

preparatis samedicino gamoyenebis

instruqcia

depakini® enteriki 300

saregistracio nomeri: II #013995/01.

preparatis savaWro dasaxeleba: depakini® enteriki 300.

saerTaSoriso arapatentirebuli dasaxeleba: valprois mJava.

samkurnalwamlo forma: nawlavSi xsnadi garsiT dafaruli tabletebi.

Semadgenloba

nawlavSi xsnadi garsiT dafaruli 1 tableti Seicavs:P

birTvi: moqmedi nivTiereba: natriumis valproati – 300 mg; *damxmare nivTierebebi:* povidoni K-90 (polividoni K-90), kalciumis silikatis hidrati, talki, magniumis stearati; *garsji:* metakrilis mJavis da meTilmetakrilatis sopolimeri (1:1), talki, opasprei TeTri* (tipi K1-7000), celacefati (celulozis acetatftalati), dieTilftalati.

* opasprei TeTri: titanis dioqsidi, hiproloza.

aRweriloba: mrgvali ormxrivamoburculi TeTri feris garsiT dafaruli tabletebi.

farmakoTerapiuli jgufi: epilefsiis sawinaaRmdego saSualeba.

aTq kodi: N03AG01.

farmakologiuri Tvisebebi

farmakodinamika

epilefsiis sawinaaRmdego preparati, romelsac aqvs centraluri miorelaqsanturi da sedatiuri moqmedeba.

avlens epilefsiis sawinaaRmdego aqtivobas sxvadasxva tipis epilefsiis mimarT.

preparatis moqmedebis ZiriTadi meqanizmi, rogorc Cans, dakavSirebulia gaem-ergul sistemaze valprois mJavis zegavleniT: centralur nervul sistemaSi (cns) zrdis gamaaminoerbovani mJavis (gaem) Semcvelobas da aaqtiurebs gaem-ergul gadacemas.

farmakokinetika

absorbcia

peroraluri miRebisas valprois mJavis bioSeRwevadoba daaxloebiT 100%. sakvebis miReba ar axdens gavlenas preparatis farmakokinetikur profilze.

Sratismieri koncentraciebis saSualo Terapiuli diapazoni Seadgens 50-100 mg/l. sisxlis plazmaSi ufro maRali koncentraciebis miRebis dasabuTebuli aucileblobis SemTxvevaSi saWiroa mosalodneli sargeblanobisa da gansakuTrebiT, dozadamokidebuli gverdiTi movlenebis gamovlenis riskis Sefardebis saguldagulo Sefaseba, radgan valprois mJavis 100 mg/l-ze maRali koncentraciebisas mosalodnelia gverdiTi movlenebis momateba intoqsikaciis ganviTarebamde. valprois mJavis 150 mg/l-ze maRali plazmuri koncentraciebis SemTxvevaSi saWiroa preparatis dozis Semcireba.

preparatiT mkurnalobis kursis Catarebisas sisxlis SratSi valprois mJavis wonasworuli koncentracia miiRweva 3-14 dReSi.

ganawileba

ganawilebis moculoba damokidebulia pacientis asakze da Cveulebriv Seadgens 0,13-0,23 l/sxeulis masis kg-ze, axalgazrda asakis pirebSi – 0,13-0,19 l/sxeulis masis kg-ze.

valprois mJavis kavSiri sisxli plazmis cilebTan (upiratesad albuminTan) maRalia (90-95%), dozadamokidebuli da gamajerebelia. xandazmul pacientebSi, Tirkmelebisa da RviZlis ukmarisobis mqone pacientebSi kavSiri sisxli plazmis cilebTan mcirdeba. Tirkmelebis mZime ukmarisobis dros valprois mJavis Tavisufali (Terapiulad aqtiuri) fraqciis koncentracia SeiZleba gaizardos 8,5-20%-mde.

hipoproteinemiis dros valprois mJavis saerTo koncentracia (Tavisufali + sisxli plazmis cilebTan SekavSirebuli fraqcia) SeiZleba ar Seicvalos, magram SeiZleba Semcirdes valprois mJavis Tavisufali (sisxli plazmis cilebTan SeukavSirebeli) fraqciis metabolizmis gazrdis gamo.

valprois mJava gamoiyofa cerebrospinalur siTxesa da Tavis tvinSi. liqvorSi valprois mJavis koncentracia Seadgens sisxli Sratsi misi koncentraciis 10%-s.

valprois mJava gamoiyofa dedis rZeSi. sisxli Sratsi valprois mJavis wonasworuli koncentraciis miRwevisas misi koncentracia dedis rZeSi Seadgens sisxli Sratsi misi koncentraciis 1%-dan 10%-mde.

metabolizmi

valprois mJavis metabolizmi xdeba RviZiSi glukuronirebis, aseve beta-, omega- da omega-1-Jangvis gziT. gamovlenilia 20-ze meti metaboliti, omega-Jangvis Semdeg metabolitebs axasiaTebis hepatotoqsiuri moqmedeba.

valprois mJavas ar axasiaTebis mainducirebeli moqmedeba citoqromi P450-is metaboluri sistemis fermentebze: epilefsiis sawinaaRmdego sxva umravlesi preparatisgan gansxvavebiT, valprois mJava ar moqmedebis arc sakuTari metabolizmis siCqareze, arc sxva nivTierebebis, magaliTad, estrogenebis, progestagenebis da arapirdapiri antikoagulantebis metabolizmis siCqareze.

gamoyofa

valprois mJava ZiriTadad gamoiyofa TirkmelebiT glukuronis mJavasTan koniugaciisa da beta-Jangvis Semdeg. valprois mJavis 5%-ze naklebi gamoiyofa TirkmelebiT ucveleli saxiT.

epilefsiis mqone pacientebSi valprois mJavis plazmuri klirensi Seadgens 12,7 ml/wT.

naxevargamoyofis periodi ($T_{1/2}$) Seadgens 15-17 saaTs. iseT epilefsiis sawinaaRmdego preparebTan kombinaciaSi, romlebic axdens RviZlis mikrosomuli fermentebis inducirebas, valprois mJavis plazmuri klirensi izrdeba, xolo $T_{1/2}$ mcirdeba, maTi Secvlis xarisxi damokidebulia epilefsiis sawinaaRmdego sxva preparebiT RviZlis mikrosomuli fermentebis induqciis xarisxe.

2 Tveze ufrosi asakis bavSvebSi $T_{1/2}$ aris mozrdilebSi aRniSnulis msgavsi.

pacientebSi RviZlis daavadebebiT valprois mJavis $T_{1/2}$ izrdeba.

dozis gadaWarbebisas aRniSna naxevargamoyofis periodis gaxangrZliveba 30 saaTamde. hemodializis ganicdis sisxli valprois mJavis mxolod Tavisufali fraqcia (10%).

literaturuli monacemebis Tanaxmad estrogenis Semcveli preparebis miRebisas zog patients aRniSna valprois mJavis klirensis daaxloebiT 20%-iT gazrda, ramac SeiZleba gamoiwvios Sratsi misi

koncentraciis Semcireba (ix. paragrafi ~urTierTqmedeba sxva samkurnalo saSualebebTan~). aRiniSna individTaSorisi variabeluroba.

gamovlenil urTierTqmedebasTan dakavSirebiT farmakokinetikuri da farmakodinamikuri parametrebis sarwmuno urTierTkavSiris dasadgenad monacemebi arasakmarisia.

farmakokinetikis Taviseburebebi orsulobis dros

valprois mJavis ganawilebis moculobis gazrdisas orsulobis mesame trimestrSi izrdeba misi Tirkmlismieri da RviZlismieri klirensi. amavdroulad, miuxedavad preparatis miRebisa mudmivi doziT, SesaZlebelia SratSi valprois mJavis koncentraciis daqveiTeba. garda amisa, orsulobis dros SeiZleba Seicvalos valprois mJavis kavSiri sisxlis plazmis cilebTan, ramac SeiZleba gamoiwvios sisxlis SratSi valprois mJavis Tavisufali (Terapiulad aqtiuri) fraqciis Semcvelobis momateba.

placenturi barieri

valprois mJava aRwevs placentur barierSi. zogierT publikaciaSi Sefasda valproatis koncentracia axalSobilTa WiplarSi mSobiarobisas. WiplarSi valproatis Sratismieri koncentracia, romelic asaxavs nayofis sisxliSi valproatis koncentracias, iyo igive an mcirediT ufro maRali, vidre dedis sisxlis SratSi.

gamoyenebis Cveneba

mozrdili pacientebi: monoTerapiis saxiT an epilefsiis sawinaaRmdego sxva saSualebebTan kombinaciaSi:

- generalizebuli epilefsiuri Setevebis mkurnaloba: klonuri, tonuri, tonur-klonuri, absansebi, mioklonuri, atonuri;
- lenoqs-gastos sindromis mkurnaloba;
- parcialuri epilefsiuri Setevebis, meoradi generalizaciiT an mis gareSe parcialuri Setevebis mkurnaloba;
- bipolaruli afeqturi aSlilobebis mkurnaloba da profilaqtika.

bavSvTa asakis pacientebi: monoTerapiis saxiT an epilefsiis sawinaaRmdego sxva saSualebebTan kombinaciaSi:

- generalizebuli epilefsiuri Setevebis mkurnaloba: klonuri, tonuri, tonur-klonuri, absansebi, mioklonuri, atonuri;
- lenoqs-gastos sindromis mkurnaloba;
- parcialuri epilefsiuri Setevebis, meoradi generalizaciiT an mis gareSe parcialuri Setevebis mkurnaloba;
- krunCxvebis profilaqtika maRali temperaturis dros, saWiroebis SemTxvevaSi.

ukuCveneba

- momatebuli mgrZnobeloba natriumis valproatis, valprois mJavis, seminatriumis valproatis, valpromidis an preparatis romelime komponentis mimarT;
- mwvave hepatiti;

- qronikuli hepatiti;
- RviZlis mZime daavadebebi (gansakuTrebiT, samkurnalo saSualebebiT gamowveuli hepatiti) pacientis an/da misi ojaxis anamnezSi;
- RviZlis mZime dazianebebi letaluri SedegiT valprois mJavis gamoyenebisas pacientis ojaxis wevrebSi;
- RviZlis an kuWqveSa jirkvlis funqciis mZime darRvevebi;
- RviZlis porfiria;
- dadgenili mitoqondrialuri daavadebebi, gamowveuli birTvuli genis mutaciebiT, romelic axdens mitoqondrialuri fermentis γ -polimerazis (POLG) kodirebas, magaliTad alpers-hutenloheris sindromi, an eWvi daavadebebeze, romlebic gamowveulia γ -polimerazis defeqtebiT, or wlamde asakis bavSvebSi (exeba preparat depakinis[®] bavSvebisTvis gankuTvnil samkurnalwamlo forme bis gamoyenebas) (ix. paragrafi ~gansakuTrebuli miTiTeba~);
- pacientebi karbamiduli ciklis dadgenili darRvevebiT (Sardovanas cikli) (ix. paragrafi ~gansakuTrebuli miTiTeba~);
- hemoragiuli diaTezi, Trombocitopenia;
- mefloqinTan kombinacia;
- krazanas preparetebTan kombinacia;
- orsulobis periodi epilefsiis dros, mkurnalobis alternatiuli meTodebis ar arsebobis SemTxvevebis garda (ix. paragrafebi ~gansakuTrebuli miTiTeba~, ~gamoyeneba orsulobis da ZuZuTi kvebis periodSi~);
- orsulobis periodi bipolaruli afeqturi aSlilobis mkurnalobis da profilaqtikis dros;
- qalebi Svilosnobis SenarCunebuli potencialiT, Tu ar aris Sesrulebuli orsulobisgan Tavis dacvis programis yvela piroba (ix. paragrafebi ~gansakuTrebuli miTiTeba~, ~gamoyeneba orsulobis da ZuZuTi kvebis periodSi~);
- bavSvTa asaki 6 wlamde (tabletis gadaylapvis dros sasunTq gzebSi moxvedris riski).

