi.

nervuli sistemis darRvevebi: madopariT mkurnalobisas gamovlenialia ageziisa da disgeziis erTeuli SemTxvevebi. Mkurnalobis mogvianebiT etapze SeiZleba ganviTardes qoreasa da aTetozis formis diskineziebi, rac gaivlis TviTneburad an dozis SemcirebiT. Mmadoparis xangrZlivad gamoyenebisas mosalodnelia Terapiული მოყმედების მერეობა, რაც გამოიხატება ~გაSeSebis~ epizodebiT, ეფეტის SemcirebiT დოზის მოყმედების periodის ბოლო დროს და ~CarTva-gamorTvis~ fenomenის SemcirebiT. ამ მოვლენების მოხსნა და Semcireბა xდება preparatis დოზის დაკვეითებით ან patara დოზების უფრო xSირი დანიSვნით. SemdgomSi SesaZlebelია preparatis დოზის გავრცელების ეფეტის გასაZლიერებლად. Madoparis miRebisas mosalodnelia somnolenciisa და uecari CaZინების epizodeბის განვითარება.

kardiologiuri darRvevebi: Zalian iSviaTia aRiTmia .

sixlZarRvovani darRvevebi: Zalian iSviaTia orTostaturi hipotonia. orTostaturi darRvevebi mcirdeba დოზის Semcireბის Semdeg.

kuW-nawlavis traqtის darRvevebi: gulisreva, Rebineba, diarea, gemos SegrZნების დაკარგვის და ცვლილების SemTxvevebi. es gverdiTi მოვლენები

viTardeba preparatis miRebis sawyis stadiaze, maTi Tavidan acileba SesaZlebelia, Tu preparati dainiSneba Wamis dros an sakvebis an wylis sakmarisi raodenobis dayolebiT, aseve dozis TandaTanobiTi gazrdiT.

kanisa da kanqvesa qsovilis dazianeba: kanis alergiuli reaqciebi gamonayaris da qavilis saxiT Zalian iSviaTad viTardeba.

klinikuri gamokvlevebi: Zalian iSviaTad SeiZleba ganviTardes RviZlis transaminazebis aqtivobis da tute fosfatazas tranzitoruli momateba. madoparis miRebis fonze aRiniSneba sisxISi Sardovanas momateba. SeiZleba Seicvalos Sardis feri, Cveulebriv wiTel feramde, romelic muqdeba misi dgomis dros.

2.6.1.1. laboratoriuili analizebis darrvevebi: ix. 2.6.1.

2.7. dozis gadaWarbeba: madoparis dozis gadaWarbebisas ganviTarebuli simptomebi da niSnebi misi Terapiuili dozis mirebistvis damaxasiaTebeli gverdiTi efeqtebis msgavsia, magram ufro mkveTradaa gamoxatuli. Madoparis dozis gadaWarbebam SeiZleba gamoiwvios kardiologiuri gverdiTi efeqtebi (ariTmiebi), fsiqiatriuli aSlilobebi- cnobierebis dabindva, uZiloba, kuW-nawlavis traqtis darRvevebi (gulisreva, Rebineba), uneblic moZraobebi. (ix. 2.6.1)

madoparis kontrolirebadi gamonTavisuflebis formiT dozis gadaWarbebisas simptomebis gamovlena SeiZleba dagviandes aqturi nivTierebis kuWidan dayovnebuli Sewovis gamo.

Warbi dozirebis mkurnaloba: madoparis Warbi doziT miRebisas rekomendirebulia sasicocxlo funqciebis kontroli da simptomuri mkurnaloba antiaritmuli, sunTqvis amgznebi da neirolefsiuri preparatebiT.

3. farmakologiuri moqmedeba da maxasiaTebeli

3.1. farmakologiuri maxasiaTebeli

3.1.1. moqmedebis meqanizmi: dofamini, romelic warmoadgens Tavis tvinis neiromediators, arasakmarisi raodenobiT warmoiqmneba parkinsonis daavadebis mqone avadmyofebis bazalur gangliebSi. CanacvlebiTi Terapia warmoebs levodopas daniSvniT, romelic warmoadgens dofaminis metabolur winamorbeds, vinaidan es ukanaskneli cudad aRwevs hematoencefalur bariers.

peroraluri miRebisas levodopa ganicdis swraf dekarboqsilirebas dofaminad, rogorc cerebrul, aseve eqstracerebrul qsovilebSi. amis Sedegad miRebuli levodopas umetesi nawili ver aRwevs bazalur gangliebs, xolo periferiuli dofamini iwvevs gverdiT movlenebs, romelTa Tavidan asacileblad sasurvelia levodopas eqstracerebruli dekarboqsilireba, rac SesaZlebelia levodopas da benserazidis, periferiuli dekarboqsilazas inhibitoris, erTdrouli SeyvaniT. madopari warmoadgens am nivTierebebis kombinacias SefardebiT 4:1, misi

optimaluroba damtkicebulia klinikuri kvleviT da samkurnalo praqtikiT da gaaCnia iseTive efeqturoba, rogorc levodopas did dozebs.