sifrTxiliT

- RviZlis da kuWqveSa jirkvlis daavadebebi anamnezSi;
- Tandayolili fermentopaTiebi;
- Zvlis tvinSi sisxlis warmoqmnis daTrgunva (leikopenia, Trombocitopenia, anemia);
- Tirkmelebis ukmarisoba (saWiroebs dozis koreqcias);
- hipoproteinemia;
- krunCxvis sawinaaRmdago ramdenime preparatis erTdroulad miReba (RviZlis dazianebis momatebuli riski);
- erTdroulad miReba krunCxviTi Setevebis gamomwvev an krunCxviTi mzaobis zRurblis Sesamcirebel preparetebTan, rogoricaa, tricikluri antidepressantebi, serotoninis ukumitacebis seleqciuri inhibitorebi, fenoTiazinis warmoebulebi, butirofenonis warmoebulebi, qloroqini, bupropioni, tramadoli (krunCxviTi Setevebis provocirebis riski);

- neirolefsiuri saSualebebis, monoaminooqsidazas (mao) inhibitorebis, antidepresantebis, benzodiazepinebis erTdroulad miReba (SesaZlebelia maTi efeqtebis potencireba);
- fenobarbitalis, primidonis, fenitoinis, lamotrijinis, zidovudinis, felbamatis, acetilsalicilis mJavis, arapirdapiri antikoagulantebis, cimetidinis, eriTromicinis, karbapenemebis, rifampicinis, nimodipinis, rufinamidis (gansakuTrebiT, bavSvebSi), proteazis inhibitorebis (lopinaviri, ritonaviri), kolestiraminis erTdroulad miReba (farmakokinetikuri urTierTqmedebis gamo metabolizmis an sisxlis plazmis cilebTan kavSiris doneze SesaZlebelia am preparetebis an/da valprois mJavis plazmuri koncentraciebis Secvla, detalurad ixileT paragrafi ~urTierTqmedeba sxva samkurnalo saSualebebTan~);
- karbamazepinis erTdroulad miReba (karbamazepinis toqsiuri efeqtebis potencirebisa da valprois mJavis plazmuri koncentraciis daqveiTebis riski);
- topiramatis an acetazolamidis erTdroulad gamoyeneba (encefalopaTiis ganviTarebis riski);
- II tipis karnitin-palmitoiltransferazis (kpt) ukmarisobis mqone pacientebSi (rabdomiolizis ganviTarebis ufro maRali riski valprois mJavis miRebis fonze);
- estrogenis Semcvel preparetebTan erTdroulad gamoyeneba.

gamoyeneba orsulobis da ZuZuTi kvebis periodSi

valprois mJavis gamoyeneba ukunaCvenebia:

- orsulobis periodSi epilefsiis dros, mkurnalobis alternatiuli meTodebis ararsebobs SemTxvevebis garda (ix. paragrafebi ~gansakuTrebuli miTiTeba~, ~gamoyeneba orsulobis da ZuZuTi kvebis periodSi~);
- orsulobis periodSi bipolaruli afeqturi aSlilobis mkurnalobisas da profilaqtikisas;
- qalebSi Svilosnobis potencialiT, Tu ar aris Sesrulebuli orsulobisgan Tavis dacvis programis yvela piroba (ix. paragrafebi ~gansakuTrebuli miTiTeba~, ~gamoyeneba orsulobis da ZuZuTi kvebis periodSi~).

orsuloba

orsulobis dros epilefsiuri Setevebis ganviTarebasTan dakavSirebuli riski

orsulobis dros generalizebuli tonur-klonuri epilefsiuri Setevebis, hipoqsiis ganviTarebiT mimdinare epilefsiis statusis ganviTareba SeiZleba warmoadgendes gansakuTrebul risks rogorc dedisTvis, aseve nayofisTvis, radgan arsebobs letaluri Sedegis riski.

orsulobis dros preparatis gamoyenebasTan dakavSirebuli riski

mRrRnelebze Catarebuli reproduqciuli toqsiurobis eqsperimentulma kvlebebma aCvena valprois mJavis teratogenuli moqmedebis arseboba.

dadgenilia, rom valprois mJava gadis placentur barriers rogorc cxovelebSi, aseve adamianebSi.

teratogenoba da ganviTarebis Tandayolili defeqtebi

arsebuli klinikuri monacemebi naCvenebia ganviTarebis mcire da mZime defeqtebis gamovlenis ufro maRali sixSire, magaliTad, nervuli milis ganviTarebis Tandayolili defeqtebi, qala-saxis deformacia, kidurebis ganviTarebis defeqtebi da gul-sisxlZarRvTa sistemis darRvevebi, hipospadia, aseve ganviTarebis mravlobiTi defeqtebi organoTa sxvadasxva sistemebis mxriv orsulobis periodSi valprois mJaviT namkurnalevi dedebis SvilebSi, orsulobSi epilefsiis sawinaaRmdego zogierTi sxva preparatis miRebisas maTi ganviTarebis sixSiresTan SedarebiT. aRniSnulidan gamomdinare, epilefsiis mqone dedebis SvilebSi ganviTarebis Tandayolili defeqtebis riski, orsulobis dros valprois mJavis monoTerapiis SemTxvevaSi, Sesabamisad iyo daaxloebiT 1.5, 2.3, 2.3 da 3.7 jer maRali, fenitoinis, karbamazepinis, fenobarbitalis da lamotrijinis monoTerapiasTan SedarebiT.

metaanalisis monacemebma, romlebic iTvaliswinebs registrirebul da kohortul kvlevebs, aCvena, rom epilefsiis mqone dedebis SvilebSi ganviTarebis Tandayolili defeqtebis ganviTarebis sixSire, orsulobis dros valprois mJavis monoTerapiis SemTxvevaSi Seadgenda 10.73%-s (95% ndobis intervali 8.16-13.29%). es riski ufro maRalia, vidre saerTo populaciaSi ganviTarebis mZime Tandayolili defeqtebis ganviTarebis riski, romelic Seadgens 2-3%-s. aRniSnuli riski dozadamokidebulia, magram SeuZlebelia zRvruli dozis dadgena, romlis qvemoTac ar arsebobs aseTi riski.

xelmisawvdomi monacemebi adasturebs ganviTarebis mcire da mZime defeqtebis SemTxvevebis gaxSirebas. ganviTarebis defeqtebis yvelaze gavrcelebuli tipebi iTvaliswinebs nervuli milis ganviTarebis defeqtebs, saxis dismorfizms, saxis naprals, kraniostenozs, gulis, Tirkmelebis da Sardasqeso sistemis ganviTarebis mankebs, kidurebis defeqtebs (radiusis ormxrivi aplaziis da organizmis sxvadasxva sistemebis mravlobiTi anomaliebis CaTvlit).

muclad yofnis periodSi zemoqmedebisas valprois mJavam SeiZleba aseve gamoiwvios smenis gauareseba an dakargva yurebis an/da cxviris ganviTarebis defeqtebis (meoreuli efeqti) an/da smenis organoebze pirdapiri toqsiuri moqmedebis Sedegad. aRwerilia calmxrivi an ormxrivi siyruis an smenis daqveiTebis ganviTarebis SemTxvevebi. Sedegi ar aris cnobili yvela SemTxvevaSi. gamojanmrTeleba ar aRiniSna umravles SemTxvevebSi cnobili SedegiT. rekomendebulia ototoqsiurobis niSnebisa da simptomebis monitoringi.

bavSvebSi fsiqikuri da fizikuri ganviTarebis darRvevebi

naCvenebia, rom valprois mJavis saSvilosnosSida zemoqmedeba SeiZleba axdendes arasasurvel moqmedebas bavSvis fsiqikur da fizikur ganviTarebaze, aseTi zemoqmedebis SemTxvevaSi. rogorc Cans, es riski dozadamokidebulia, magram SeuZlebelia zRvruli dozis dadgena, romlis qvemoTac ar arsebobs aseTi riski. am efeqtebis ganviTarebis riskis zusti gestaciuri periodi dadgenili ar aris, da riski ar gamoiricxeba orsulobis mTel periodSi.

muclad yofnis periodSi valprois mJavis zemoqmedebis qveS myofi skolamdeli asakis bavSvebis kvlevam aCvena, rom am bavSvebis 30-40%-mde aReniSneboda adreuli ganviTarebis Seferxeba (rogoricaa siarulis da metyvelebis ganviTarebis Seferxeba), aseve ufro dabali inteleqtualuri SesaZleblobebi, cudi metyveleba (sakuTari metyveleba da metyvelebis gageba) da mexsierebis problemebi.

muclad yofnis periodSi valprois mJavis zemoqmedebis anamneziT 6 wlis asakis bavSvebSi gansazRvruli gonebrivi ganviTarebis koeficienti (IQ indeqsi) iyo saSualod 7-10 punqtiT dabali, vidre bavSvebSi, romlebic muclad yofnis periodSi ganicdidnen epilefsiis sawinaaRmdego sxva preparatebis zemoqmedebas. miuxedavad imisa, rom ar SeiZleba gamoirixos muclad yofnis periodSi valprois mJavis zemoqmedebis qveS myofi bavSvebis intelektualur ganviTarebaze arasasurveli gavlenis mqone sxva faqtorebis roli, naTelia, rom am bavSvebSi intelektualuri darRvevebis riski SeiZleba ar iyos damokidebuli dedis IQ indeqsze.

xangrZlivi gamoyenebis Sedegebis monacemebi SezRudulia

arsebobs monacemebi, miRebuli daniis pacientebis reestris gamoyenebiT Catarebuli kvlevebis Sedegebis safuZvelze, romlebic adasturebs, rom muclad yofnis periodSi valprois mJavis zemoqmedebis qveS myof bavSvebSi arsebobs autisturi aSlilobebis speqtris ganviTarebis, maT Soris bavSvTa autizmis, momatebuli riski (riskis daaxloebiT sam-xuTjeradi gazrda), pacientebis im populaciasTan SedarebiT, romlebic ar ganicdidnen valprois mJavis zemoqmedebas.