3.2. **farmakologiuri Tvisebebi:**

3.2.1 **Sewova:**

gamoSvebis standartuli forma. levodopa da benserazidi Seiwoveba wvrili nawlavis zemo nawilebSi. madoparis Cveulebrivi miRebis Semdeg levodopas maqsimaluri koncentracia sixlis plazmaSi aRiniSneba 1 saaTis Semdeg. levodopas absoluturi bioSeRwevadoba Seadgens 98%, romelic meryeobs 74%-dan 112%-mde. Cveulebriv madoparis kafsulebi da tabletebi bioeqivalenturia.

levodopas maqsimaluri koncentracia plazmaSi da levodopas Sewovis xarisxi izrdeba dozis proporciulad (50mg-dan 200mg-mde).

sakvebis miReba amcirebs preparatis Sewovis siCqares da xarisxs. madoparis daniSvna Wamis Semdeg amcirebs levodopas maqsimalur koncentracias plazmaSi 30%-iT da igi miiRweva mogvianebiT. Sewovis xarisxi mcirdeba 15%-iT.

gamoSvebis dispergirebuli forma. janmrTel moxaliseebSi da parkinsonis daavadebis mqone pirebSi swrafad moqmedi madoparis da Cveulebrivi madoparis levodopas farmakokinetikuri parametrebi emTxveva erTmaneTs. dispergirebuli tabletebis Sewovis parametrebi Cveulebrivi samkurnalo formebsagan gansxvavebiT erTnairia sxvadasxva avadmyofebSi.

gamoSvebis forma aqtiuri nivTierebis kontrolirebadi gamoTavisuflebiT.

hds madopars gaaCnia gansxvavebuli farmakokinetikuri Tvisebebi Cveulebriv da dispergirebul formeTan SedarebiT. aqtiuri nivTiereba kuWSi Tavisufledeba nela. maqsimaluri koncentracia plazmaSi 20-30%-iT naklebia, vidre Cveulebrivi samkurnalo formebs, da aRiniSneba miRebidan 3 saaTis Semdeg. koncentraciis dinamika plazmaSi xasiaTdeba naxevargamoyofis xangrZlivi periodiT Cveulebrivi formebsagan gansxvavebiT, rac mowmobs aqtiuri nivTierebis kontrolirebad gamoTavisuflebas. hds madoparis bioSeRwevadoba Seadgens 50-70% da ar aris damokidebuli sakvebis miRebaze. aseve sakvebis miReba ar moqmedebs levodopas maqsimalur koncentraciaze, romelic miiRweva madopari hds-s miRebidan 5 saaTis Semdeg.

3.2.2 **ganawileba**

levodopa gaivlis hematoencefalur bariers najeri transportuli sistemis meSveobiT. igi ar ukavSirdeba plazmis cilebs, xolo ganawilebis moculoba Seadgens 57 litrs. farTi `koncentracia-dro` levodopas mrudis qveS Seadgens zurgis tvinis siTxeSi plazmis Semcvelobis 12%-s.

benserazidi ar gadis hematoencefalur barriers. igi grovdeba ZiriTadad TirkmelebSi, filtvebSi, wvril nawlavebSi da RviZISi.

3.2.3 metabolizmi

levodopa metabolizdeba 2 ZiriTadi gziT: dekarboqsilirebis da O-meTilirebis gziT, aseve 2 naklebad mniSvnelovani gziT transaminirebiT da JangviT.

aromatuli aminomjavebis dekarboqsilaza gardaqmnis levodopas dofaminad. am cvlis saboloo produqti homovanilinis da dihidroqsifenilZmarmjavebi.

kateqol-O-meTil-transferaza iwvevs levodopas meTilirebas 3-O-meTildofas warmoqmniT. misi naxevargamoyofis periodi Seadgens 15-17 saatS, da avadmyofebSi, romlebic iReben madoparis Terapiul dozebs, adgili aqvs mis dagrovebas.

levodofas periferiuli dekarboqsilirebis Semcireba, Tu igi iniSneba benserazidTan erTad xasiaTdeba 3-o-meTildopas ufro maRali plazmuri koncentraciebiT da kateqolaminebis (dofamini, noradrenalini) da fenokarboqsiluri mjavebis (homovanilinis mJava, dihidrofenilZmrarmJava) ufro dabali koncentraciebiT.

nawlavebis lorwovanSi da RviZISi benserazidi ganicdis hidroqsilirebas sami-hidroqsibenzilhidrazinis warmoqmniT. es metaboliti warmoadgens aromatuli aminomjavebis dekarboqsilazas Zlier inhibitors.