arsebobs monacemebi, miRebuli daniis pacientebis reestris gamoyenebiT Catarebuli kvlevebis Sedegebis safuZvelze, romlebic adasturebs, rom muclad yofnis periodSi valprois mJavis zemoqmedebis qveS myof bavSvebSi arsebobs yuradRebis deficitis sindromis da hiperaqtivobis ganviTarebis momatebuli, daaloeniT 1.5-jer ufro maRali riski, pacientebis im populaciasTan SedarebiT, romlebic ar ganicdidnen valprois mJavis zemoqmedebas.

rogorc valprois mJavis monoTerapia, aseve kombinirebuli Terapia valprois mJavis gamoyenebiT dakavSirebulia orsulobis arasasikeTo dasasrulTan. magram, arsebuli monacemebiT epilefsiis sawinaaRmdego kombinirebuli Terapia valprois mJavis gamoyenebiT dakavSirebulia orsulobis arasasikeTo dasasrulis ufro maRal riskTan, vidre valprois mJavis monoTerapia (e.i. nayofis darRvevebis ganviTarebis riski ufro dabalia valprois mJaviT monoTerapiis SemTxvevaSi).

nayofis ganviTarebis defeqtebis gamovlenis riskis faqtorebia: dRe-RameSi 1000 mg-ze meti doza (magram, ufro mcire doza ar gamoricxavs am risks) da valprois mJavis kombinireba epilefsiis sawinaaRmdego sxva preparatebTan.

zemoaRniSnulTan dakavSirebiT preparati ukunaCvenebia orsulobis periodSi epilefsiis dros, mkurnalobis alternatiuli meTodebis ararsebobs SemTxvevebis garda (ix. paragrafebi ~gansakuTrebuli miTiTeba~, ~gamoyeneba orsulobis da ZuZuTi kvebis periodSi~, ~ukuCveneba~); orsulobis periodSi bipolaruli afeqturi aSlilobebis mkurnalobisas da profilaqtikisTvis.

estrogenis Semcveli preparatebTan erTdroulad gamoyeneba

valprois mJava ar amcirebs hormonaluri kontraceptivebis Terapiul efeqtianobas. miuxedavad amisa, estrogenis Semcveli preparatebi, estrogenis Semcveli hormonaluri kontraceptivebis CaTvliT, SeiZleba zrdides valprois mJavis klirens, ramac SeiZleba gamoiwvios SratSi misi koncentraciis da, Sedegad, efeqtianobis Semcireba. saWiroa sixlis SratSi valprois mJavis koncentraciis da klinikuri efeqtianobis kontroli (Setevebis da guneba-ganwyobis kontroli) estrogenis Semcveli samkurnalo saSualebebis daniSvnis an moxsnis dros. preparatis gamoyenebis aucileblobis an mis gamoyenebaze Tavis

Sekavebis sakiTxi unda gadawydes preparatis gamoyenebis dawyebamde da xelaxla ganixilos orsulobis dagegmvis SemTxvevaSi (ix. paragrafebi ~sifrTxiliT~, ~urTierTqmedeba sxva samkurnalo saSualebebTan~).

orsulobis dagegmva

orsulobis dagegmvis SemTxvevaSi epilefsiis mkurnalobis specialistma unda Caataros valprois mJavis Semcveli preparetebiT Terapiis Sefaseba da ganixilos alternatiuli Terapiis SesaZlebloba. saWiroa zomebis miReba, raTa pacienti gadayvanili iqnas valprois mJavis Semcveli preparetebiT Terapiidan Casaxvamde da kontracefcis gamoyenebis Sewyvetis momentamde (ix. paragrafi ~gansakuTrebuli miTiTeba~). alternatiuli Terapiis ararsebobs SemTxvevaSi patients unda ganemartos valprois mJavis Semcvel preparetebTan dakavSirebuli yvela riski momavali bavSvisTvis, ojaxis dagegmvis Sesaxeb informirebuli gadawyvetilebis misaRebad.

orsulebi

orsulobis periodSi valprois mJavis Semcveli preparetebis gamoyeneba ukunaCvenebia, mkurnalobis alternatiuli meTodebis ararsebobs SemTxvevebis garda, epilefsiis dros, (ix. paragrafebi ~ukuCveneba~, ~gansakuTrebuli miTiTeba~), aseve ukunaCvenebia bipolaruli afeqturi aSlilobebis mkurnalobisas da profilaqtikisas.

orsulobis dadgomis SemTxvevaSi dauyovnebliv unda mimarToT Tqvens mkurnal eqims, Terapiis Sefasebis da alternatiuli Terapiis daniSvnis sakiTxis ganxilvis mizniT.

reproduqciul asakSi myofi qalebi unda iyenebdnen kontracefcis efeqtur meTodebs preparatiT mkurnalobis dros (ix. paragrafi ~gansakuTrebuli miTiTeba~).

aucilebelia reproduqciul asakSi myofi qalebis informireba orsulobis dros valprois mJavis gamoyenebis riskebisa da sargeblanobis Sesaxeb.

Tu orsulobis periodSi valprois mJavis Semcveli preparetebis gamoyenebis cnobili riskis miuxedavad qali gegmavs orsulobas an daorsulda, saWiroa xelaxla Sefasdes valprois mJaviT mkurnalobis aucilebloba, Cvenebis mixedviT:

- ~bipolaruli afeqturi aSlilobebis~ Cvenebisas unda iqnas ganxiluli valprois mJaviT mkurnalobis Sewyvetis sakiTxi;
- ~epilefsiis~ Cvenebisas valprois mJaviT mkurnalobis gagrZeლების an misi moxsnis sakiTxi gadawydeba sargeblisa da riskis Sefardebis xelaxali Sefasebis Semdeg. Tu aRniSnulis Semdeg preparatiT mkurnaloba unda gagrZeldes orsulobis dros, rekomendebulia misi gamoyeneba umciresi efeqtiani sadReRamiso doziT, romelic gaiyofa ramdenime miRebaze. unda aRiniSnos, rom orsulobisas upiratesoba eniWeba preparatis xangrZlivi gamoTavisuflebis samkurnalwamlo formebs, sxva samkurnalwamlo formebsTan SedarebiT;
- damatebiT, SeZlebisdagvarad orsulobis dadgomamde saWiroa foliumis mJavis miRebis dawyeba (doziT 5 mg dRe-RameSi), radgan foliumis mJavas SeuZlia Seamciros nervuli milis ganviTarebis defeqtebis formirebis riski. magram, am momentisaTvis arsebuli cnobebiT ar dasturdeba misi

profilaqtikuri moqmedeba valprois mJavis zemoqmedebiT gamovlenili ganviTarebis Tandayolili defeqtebis mimarT;

- saWiroa mudmivi (maT Soris orsulobis mesame trimestrSi) specialuri prenataluri diagnostika nervuli milis formirebis an nayofis ganviTarebis sxva defeqtebis Sesazlo ganviTarebis gamosavlenad, rac aseve iTvaliswinebs safuZvlian ultrabgeriT gamokvlevas.

riski axalSobilebisTvis

cnobilia hemoragiuli sindromis ganviTarebis erTeuli SemTxvevebi axalSobilebSi, romelTa dedebic iRebden valprois mJavas orsulobis dros. es hemoragiuli sindromi dakavSirebulia TrombocitopeniasTan, hipofibrinogenemiasTan an/da sisxlis Sededebis sxva faqtorebis SemcirebasTan. aseve, cnobilia afibrinogenemiis ganviTarebis Sesaxeb, romelsac SeiZleba gamoewvia letaluri Sedegi. es hemoragiuli sindromi unda gamoirCeodes K vitaminis deficitisgan, romelsac iwvevs fenobarbitali da RviZlis mikrosomuli fermentebis sxva induqtorebi.

amitom, axalSobilebSi, romelTa dedebic orsulobis dros iRebden valprois mJavas, aucileblad unda Catardes koagulaciuri analizebi (ganisazRvros periferiul sisxliSi Trombocitebis raodenoba, fibrinogenis plazmuri koncentracia, sisxlis Sededebis faqtorebi da koagulograma).

cnobilia hipoglikemiis SemTxvevebi axalSobilebSi, romelTa dedebic iRebden valprois mJavas orsulobis mesame trimestrSi.

cnobilia hipoTireozis SemTxvevebi axalSobilebSi, romelTa dedebic iRebden valprois mJavas orsulobis dros.

axalSobilebSi, romelTa dedebic iRebden valprois mJavas orsulobis bolo trimestrSi, SeiZleba ganviTardes moxsnis sindromi (magaliTad, alitacia, gaRizianebadoba, hiperrefleksia, kankali, hiperkinezia, kunTebis tonusis darRveva, tremori, krunCxva da sirTule kvebis dros).

fertiloba

qalebSi dismenoreis, amenoreis, polikistozuri sakvercxeebis, sisxliSi testosteronis koncentraciis gazrdis riskis gamo Sesazlebelia fertilobis daqveiTeba (ix. paragrafi ~gverdiTi moqmedeba~). mamakacebSi valprois mJavam SeiZleba daaqveiTos spermatozoidebis moZraoba da daarRvios fertiloba (ix. paragrafi ~gverdiTi moqmedeba~). im iSviaTi SemTxvevebis umravlesobaSi (magram ara yvela SemTxvevaSi), rodesac valprois mJava Secvlili iyo epilefsiis sawinaaRmdego sxva preparatiT, iyo moxsnili an Semcirebuli sadReRamiso doza, cnobilia mamakacis fertilobis daqveiTebis Semcirebis Sesaxeb; aseve, aRniSnuli warmatebuli Casaxva.

ZuZuTi kvebis periodi

dedis rZeSi valprois mJavis eqskrecia mcirea, rZeSi misi koncentracia Seadgens sisxlis SratSi misi koncentraciis 1-10%-s.

literaturis monacemebidan da mcire klinikuri gamocdilebidan gamomdinare, preparatis miRebisas dedebis SeuZliaT dagegmon ZuZuTi kveba, magram am SemTxvevaSi mxedvelobaSi unda iqnas miRebuli preparatis gverdiTi efeqtebis profili, gansakuTrebiT mis mier gamowveuli hematologiuri darRvevebi.

miRebis wesi da dozebi

mozemuli samkurnalwamlo forma ukunaCvenebia 6 wlamde asakis bavSvebisaTvis (gadaylapvis dros sasunTq gzebSi tabletis moxvedris riski). 11 wlamde asakis bavSvebSi upiratesoba eniWeba samkurnalwamlo formas –sirofi.

peroralurad, sasurvelia sakvebis miRebis dros.

doza unda ganisazRvros pacientis asakisa da sxeulis masis gaTvaliswinebiT.

monoTerapiaSi dRe-Ramis sawyisi doza mozdilebisTvis da bavSvebisaTvis Seadgens 5-10 mg/kg, Semdeg yovel 4-7 dReSi dozas zrdian 5 mg-iT/kg-ze optimaluri dozis miRwevamde.

dRe-Ramis saSualo doza:

- 6-14 wlis bavSvebisTvis (sxeulis masa 25-40 kg) - 30 mg/sxeulis masis kg-ze (600-1200 mg);
- 14-18 wlis mozardebisTvis (sxeulis masa 40-60 kg) - 25 mg/sxeulis masis kg-ze (1000-1500 mg);
- mozdilebisTvis (sxeulis masa 60 kg-dan zemoT) – 20 mg/sxeulis masis kg-ze (1200-2100 mg).

rekomendebulia dRe-Ramis dozis gayofa 2-3 miRebaze.

dRe-Ramis saSualo dozis gazrda SesaZlebelia sisxI Si valprois mJavis koncentraciis kontrolit.

zog SemTxvevaSi valprois mJavis sruli Terapiuli efeqti viTardeba 4-6 kviris ganmavlobaSi. amitom, am vadaze adre rekomendebuli saSualo dRiuri dozis gazrda ar SeiZleba.

pacientebisaTvis, romlebic adre iRebden epilefsiis sawinaaRmdego sxva saSualebebs, preparat depakini® enteriki 300-is miRebaze gadayvana unda ganxorcieldes TandaTonobiT, preparatis optimaluri dozis miRebiT daaxloebiT 2 kviris ganmavlobaSi. amasTanave, dauyovnebliv unda moxdes epilefsiis sawinaaRmdego pirveli preparatis, gansakuTrebiT fenobarbitalis, dozis Semcireba. epilefsiis sawinaaRmdego pirveli preparatis moxsna unda ganxorcieldes TandaTanobiT.

epilefsiis sawinaaRmdego sxva preparetbs SeuZlia moaxdinos RviZlis mikrosomuli fermentebis Seqcevadi inducireba, amitom epilefsiis sawinaaRmdego am preparetbis bolo dozis miRebidan 4-6 kviris ganmavlobaSi saWiroa sisxI Si valprois mJavis koncentraciis monitoringi da, saWiroebis SemTxvevaSi (am preparetbis metabolismis inducirebis efeqtis SemcirebasTan erTad), valprois mJavis dRe-Ramis dozis Semcireba.

pacientebis gansakuTrebuli iqufebi

mdedrobiTi sqesis bavSvebi da mozardebi, qalebi Svilosnobis potencialiT da orsulebi: preparatiT mkurnalobis dawyeba saWiroa epilefsiis da bipolaruli aSlilobebis sferoSi specialistis dakvirvebis qveS. mkurnalobis dawyeba saWiroa mxolod im SemTxvevaSi, Tu sxva saxis mkurnaloba araefeqtiania an ar aitaneba pacientis mier (ix. paragrafebi ~gansakuTrebuli miTiTeba~, ~gamoyeneba orsulobis da ZuZuTi kvebis periodSi~), xolo mkurnalobis regularuli gadaxedvis SemTxvevaSi saWiroa sargeblisa da riskis Sefardebis ganmeorebiT guldasmiT Sefaseba. preparati unda dainiSnos orsulobisgan Tavis dacvis programis dacviT (ix. paragrafebi ~gansakuTrebuli miTiTeba~, ~gamoyeneba orsulobis da ZuZuTi kvebis periodSi~).

upiratesoba eniWebi valprois mJavis Semcveli preparatebis gamoyenebas monoTerapiaSi da umciresi efeqtiani doziT, da Tu SesaZlebelia, xangrZlivi gamoTavisuflebis preparatis samkurnalwamlo formebiT. orsulobis dros, epilefsiis mkurnalobis alternatiuli meTodebis ararsebobis SemTxvevaSi, preparatis dRiuri doza unda ganawildes, sul mcire 2 miRebaze.

estrogenis Semcvel preparatebTan erTdroulad gamoyeneba

valprois mJava ar amcirebs hormonaluri kontrceptivebis Terapiul efeqtianobas.

miuxedavad amisa, estrogenis Semcveli preparatebi, estrogenis Semcveli hormonaluri kontractivebis CaTvliT, SeiZleba zrdides valprois mJavis klirens, rama SeiZleba gamoiwvios SratSi misi koncentraciis da, Sedegad, efeqtianobis Semcireba. saWiroa sisxlis SratSi valprois mJavis koncentraciis da klinikuri efeqtianobis kontroli (Setevebis da guneba-ganwyobis kontroli) estrogenis Semcveli samkurnalo saSualebebis daniSvnis an moxsnis dros. (ix. paragrafi ~urTierTqmedeba sxva samkurnalo saSualebebTan~).

xandazmulu pacientebi: miuxedavad imisa, rom xandazmulu pacientebSi aRiniSneba valprois mJavis farmakokinetikis cvlilebebi, maT aqvT SezRuduli klinikuri mniSveloba da xandazmulu asakis pacientebSi valprois mJavis doza unda SeirCes epilefsiis Setevebze kontrolis uzrunvelyofis maCveneblis Sesabamisad.

Tirkmelebis ukmarisobis an/da hipoproteinemiis mqone pacientebi: saWiroa sisxlis SratSi valprois mJavis Tavisufali (Terapiulad aqtiuri) fraqciis koncentraciis gazrdis gaTvaliswineba da, saWiroebis SemTxvevaSi, valprois mJavis dozis Semcireba, dozis arCevisas, ZiriTadad, klinikuri suraTis, da ara sisxlis SratSi valprois mJavis saerTo Semcvelobis (Tavisufali fraqcia da sisxlis plazmis cilebTan SekavSirebuli fraqciebi erTad) gaTvaliswinebiT, raTa Tavidan iqnas acilebuli SesaZlo Secdomebi dozis SerCevisas.

gverdiTi moqmedeba

arasasurveli reaqciebis ganviTarebis sixSire ganisazRvra jandacvis msofliო organizaciis klasifikaciis safuZvelze: Zalian xSirad ($\geq 1/10$), xSirad ($\geq 1/100$ da $< 1/10$); arc ise xSirad ($\geq 1/1000$ da $< 1/100$); iSviaTad ($\geq 1/10000$ da $< 1/1000$); Zalian iSviaTad ($< 1/10000$); sixSire ucnoibia (arsebuli monacemebis safuZvelze SeuZlebelia arasasurveli reaqciebis dadgena).

Tandayolili, memkvidreobiTi da genetikuri darRvevebi: teratogenuli riski (ix. paragrafi ~gamoyeneba orsulobisa da ZuZuTi kvebis periodSi~).

darRvevebi sisxlisa da limfuri sistemis mxriv:

xSirad: anemia, Trombocitopenia (ix. paragrafi ~gansakuTrebuli miTiTeba~); *arc ise xSirad:* pancitopenia, leukopenia, neutropenia (leukopenia da pancitopenia SeiZleba iyos rogorc Zvlis tvinis depresiiT, aseve mis gareSe.

preparatis moxsnis Semdeg sisxlis suraTi ubrundeba normas); *iSviaTad:* Zvlis tvinSi sisxlis warmoqmnis darRvevebi, maT Soris eriTrocitebis izolirebuli aplazia/hipoplazia, agranulocitozi, makrocituli anemia, makrocitozi; sisxlis Sededebis faqtorebis maCveneblebis Semcireba (sul mcire, erTis), sisxlis Sededebis

maCveneblebis normidan gadacdena (rogoricaa, proTrombinis drois gazrda, aqtvirebuli parcialuri Tromboplastinuri drois gazrda, Trombinis drois gazrda, snT [saerTaSoriso normalizebuli Tanafardobis] gazrda) (ix. paragrafebi ~gamoyeneba orsulobisa da ZuZuTi kvebis periodSi~, ~gansakuTrebuli miTiTeba~).

spontanuri ekqimozebis da sisxldenis ganviTareba miuTiTebis preparatis moxsnisa da gamokvlevis Catarebis aucileblobaze.

laboratoriuli da instrumentuli monacemebi:

iSviaTad: biotinis deficiiti/biotinidazის ukmarisoba.

darRvevebi nervuli sistemis mxriv:

Zalian xSirad: tremori; *xSirad:* eqstrapiramiduli darRvevebi, stupori*, Zilianoba, krunCxva*, mexsierebis darRveva, Tavis tkivili, nistagmi; Tavbrusxveva (intravenuri Seyvanis dros Tavbrusxveva SeiZleba ganviTardes ramdenime wuTis ganmavlobaSi da gaqres spontanurad ramdenime wuTis ganmavlobaSi); *arc ise xSirad:* koma*, encefalopaTia*, leTargia*, Seqcevadi parkinsonizmi, ataqsia, paresTezia, krunCxviTi Setevebis sixSirisa da simZimis gazrda (epilefsiuri statusis ganviTarebis CaTvlit) an axali tipis krunCxvis gamovlena (ix. paragrafi ~gansakuTrebuli miTiTeba~); *iSviaTad:* Seqcevadi demencia Tavis tvinis Seqcevadi atrofiis TanxlebiT, kognitiuri darRvevebi; *sixSire ucnobia:* sedacia.

* stupori da leTargia zogjer iwvevda gardamaval komas/encefalopatiას da iyo izolirebuli an mimdinareobda krunCxviTi Setevebis gaxSirebiT mkurnalobis fonze, aseve Semcirda preparatis moxsnis an misi dozის Semcirebisას. aseTi SemTxvevebis umravlesoba aRwerilia kombinirebuli Terapiis fonze, gansakuTrebiT fenobarbitalis an topiramatis erTdroulad miRebisას, an valprois mJavis dozის mkveTrad gazrdis Semdeg.

darRvevebi smenis organos mxriv da labirinTuli darRvevebi:

xSirad: Seqcevadi da Seuqcevadi siyrue.

darRvevebi mxedvelobის organos mxriv:

sixSire ucnobia: diplopia.

darRvevebi sasunTqi organoebis, gul-mkerdisა da Suasayaris organoebis mxriv:

arc ise xSirad: plevruli gamonadeni.

darRvevebi saWmlis momnelebeli sistemis mxriv:

Zalian xSirad: gulisreva; *xSirad:* Rebineba, RrZilebis cvlileba (ZiriTadad, RrZilebis hiperplazia), stomatiti, tkivili epigastriumSi, diarea, romlebic zogierT pacientSi xSirad viTardeba mkurnalobის dasawyisSi, magram, rogorc wesi, qreba ramdenime dReSi da ar saWiroebs Terapiis Sewyvetas.

am reaqciebis Semcireba SeiZleba preparatis miRebiT Wamis dros an Wamis Semdeg; *arc ise xSirad:* pankreatiti, zogjer letaluri SedegiT (pankreatiti SeiZleba ganviTardes mkurnalobის dawyebidan pirveli 6 Tvis ganmavlobaSi; muclis areSi mkveTri tkivilis ganviTarebis SemTxvevaSi saWiroa SratSi amilazის aqtvobის kontroli, ix. paragrafi ~gansakuTrebuli miTiTeba~); *sixSire ucnobia:* spazmi muclis areSi, anoreqsia, madis gazrda.

darRvevebi Tirkmelebisa da saSarde sistemis mxriv:

xSirad: uneblie Sardva; *arc ise xSirad*: Tirkmelebis ukmarisoba; *iSviaTad*: enurezi, tubulointersticiuli nefriti, Seqcevadi fankonis sindromi (Tirkmlis proqsimuli arxebis dazianebis bioqimiuri da klinikuri gamovlenebis kompleksi fosfatis, glukozis, aminomJavebis da bikarbonatis milakovani reabsorbciis darRveviT), romlis ganviTarebis meqanizmi jer gaurkvevelia.