3.2.4. eliminicia.

dekarboqsilazas periferiuli inhibirebis fonze levodofpas naxevar gamoyofis periodi Seadgens 1,5 saatS. xandazmul pacientebSi (65-78 weli) parkinsonis daavadebiT naxevargamoyofis periodi grZeldeba (daaxlovebiT 25%-iT). levodofas plazmis klirensi Seadgens 430ml/wuTSi. benserazidi ganicdis srul eliminacias metabolizmis gziT. metabolitebi eliminirdeba ZiriTadad, SardiT (64%) da naklebad ganavaliT (24%).

3.2.5. farmakokinetika spacialur populaciebSi: ar arsebobs monacemebi uremiis da RviZlis ukmarisobis dros madoparis farmakokinetikis Taviseburebebis Sesaxeb.

asakis gavlena levodofas farmakokinetikaze: xandazmul pacientebSi parkinsonizmiT (65-78 w) levodofas naxevarradaSlis periodi da AUC 25%-iT maRalia axlgazrda populaciis (34-64 w) amave maCveneblebTan SedarebiT. asaks ar aqvs klinikurad mniSvnelovani gavlena madoparis farmakokinetikaze.

3.3. preklinikuri usafrTxoeba

3.3.1. kancerogenoba: kvlevebi madoparis kancerogenobis sesaxeb catarebulia ar aris.

3.3.2. mutagenoba: Ames testis mixedviT madoparsa da mis Semadgenel komponentebs (levodofas da benserazins) mutagenuri efqti ar aRmoaCndaT. Sxva monacemebi madoparis mutagenobis sesaxeb ar arsebobs.

3.3.3. reproduqciaze gavlena: reproduqciaze madoparis gavlenis Sesaxeb cxovelebSi Catarebuli ar aris.

3.3.4. teratogenoba: madoparis teratogenoba an /da ConCxis ganviTarebis Seferxeba ar gamovlenila TagvebSi (400 mg/kg) , virTxebSa (600 mg/kg; 250mg/kg) da bocvrebSi (120 mg/kg; 150mg/kg) Catarebul kvlevebSi. dedisTvis madoparis toqsiuri doziT miRebisas aRiniSna saSvilosnosSida sikvdilobis gazrda (bocvrebSi) da nayofis wonis Semcireba (virTagvebSi).

3.3.5 sxva. cxovelebze Catarebuli ZiriTadi toqsikologiuri kvlevebi miuTiTebS ConCxis ganviTarebis darRvevis SesaZleblobaze. sxva cxovelebze kvlevebi Catarebuli ar aris.

4. farmakologiuri maxasiaTeblebi

4.1. Senaxvis pirobebi: dauSvebelia madoparis miReba SefuTvaze miTiTebuli Senaxvis vadis gasvl;is Semdeg. dispersuli-swrafad moqmedi madopari miiReba tabletis wyalSi gaxsnidan araumetes naxevari saatis ganmavlobaSi

5. SefuTvva

madopari '62.5' :

kafsulebi - 50 mg levodopa + 12.5 mg benserazidi 30, 100

madopari '125' :

kafsulebi - 100 mg levodopa + 25 mg benserazidi 30, 100

jvaredindanayofiani tabletebi: 100 mg levodopa + 25 mg benserazidi 30, 100

madopari '250' :

kafsulebi - 200 mg levodopa + 50 mg benserazidi 30, 100

jvaredindanayofiani tabletebi- 200 mg levodopa + 50 mg benserazidi 30, 100

madopari dispersuli forma 62.5:

tabletebi-50 mg levodopa + 12.5 mg benserazidi 30, 100

madopari dispersuli forma '125':

tabletebi: 100 mg levodopa + 25 mg benserazidi 30, 100

madopari HBS kontrolirebulad gamonTavisuflebadi kafsulebi: 100 mg levodopa + 25 mg benserazidi 30, 100

preparati ar SeinaxoT bavSvebisaTvis xelmisawvdom adgilas.

madoparis dispersuli abebi:

damzadebulia "F. Hoffmann-La Roche Ltd, Basel, Sveicaria" SekveTiT

"Roche S.p.A. ,milani" mier. production site Segrate, italia.

kafsulebi, tabletebi, madopari damzadebulia
SveicariaSi "F. Hoffmann-La Roche Ltd, Basel" mier