darRvevebi kanisa da kanqveSa qsovilebis mxriv:

xSirad: hipermgrZnobelobis reaqciebi, magaliTad, WinWris cieba, qavili; gardamavali (Seqcevadi) an/da dozadamokidebuli paTologiuri Tmis cvena (alopecia), maT Soris androgenuri alopecia ganviTarebuli hiperandrogeniis, sakvercxeebis polikistozis fonze (ix. qvemoT punqtebi ~darRvevebi sasqeso organoebis da sarZeve jirkvlis mxriv~ da ~darRvevebi endokrinuli sistemis mxriv~), aseve alopecia ganviTarebuli hipoTireozis fonze (ix. qvemoT punqti ~darRvevebi endokrinuli sistemis mxriv~), darRvevebi frCxilebisa da frCxilis budis mxriv; *arc ise xSirad*: angionevrozuli SeSupeba, gamonayari, darRvevebi Tmis mxriv (rogoricaa, Tmis normaluri struqturis darRveva, Tmis feris Secvla, Tmis uCveulo zrda [talRovani an xveuli Tmis gasworeba an piriqiT, swori Tmis daxveva]); *iSviaTad*: toqsiuri epidermul nekrolizi, stivens-jonsonis sindromi, multiformuli eriTema, samkurnalwamlo gamonayaris sindromi eozinofiliit da sistemuri simptomebit (DRESS-sindromi).

darRvevebi Zval-kunTovani da SemaerTebeli qsovilis mxriv:

arc ise xSirad: Zvlis qsovilis mineraluri simkvrivis Semcireba, osteopenia, osteoporozi da motexilobebi pacientebSi, romlebic xangrZlivad mkurnaloben depakinis® preparatebit. Zvlis qsovilis metabolismze depakinis® preparatebis gavlenis meqanizmi dadgenili ar aris; *iSviaTad*: sistemuri wiTeli mglura (ix. paragrafi ~gansakuTrebuli miTiTeba~), rbdomiolizi (ix. paragrafi ~sifrTxilit~, ~gansakuTrebuli miTiTeba~).

darRvevebi endokrinuli sistemis mxriv:

arc ise xSirad: antidiurezuli hormonis araadekvaturi secreciis sindromi (adhass), hiperandrogenia (hirsutizmi, virilizacia, akne, alopecia mamrobiTi tipiT an/da sisxliSi androgenebis koncentraciis mateba); *iSviaTad*: hipoTireozi (ix. paragrafi ~gamoyeneba orsulobisa da ZuZuTi kvebis dros~).

darRvevebi nivTierebaTa cvlisa da kvebis mxriv:

xSirad: hiponatriemia, sxaulis masis gazrda (saWiroa sxaulis masis zrdis mkacri monitoringi, radgan es mdgomareoba warmoadgens polikistozuri sakvercxeebis sindromis ganviTarebis xelSemwyob faqtors); *iSviaTad*: hiperamoniemia* (ix. paragrafi ~gansakuTrebuli miTiTeba~), simsuqne.

* SeiZleba ganviTardes izolirebuli da zomieri hiperamoniemiis SemTxvevebi RviZlis funqciis maCveneblebis Secvlis gareSe, rac ar saWiroebs mkurnalobis Sewyvetas. aseve, cnobilia hiperamoniemiis ganviTarebis Sesaxeb, romelsac Tan axlavs nevrologiuri simptomatikis gamovlena (magaliTad, encefalopaTiis, Rebinebis, ataqsii da sxva nevrologiuri simptomebis ganviTarebit), romelic saWiroebda valprois mJavis miRebis Sewyvetas da damatebiti gamokvlevis Catarebas (ix. paragrafi ~gansakuTrebuli miTiTeba~).

keTilTvisebiani, avTvisebiani da daudgeneli genezis simsiVneebi (kistebisa da polipebis CaTvlit):

iSviaTad: mielodisplastiuri sindromi.

darRvevebi sisxlZarRvebis mxriv:

xSirad: sisxldenebi da sisxlCaqcevebi (ix. paragafebi ~gansakuTrebuli miTiTeba~ da ~gamoyeneba orsulobisa da ZuZuTi kvebis periodSi~); *arc ise xSirad:* vaskuliti.

zogadi darRvevebi da cvlilebebi Seyvanis adgilze:

arc ise xSirad: hipoTermia, msubuqi periferiuli SeSupeba.

darRvevebi RviZlisa da naRvlqamomyofi qzebis mxriv:

xSirad: RviZlis dazianebebi: RviZlis funqciuri mdgomareobis maCveneblebis normidan gadacdena, rogoricaa proTrombinuli indeqsis Semcireba, gansakuTrebiT fibrinogenis Semcvelobisa da sisxlis Sededebebis faqtorebis mniSvnelovan SemcirebasTan, bilirubinis koncentraciis gazrdasTan da sisxlSi ~RviZlis~ transaminazebebis aqtivobis momatebasTan erTad; RviZlis ukmarisoba, erTeul SemTxvevebSi - letaluri SedegiT; saWiroa pacientebis kontroli RviZlis funqciis SesaZlo darRvevebis TvalsazrisiT (ix. paragrafi ~gansakuTrebuli miTiTeba~).

darRvevebi sasqeso organoebisa da sarZeve jirkvlis mxriv:

xSirad: dismenorea; *arc ise xSirad:* amenorea; *iSviaTad:* mamakacis unayofoba, sakvercxeebis polikistozi; *sixSire ucnohia:* araregularuli menstruacia, sarZeve jirkvlebis gadideba, galaqtorea.

fsiqikis darRveva:

xSirad: cnobierebis arevis mdgomareoba, halucinacia, agresiuloba*, aJitacia*, yuradRebis darRveva*; depresia (valprois mJavis kombinirebisas krunCxvis sawinaaRmdego sxva preparatebTan); *iSviaTad:* qceviTi darRvevebi*, fsiqomotoruli hiperaqtivoba*, swavlis unaris darRveva*; depresia (valprois mJaviT monoTerapiis dros).

* arasasurveili reaqciebi, romlebic, ZiriTadad, aReniSnebaT bavSvTa asakis pacientebis.

Warbi doza

dozis mwvave masiuri gadaWarbebis klinikuri gamovlenebi Cveulebriv mimdinareobs komis saxiT kunTebis hipotoniIT, hiporefleqsiiT, mioziT, sunTqvis daTrgunviT, metaboluri acidoziT, arteriuli wnevis Warbi daqveiTebiT da sisxlZarRvovani kolafsiT/SokiT.

aRwerilia Tavis tvinis SeSupebasTan dakavSirebuli qalasSida hipertenziis SemTxvevebi.

valprois mJavis preparatebSi natriumis arseboba dozis gadaWarbebis SemTxvevaSi SeiZleba iwvevdes hipernatriemiis ganviTarebas.

dozis masiuri gadaWarbebis SemTxvevaSi SesaZlebelia letaluri Sedegi, magram Cveulebriv dozis gadaWarbebisas prognozi sasikeToa.

dozis gadaWarbebis simptomebi SeiZleba varirebdes, cnobilia krunCxviTi Setevebis ganviTarebis Sesaxeb valprois mJavis Zalian maRali plazmuri koncentraciebis SemTxvevaSi.

dozis gadaWarbebis mkurnaloba

stacionarSi dozis gadaWarbebis gadaudebeli daxmareba unda iTvaliswinebdes Semdegs: kuWis amorecxva, romelic efeqtiania preparatis miRebidan 10-12 saaTis ganmavlobaSi. valprois mJavis Sewovis Sesamcireblad SeiZleba efeqtiani iyos aqtivirebuli naxSiris miReba, maT Soris misi Seyvana

nazogastraluri zondiT. saWiroa gul-sisxlZarRvTa da sasunTq sistemaze dakvirveba da efeqtiani diurezis SenarCuneba. saWiroa RviZlisa da kuWqveSa jirkvlis funqciis kontroli. sunTqvis daTrgunvis SemTxvevaSi SeiZleba saWiro gaxdes filtvis xelovnuri ventilacia. calkeul SemTxvevebSi warmatebiT gamoiyeneboda naloqsoni. dozis masiuri gadaWarbebis Zalian mZime SemTxvevebSi efeqtiani iyo hemodializi da hemoperfuzia.

urTierTqmedeba sxva samkurnalo saSualebebTan

valprois mJavis gavlena sxva preparatebze

neirolefsiuri saSualebebi, monoaminoaqsidazis (mao) inhibitorebi, antidepressantebi, benzodiazepinebi valprois mJavas SeuZlia gamoiwvios sxva fsiqotropuli preparatebis moqmedebis potencireba, rogoricaa *neirolefsiuri saSualebebi, mao-s inhibitorebi, antidepressantebi da benzodiazepinebi*; amitom, valprois mJavasTan maTi erTdroulad miRebisas rekomendebulia mkacri samedicino dakvirveba da, aucileblobis SemTxvevaSi, dozebis koreqtireba.

liTiumis preparatebi: valprois mJava ar moqmedebSratSi liTiumis koncentraciaze.

fenobarbitali

valprois mJava zrdis fenobarbitalis plazmur koncentracias (misi RviZlismieri metabolismis Semcirebis Sedegad), amasTan dakavSirebiT SesaZlebelia am ukanasknelis sedatiuri efeqtis ganviTareba, gansakuTrebiT bavSvebSi. amitom, rekomendebulia pacientebis mkacri samedicino dakvirveba kombinirebuli Terapiis pirveli 15 dRis ganmavlobaSi fenobarbitalis dozis dauyovnebliv SemcirebiT sedatiuri efeqtis ganviTarebis SemTxvevaSi, xolo saWiroebis SemTxvevaSi, fenobarbitalis plazmuri koncentraciebis gansazRvra.

primidoni

valprois mJava zrdis primidonis plazmur koncentracias misi gverdiTi movlenebis gaZlierebiT (rogoricaa sedatiuri moqmedeba); xangrZlivi mkurnalobis dros es simptomebi qreba. rekomendebulia patientis saguldagulo klinikuri dakvirveba, gansakuTrebiT kombinirebuli Terapiis dasawyisSi, aucileblobis SemTxvevaSi primidonis dozis koreqtirebiT.

fenitoini

valprois mJava amcirebs fenitoinis saerTo plazmur koncentraciebs. garda amisa, valprois mJava zrdis fenitoinis Tavisufali fraqciis koncentracias dozis gadaWarbebis simptomebis SesaZlo ganviTarebiT (valprois mJava gamodevnis fenitoinis plazmis cilebTan kavSiridan da anelebs mis RviZlismier katabolizms). amitom, fenitoinisa da valprois mJavas erTdroulad gamoyenebisas rekomendebulia patientis saguldagulo klinikuri dakvirveba da sisxlSi fenitoinisa da misi Tavisufali fraqciis koncentraciebis gansazRvra.

karbamazepini

valprois mJavisa da karbamazepinis erTdroulad gamoyenebisas cnobilia karbamazepinis toqsiurobis klinikuri gamovlenebis Sesaxeb, radgan valprois mJavam SeiZleba gamoiwvios karbamazepinis toqsiuri efeqtiebis potencireba. rekomendebulia am pacientebis saguldagulo klinikuri dakvirveba,

gansakuTrebiT kombinirebuli Terapiis dasawyisSi, aucileblobis SemTxvevaSi karbamazepinis dozis Sesabamisi koreqtirebiT.

lamotrijini

valprois mJava axangrZlivebs RviZiSi lamotrijinis metabolizms da TiTqmis orjer zrdis lamotrijinis naxevargamoyofis periods. am urTierTqmedebam SeiZleba gamoiwvios lamotrijinis toqsiurobis gazrda, kerZod, kanis mZime reaqsiebis, maT Soris toqsiuri epidermulu nekrolizis, ganviTareba. amitom, rekomendebulia saguldagulo klinikuri dakvirveba da, aucileblobis SemTxvevaSi, lamotrijinis dozis koreqtireba (Semcireba).

zidovudini: valprois mJavas SeuZlia gazardos zidovudinis plazmuri koncentracia, raciwvevs zidovudinis toqsiurobis momatebas.

felbamati: valprois mJavam SeiZleba 16%-iT Seamciros felbamatis klirensis saSualo mniSvnelobebi.

olanzapini: valprois mJavas SeuZlia Seamciros olanzapinis plazmuri koncentracia.

rufinamidi: valprois mJavas SeuZlia gamoiwvios rufinamidis plazmuri koncentraciis gazrda. es gazrda damokidebulia sisxliSi valprois mJavis koncentraciaze. saWiroa sifrTxilis zomebis dacva, gansakuTrebiT bavSvebSi, radgan es efeqti ufro gamoxatulia am populaciaSi.

propofoli: valprois mJavas SeuZlia gamoiwvios propofolis plazmuri koncentraciis gazrda. valprois mJavasTan erTad propofolis gamoyenebis unda iqnas ganxiluli propofolis dozis Semcirebis sakiTxi.

nimodipini (peroraluri da eqstrapolaciIT parenteraluri xsnari): nimodipinis hipotenziuri efeqtis gaZliereba imis gamo, rom nimodipinisa da valprois mJavas erTad gamoyenebam SeiZleba 50%-iT gazardos nimodipinis plazmuri koncentraciebi (valprois mJavis mier nimodipinis metabolizms inhibirebis xarjze).

temozolomidi: valprois mJavasTan erTdroulad miRebisas SesaZlebelia temozolomidis klirensis msubuqad gamoxatuli, magram statistikurad mniSvnelovani Semcireba.

sxva preparebis gavlena valprois mJavaze

epilefsiis sawinaaRmdego preparetebi, romlebsac SeuZlia RviZiis mikrosomuli fermentebis inducireba (fenitoinis, fenobarbitalis, karbamazepinis CaTvliT), amcirebs valprois mJavis plazmur koncentraciebs. kombinirebuli Terapiis SemTxvevaSi valprois mJavis dozis koreqtireba unda ganxorcieldes klinikuri reaqsia da sisxliSi valprois mJavis koncentraciis mixedviT.

sisxlis SratSi valprois mJavis metabolitebis koncentracia SeiZleba gaizardos fenitoinTan an fenobarbitalTan misi erTdroulad gamoyenebis SemTxvevaSi. amitom, am ori preparatis kombinaciIT mkurnalobis SemTxvevaSi, pacienti saWiroebs saguldagulo monitorings hiperamoniemiis niSnebis da simptomebis TvalsazrisiT, radgan valprois mJavis zogierT metabolits SeuZlia karbamiduli ciklis fermentebis (Sardovanas ciklis) inhibireba.

felbamati: valprois mJavasTan erTdroulad gamoyenebis SemTxvevaSi valprois mJavis klirensi mcirdeba 22-50%-iT da, Sesabamisad, izrdeba valprois mJavis plazmuri koncentracia. saWiroa valprois mJavis plazmuri koncentraciis kontroli.

mefloqini: aCqarebs valprois mJavis metabolizms da SeuZlia gamoiwvios krunCxva, amitom maTi erTdroulad gamoyenebisas SesaZlebelia epilefsiuri Setevis ganviTareba.

krazanas preparetebi: valprois mJavasTan erTdroulad gamoyenebisas SesaZlebelia valprois mJavis krunCxvis sawinaaRmdego efeqtis daqveiTeba.

plazmis cilebTan maRali da Zlieri kavSiris mqone preparetebi (acetilsalicilis mJava): valprois mJavasTan erTdroulad gamoyenebisas SesaZlebelia valprois mJavis Tavisufali fraqciis koncentraciis momateba.

arapirdapiri antikoagulantebi (varfarini da kumarinis sxva warmoebulebi): valprois mJavasTan erTdroulad gamoyenebisas saWiroa proTrombinis indeqsis saguldagulo kontroli.

cimetidini, eriTromicini: valprois mJavis Sratismieri koncentraciebi SeiZleba gaizardos (misi RviZlismieri metabolizms gaxangrZlivebis Sedegad).

karbapenemebi (panipenemi, meropenemi, imipenemi)

sisxSi valprois mJavis koncentraciis daqveiTeba karbapenemebTan erTdroulad gamoyenebisas: kombinirebuli Terapiis 2 dRis Semdeg aRiniSneboda sisxSi valprois mJavis koncentraciis daqveiTeba 60-100%-iT, rasac zogjer Tan axlda krunCxvis gamovlena. saWiroa karbapenemebis erTdroulad miRebisgan Tavis Sekaveba pacientebSi, romlebsac SerCeuli aqvT valprois mJavis doza, radgan maT SeuZlia swrafad da intensiurad Seamciros sisxSi valprois mJavis koncentracia. karbapenemebiT mkurnalobis aucileblobis SemTxvevaSi saWiroa sisxSi valprois mJavis koncentraciis saguldagulo monitoringi.

rifampicini: SeuZlia Seamciros sisxSi valprois mJavis koncentracia, rac iwvevs valprois mJavis Terapiuli moqmedebis dakargvas, amitom, SeiZleba saWiro gaxdes valprois mJavis dozis gazrda.

proteazas inhibitorebi (magaliTad, lopinaviri, ritonaviri): amcirebs valprois mJavis plazmur koncentracias.

kolestiramini: SeuZlia gamoiwvios valprois mJavis plazmuri koncentraciis Semcireba erTdroulad gamoyenebisas.

estrogenis Semcveli preparetebi

estrogenis Semcvel preparetebs, maT Soris estrogenis Semcvel hormonalur kontractivebs, SeuZlia gazardis valprois mJavis klirensi, rac SeiZleba iwvevdes misi Sratismieri koncentraciis Semcirebas, Sedegad ki misi efeqtianobis Semcirebas. estrogenis Semcveli preparetebis daniSvnis an moxsnis dros saWiroa sisxSi valprois mJavis koncentraciis da klinikuri efeqtianobis kontroli (Seteveis da guneba-ganwyobis kontroli). valprois mJavas ar gaaCnia RviZlis fermentebis inducirebis unari, Sesabamisad, qalebSi, romlebic iyeneben kontracfcis hormonalur meTodebs, valprois mJava ar amcirebs estrogen-progestagenuli preparetebis efeqtianobas.

sxva urTierTqmedeba

topiramati an acetazolamidi

valprois mJavisa da topiramatis an acetazolamidis erTdroulad gamoyeneba iyo dakavSirebuli encefalopaTiasTan an/da hiperamoniemiasTan. pacientebi, romlebic valprois mJavasTan erTad iReben

am preparatebs, unda imyofebodnen mkacri samedicino dakvirvebis qveS hiperamoniemiuri encefalopaTiis simptomebis ganviTarebasTan dakavSirebiT.

qvetiapini: valprois mJavasTan erTdroulad gamoyenebam SeiZleba gazardos neitropeniis/leikopeniis ganviTarebis riski.

eTanoli da sxva potenciurad hepatotoqsiuri preparatebi: valprois mJavasTan erTdroulad gamoyenebisas SesaZlebelia valprois mJavis hepatotoqsiuri efeqtis gaZliereba.

klonazepami: valprois mJavasTan erTdroulad gamoyenebisas erTeul SemTxvevebSi SesaZlebelia absansuri statusis gamoxatulobis gaZliereba.

mielotoqsiuri samkurnalo saSualebebi: valprois mJavasTan erTdroulad gamoyenebisas izrdeba Zvlis tvinSi sixlis warmoqmnis daTrgunvis riski.

gansakuTrebuli miTiTeba

preparatis miRebis dawyebamde da periodulad mkurnalobis pirveli 6 Tvis ganmavlobaSi, gansakuTrebIT RviZlis dazianebs ganviTarebis riskis jgufis pacientebSi, saWiroa RviZlis funqciis gamokvleva.

iseve, rogorc epilefsiis sawinaaRmdego umravlesi preparatis gamoyenebisas, valprois mJavis gamoyenebisas SesaZlebelia ~RviZlis~ transaminazebis aqtivobis umniSvnelo momateba, gansakuTrebIT mkurnalobis dasawyisSi, rac mimdinareobs klinikuri gamovlenebis gareSe da aris gardamavali. am pacientebSi saWiroa biologiuri maCveneblebis metad guldasmiT kvleva, proTrombinuli indeqsis CaTvliT. SeiZleba saWiro gaxdes preparatis dozis koreqtireba, xolo saWiro ebis SemTxvevaSi, ganmeorebiTi klinikuri da laboratoriuili gamokvleva.

Terapiis dawyebamde an qirurgiuli Carevis win, aseve spontanurad ganviTarebuli kanqveSa hematomebis an sixlidenis SemTxvevaSi rekomendebulia sixlidenis drois, periferiul sixlSi formiani elementebis, maT Soris Trombocitebis, raodenobis, gansazRvra.

RviZlis mZime dazianeba

maniSnebeli faqtorebi

arwerilia RviZlis mZime dazianebs ganviTarebis calkeuli SemTxvevebi, zogjer letaluri SedegiT. klinikurma gamocdilebam aCvena, rom riskis jgufs warmoadgenen pacientebi, romlebic erTdroulad iReben epilefsiis sawinaaRmdego ramdenime preparats, sam wlamde asakis bavSvebi mZime krunCxviTi SetevebiT, gansakuTrebIT Tavis tvinis dazianebs, gonebrivi ganviTarebis CamorCenis an/da Tandayolili metaboluri an degeneraciuli daavadebebis fonze; pacientebi, romlebic erTdroulad iReben salicilatebs (radgan salicilatebi metabolizdeba igive metabolismis gziT, rac valprois mJava).

sami wlis asakidan RviZlis dazianebs riski mniSvnelovnad da progresulad mcirdeba pacientis asakis momatebasTan erTad. umravles SemTxvevaSi RviZlis aseTi dazianeba viTardeboda mkurnalobis pirveli 6 Tvis ganmavlobaSi, ufro xSirad mkurnalobis me-2-12 kvirebSi da, rogorc wesi, valprois mJavis gamoyenebisas epilefsiis sawinaaRmdego kombinirebuli Terapiis SemadgenlobaSi.

RviZlis dazianebase eWvis arseboba

RviZlis dazianebis adreuli diagnostirebisaTvis aucilebelia pacientebis klinikuri dakvirveba. gansakuTrebiT sayuradReboa Semdegi simptomebis gamovlena, romlebic SeiZleba win uswrebdes siyviTlis gamovlenas, gansakuTrebiT riskis jgufSi myof pacientebSi:

- araspecificuri simptomebi, romlebic vlindeba moulodnelad, rogoricaa asTenia, anoreqisia, leTargia, Zilianoba, zogjer ganmeorebiTi Rebinebisa da muclis tkivilis TanxlebiT.
- krunCxviTi Setevebis recidivi epilefsiis mqone pacientebSi.

rekomendebulia patientis an misi ojaxis wevrebis (Tu es patienti bavSvia) informireba, rom nebismieri aseTi simptomis ganviTarebisas saWiroa dauyovnebliv mimarTon mkurnal eqims. saWiroa saswrafod Catardes klinikuri gamokvleva da RviZlis funqciuri maCveneblebis laboratoriuili gamokvleva.

gamovlena

RviZlis funqciuri maCveneblebis gansazRvra aucilebelia mkurnalobis dawyebamde da Semdeg periodulad mkurnalobis dawyebidan pirveli 6 Tvis ganmavlobaSi. klasikur testebs Soris yvelaze informatiuili kvlevebia RviZlis cila-sinTezuri funqciis da gansakuTrebiT proTrombinuli indeqsis gansazRvra. proTrombinis indeqsis normidan Semcirebis dadastureba, gansakuTrebiT, sxva laboratoriuili maCveneblebis normidan gadacdenasTan erTad (fibrinogenis Semcvelobisa da sisxlis Sededebis faqtorebis mniSvnelovani daqveiTeba, bilirubinis koncentraciis gazrda da ~RviZlis~ transaminazebis aqtivobis momateba), aseve RviZlis dazianebis maniSnebeli sxva simptomebis gamovlena, saWiroebs preparatiT mkurnalobis Sewyvetas. sifrTxilis mizniT, unda Sewydes salicilatebiT mkurnaloba, maTi erTdroulad gamoyenebis SemTxvevaSi.

pankreatiti

bavSvebsa da mozdilebSi arsebobs pankreatitis mZime formebs registrirebuli iSviaTi SemTxvevebi, romlebic ganviTarda asakisa da mkurnalobis xangrZlivobis miuxedavad. aRiniSna hemoragiuli pankreatitis ramdenime SemTxveva daavadebis swrafi progresirebiT pirveli simptomebidan letalur Sedegamde.

bavSvebi warmoadgenen pankreatitis ganviTarebis momatebuli riskis jgufs, bavSvis asakis momatebasTan erTad riski mcirdeba. mZime krunCxva, nevrologiuri darRvevebi an krunCxvis sawinaaRmdego Terapia SeiZleba iyos pankreatitis ganviTarebis riskis faqtorebi. RviZlis ukmarisoba pankreatitis TanxlebiT zrdis letaluri Sedegis risks.

muclis areSi Zlieri tkivilis, gulisrevis, Rebinebis an/da anoreqsiis SemTxvevaSi saWiroa patientis saswrafod gamokvleva. pankreatitis dadasturebis SemTxvevaSi, kerZod ki, sisxliSi kuWqveSa jirkvlis fermentebis aqtivobis momatebisas, valprois mJavis gamoyeneba unda Sewydes da dawyebuli iqnas Sesabamisi mkurnaloba.

suiciduri azrebi da mcdeloba

cnobilia suiciduri azrebisa da mcdelobebis Sesaxeb pacientebSi, romlebic iRebden epilefsiis sawinaaRmdego preparetebs garkveuli Cvenebs mixedviT.

epilefsiis sawinaaRmdego preparetebis randomizebuli placebo-kontrolirebuli kvlevebis metaanalizi aseve gviCvenebs suiciduri azrebisa da mcdelobebis riskis gazrdas 0,19%-iT yvela patientSi, romelic

Rebulobda epilefsiis sawinaaRmdego preparatebs (maT Soris, am riskis gazrda 0,24%-iT pacientebSi, romlebic mkurnalobdnen epilefsiis sawinaaRmdego preparatebiT epilefsiis gamo), placebos jgufSi maT sixSiresTan SedarebiT. am efeqtis meqanizmi ucnobia.

amitom, preparatiT mkurnalobis dros saWiroa pacientebis mudmivi kontrolireba suicidur azrebsa da mcdelobebTan dakavSirebiT, xolo maTi gamovlenis SemTxvevaSi, saWiroa Sesabamisi mkurnalobis Catareba. pacientebisaTvis da maTi momvleli pirebisTvis rekomendebulia, rom pacientSi suiciduri azrebi an mcdelobebis gamovlenis SemTxvevaSi dauyovnebliv mimarTon eqims.

karbapenemebi

karbapenemebis erTdroulad miReba rekomendebuli ar aris (ix. paragrafi ~urTierTqmedeba sxva samkurnalo saSualebebTan~, ~sifrTxiliT~).

pacientebi dadgenili mitoqondrialuri daavadebebiT an maTze eWviT

valprois mJavas SeuZlia gamoiwvios an daamZimos arsebuli mitoqondrialuri daavadebebis gamovlineba, rac gamowveulia mitoqondrialuri dnm-is mutaciebiT, aseve birTvuli genis mutaciebiT, romelic axdens mitoqondrialuri fermentis γ -polimerazis (POLG) kodirebas. kerZod ki, pacientebSi Tandayolili neirometaboluri sindromebiT, romlebic gamowveulia γ -polimeraziT (POLG) kodirebuli genis mutaciebiT, magaliTad, alpers-hutenloheris sindromis mqone pacientebSi, valprois mJavis gamoyenebasTan asocirdeboda RviZlis mwvave ukmarisobis da RviZlis dazianebasTan dakavSirebuli letaluri Sedegebis ganviTarebis ufro maRali sixSire. daavadebebi, romlebic gamowveulia γ -polimerazis defeqtebiT, SeiZleba mosalodneli iyos pacientebSi am daavadebebis ojaxis anamneziT an maT arsebobaze maniSnebeli simptomebiT, gaurkveveli encefalopaTiis, refraqteruli epilefsiis (fokaluri, mioklonuri), epilefsiuri statusis, fsiqikuri da fizikuri ganviTarebis Seferxebis, fsiqomotoruli regresiiis, aqsonaluri sensomotoruli neiropaTiis, miopaTiis, naTxemovani ataqsiiis, ofTalmoplegiis an mxedvelobiTi (kefis) auriT mimdinare garTulebuli Sakikis da sxva mdgomareobebis CaTvliT. Tanamedrove klinikuri praqtikis Sesabamisad aseTi daavadebebis diagnostikisTvis saWioa γ -polimerazis (POLG) genis mutaciis analizis aReba (ix. paragrafi ~ukuCveneba~).

krunCxviTi Setevebis sixSirisa da simZimis paradoqsuli momateba (epilefsiuri statusis ganviTarebis CaTvliT) an axali tipis krunCxvis gamovlena

rogorc epilefsiis sawinaaRmdego sxva preparatebis gamoyenebisas, valprois mJavas miRebisas zog patients, gaumjobesebis nacvlad, aReniSna krunCxviTi Setevebis sixSirisa da simZimis Seqcevadi momateba (epilefsiuri statusis ganviTarebis CaTvliT) an axali tipis krunCxvis gamovlena. krunCxvis gaZlierebis SemTxvevaSi saWiroa saswrafo konsultacia mkurnal eqimTan (ix. paragrafi ~gverdiTi moqmedeba~).

mdedrobiTi sqesis bavSvebi da mozardebi, Svilosnobis potencialis mqone qalebi da orsulebi

orsulobisgan Tavis dacvis programa

valprois mJavas gaaCnia maRali teratogenuli efeqti, misi gamoyeneba iwvevs nayofSi Tandayolili defeqtebis ganviTarebis da cns-is mxriv darRvevebis ganviTarebis maRal risks.

valprois mJavis gamoyeneba ukunaCvenebia:

- orsulobis periodSi epilefsiis dros, mkurnalobis alternatiuli meTodebis ararsebobis SemTxvevebis garda (ix. paragrafebi ~gansakuTrebuli miTiTeba~, ~gamoyeneba orsulobis da ZuZuTi kvebis periodSi~);
- orsulobis periodSi bipolaruli afeqturi aSlilobis samkurnalod da profilaqtikisTvis;
- qalebSi Svilosnobis potencialiT, Tu ar aris daculi orsulobisgan Tavis dacvis programis yvela piroba (ix. paragrafebi ~gansakuTrebuli miTiTeba~, ~gamoyeneba orsulobis da ZuZuTi kvebis periodSi~).

valprois mJavis Semcveli preparetebis daniSvnisas saWiroa:

- yovel konkretul SemTxvevaSi preparatis daniSvnis mizezis individualuri Sefaseba, Terapiis meTodebis ganxilva da pacientisTvis potenciuri riskebisa da maTi minimumamde Sesamcireblad gasatarebeli zomebis aucileblobis Sesaxeb informaciis miwodeba;
- darwmundeT, rom patients aqvs Svilosnobis potenciali;
- darwmundeT, rom pacientisTvis gasagebia orsulobis periodSi valprois mJavis gamoyenebis riskebi da maTi sidide, kerZod, teratogenuli zemoqmedebis, aseve bavSvis fsiqikuri da fizikuri ganviTarebis darRvevebis riski;
- darwmundeT, rom pacientisTvis gasagebia orsulobis testis Catarebis aucilebloba mkurnalobis dawyebamde da mis procesSi;
- patients ganumartoT kontracefcis meTodebi, darwmundeT, rom patienti mudmivad iyenebs kontracefcis saimedო meTodebs valprois mJavis Semcveli preparetebiT mkurnalobis periodSi;
- darwmundeT, rom pacientisTvis cnobilia epilefsiisa da bipolaruli afeqturi aSlilobis mkurnalobis specialistTan regularulad mimarTvis aucileblobis Sesaxeb (sul mcire weliwadSi erTxel) daniSnuli Terapiis xelaxla Sefasebis mizniT;
- darwmundeT, rom pacientisTvis cnobilia mkurnal eqimTan mimarTvis aucileblobis Sesaxeb orsulobis dagegmvis SemTxvevaSi, raTa droulad Sefasdes alternatiul Terapiaze gadasvlis SesaZlebloba kontracefcური saSualebis Sewyvetamde;
- miawodoT informacia mkurnal eqimTan dauyovnebliv konsultaciisTvis mimarTvis aucileblobis Sesaxeb orsulobaze eWvis arsebobis SemTxvevaSi;
- darwmundeT, rom patienti saTanadod informirebulia riskebisa da saWiro usafrTxoebis zomebis Sesaxeb.

zemoT miTiTebuli informacia aseve relevanturia qalebis mimarT, romlebsac amJamad ar aqvs seqsualuri aqtivoba, garda im SemTxvevebisa, rodesac mkurnali eqimi darwmunebulia Svilosnobis potencialis ararsebobaSi.

mdedrobiTi sqesis bavSvebi

valprois mJavis Semcveli preparetebis daniSvnisas saWiroa:

- darwmundeT, rom mdedrobiTi sqesis bavSvebisTvis/maTi kanonieri warmomadgenlebisTvis gasagebia mkurnal eqimTan konsultaciis aucilebloba menarqes dadgomis SemTxvevaSi;
- darwmundeT, rom menarqes periodis dadgomisas mdedrobiTi sqesis bavSvebs an maT kanonier

warmomadgenlebs miRebuli aqvT detaluri informacia nayofSi ganviTarebis Tandayolili defeqtebis an cns-is ganviTarebis darRvevebis riskebis Sesaxeb.

mkurnalma eqimma yovelwliurad ganmeorebiT unda Seafasos valprois mJavis daniSnuli Terapiia da alternatiuli Terapiis daniSvnis SesaZlebloba. Tu valprois mJavis Semcveli preparatebi warmoadgenen arCevis preparatebs, unda darwmundeT, rom iyenebT kontracefcis saimedo meTodebs da icavT orsulobisgan Tavis dacvis programis. sqesobrivi simwifis dadgomamde mudmivad unda ganixilebodes mkurnalobis alternatiul meTodebze pacientis gadayvanis SesaZlebloba.

orsulobis testi

valprois mJavis Semcveli preparatebiT mkurnalobis dawyebamde orsuloba unda gamoiricxos. valprois mJavis Semcveli preparatebiT mkurnaloba ar unda daeniSnos Svilosnobis potencialis mqone qals, jandacvis muSakis mier dadasturebuli orsulobis testis uaryofiT Sedegis gareSe (sisxlis analizi orsulobaze), raTa gamoiricxos preparatis miReba orsulobis dros.

kontracefcis meTodebi

mdedrobiti sqesis qalebi Svilosnobis potencialiT, romlebsac daeniSnaT valprois mJavis Semcveli preparatebiT Terapiia, mkurnalobis periodSi mudmivad unda iyenebdnen kontracefcis saimedo meTodebs.

mdedrobiti sqesis pacientebis Svilosnobis potencialiT unda miewodoT detaluri informacia orsulobisgan Tavis dacvis meTodebis Sesaxeb, aseve, maT SeuZliaT konsultaciisTvis mimarTon mkurnal eqims im SemTxvevaSi, Tu ar iyeneben kontracefcis saimedo meTodebs.

saWiroa kontracefcis sul mcire erTi saimedo meTodis gamoyeneba (ZiriTadad, iseT meTodebTan erTad, rogoricaa saSvilosnoSida sistema an implantati), an ori erTmaneTis Semvsebi meTodis gamoyeneba, barieruli meTodebis CaTvlit. kontracefcis meTodis daniSvnisas saWiroa individualuri midgoma da yvela SesaZlo variantis ganxilva, raTa darwmundeT, rom pacienti icavs miRebis sqemas. amenoreis SemTxvevaSi saWiroa pacientis gafrTxileba kontracefcis efeqturi meTodebis gamoyenebis Sesaxeb.

daniSnuli Terapiis yovelwliuri analizi

mkurnalma eqimma sul mcire weliwadSi erTxel unda Seafasos warmoadgens Tu ara valprois mJavis Semcveli preparatebi arCevis Terapias. preparatis daniSvnisas da daniSnuli Terapiis yovelwliuri analizis procesSi saWiroa TerapiasTan dakavSirebuli riskebis ganxilva da pacientisTvis riskebis Sesaxeb informaciis miwodeba.

orsulobis dageqmva

Tu pacienti gegmavs orsulobas, epilefsiis da bipolaruli afeqturi aSlilobebis mkurnalobis specialistma unda ganaxorcielos valprois mJavis Semcveli preparatebiT Terapiis Sefaseba da ganxilos alternatiuli Terapiis daniSvnis sakiTxi. saWiroa zomebis miReba, raTa pacienti gadayvanili iqnas valprois mJavis Semcveli preparatebiT Terapiidan Casaxvamde da kontracefcis gamoyenebis Sewyvetis momentamde (ix. paragrafi ~gamoyeneba orsulobis da ZuZuTi kvebis periodSi~). alternatiuli Terapiis ararsebobis SemTxvevaSi pacients unda ganemartos valprois mJavis Semcvel preparatebTan dakavSirebuli yvela

riski momavali bavSvisTvis, ojaxis dagegmvis Sesaxeb informirebuli gadawyvetilebis misaRebad.

ra unda gaakeToT orsulobis dadgomis SemTxvevaSi?

orsulobis dadgomis SemTxvevaSi dauyovnebliv unda mimarToT Tqvens mkurnal eqims, Terapiis Sefasebis da alternatiuli Terapiis daniSvnis sakiTxis ganxilvis mizniT.

jandacvis muSaki unda darwmundes, rom:

- pacientisTvis gasagebia zemoT aRwerili riskebi;
- pacientma miiRo rekomendacia imis Sesaxeb, rom ar unda Sewyvitos valprois mJaviT mkurnaloba da dauyovnebliv mimarTos mkurnal eqims orsulobis dagegmvis SemTxvevaSi.

estrogenis Semcvel preparebTan erTdroulad miReba

valprois mJava ar amcirebs hormonaluri kontrceptivebis Terapiul efeqtianobas. magram, estrogenis Semcvel preparebTan, maT Soris estrogenis Semcvel hormonalur kontrceptivebs, SeuZlia gazardis valprois mJavis klirensi, rac SeiZleba iwvevdes misi Sratismieri koncentraciis Semcirebas, Sedegad ki misi efeqtianobis Semcirebas. estrogenis Semcveli preparebis daniSvnis an moxsnis dros saWiroa sisxlis SratSi valprois mJavis koncentraciis da klinikuri efeqtianobis kontroli (Setevebis da gunebaganwyobis kontroli) (ix. paragrafi ~urTierTqmedeba sxva samkurnalo saSualebebTan~).

bavSvebi (informacia exeba preparatis samkurnalwamlo formebs, romlebic gamoiyeneba sam wlamde asakis bavSvebSi)

sam wlamde asakis bavSvebSi preparatis gamoyenebis aucileblobis SemTxvevaSi rekomendebulia misi gamoyeneba monoTerapiaSi da bavSvebisaTvis rekomendebuli samkurnalwamlo formiT. magram mkurnalobis dawyebamde aucilebelia valprois mJavis gamoyenebis potenciuri sargeblis gansazRvra RviZlis dazianebs da pankreatitis ganviTarebis riskTan mimarTebaSi.

3 wlamde asakis bavSvebSi ar SeiZleba valprois mJavis da salicilatebis erTdroulad gamoyeneba RviZle toqsiuri zemoqmedebis riskTan dakavSirebiT.

Tirkmelebis ukmarisoba

SeiZleba saWiro gaxdes valprois mJavis dozis Semcireba sisxlis SratSi misi Tavisufali fraqciis koncentraciis momatebasTan dakavSirebiT. Tu SeuZlebelia valprois mJavis plazmuri koncentraciis monitoringis Catareba, saWiroa preparatis dozis koreqtireba pacientze klinikuri dakvirvebis safuZvelze.

karbamiduri ciklis (Sardovanas ciklis) fermentebis ukmarisoba

karbamiduri ciklis fermentul ukmarisobaze eWvis arsebobis SemTxvevaSi valprois mJavis gamoyeneba ukunaCveneblia. aRniSnul jgufSi myof pacientebSi aRwerilia stuporiT an komiT Tanmxlebi hiperamoniemiis ramdenime SemTxveva. am SemTxvevaSi metabolizmis gamokvleva unda Catardes valprois mJaviT mkurnalobis dawyebamde (ix. paragrafi ~ukuCveneblia~).

bavSvebSi gaurkveveli kuW-nawlavuri simptomebiT (anoreqsia, Rebineba, citolizis SemTxvevebi), leTargiiT an komiT anamnezSi, gonebrivi ganviTarebis SeferxebiT an ojaxur anamnezSi axalSobilis an bavSvis sikvdiliT, valprois mJaviT mkurnalobis dawyebamde unda Catardes metabolizmis gamokvleva,

kerZod ki, saWiroa amoniemiis gansazRvra (sisxLSi amiakisa da misi naerTebis arseboba) uz moze da sakvebis miRebis Semdeg (ix. paragrafi ~ukuCveneba~).

pacientebi sistemuri wiTeli mgluriT

miuxedavad imisa, rom preparatiT mkurnalobis procesSi naCvenebia imunuri sistemis funqciis darRvevebis Zalian iSviaTi SemTxvevebi, misi gamoyenebis potenciuri sargebeli unda iqnas Sedarebuli preparatis gamoyenebis potenciur riskTan sistemuri wiTeli mgluras mqone pacientebSi.

wonis momateba

saWiroa patientis gafrTxileba mkurnalobis dasawyisSi wonis momatebis riskis Sesaxeb, da agreTve Sesabamisi zomebis miReba, ZiriTadad, dietis daniSvnis saxiT, imisaTvis, rom es movlena minimumamde iqnas Semcirebuli.

pacientebi Saqriani diabetiT

kuWqveSa jirkvalze valprois mJavis arasasikeTo zemoqmedebis SesaZleblobis gaTvaliswinebiT, Saqriani diabetis mqone pacientebSi preparatis gamoyenebisas saWiroa sisxLSi glukozis koncentraciis guldasmiTi monitoringi. Saqriani diabetis mqone pacientebSi ketonuri sxulebis arsebobaze Sardis analizis aRebisas SesaZlebelia cru dadebiTi Sedegebis miReba, radgan valprois mJava gamoiyofa TirkmelebiT, nawilobriv ketonuri sxulebis saxiT.

adamianis imunodeficitis virusiT (aiv) inficirebuli pacientebi

In vitro kvlevebiT dadgenilia, rom valprois mJava astimulirebs aiv replikacias garkveul eqsperimentul pirobebSi. am faqtis klinikuri mniSvneloba cnobili ar aris. garda amisa, dadgenili ar aris *in vitro* kvlevebiT miRebuli am monacemebis mniSvneloba pacientebSi, romlebsac utardebaT maqsimaluri supresiuli antiretrovirusuli Terapia. magram, aRniSnuli monacemebi unda iqnas gaTvaliswinebuli virusuli datvirTvis mudmivi monitoringis Sedegebis interpretacias aiv-inficirebuli pacientebSi, romlebic iReben valprois mJavas.

II tipis karnitin palmitoiltransferazis (kpt) ukmarisobis mqone pacientebi

pacientebi II tipis karnitin palmitoiltransferazis (kpt) ukmarisobiT unda iyvnen gafrTxilebuli rabdomiolizis ganviTarebis ufro maRali riskis Sesaxeb valprois mJavis miRebis SemTxvevaSi.

eTanoli

valprois mJaviT mkurnalobis dros eTanolis miReba rekomendebuli ar aris.

sxva gansakuTrebuli miTiTeba

preparatis (xangrZlivi gamoTavisuflebis preparatis) inertuli matrica misi damxmare nivTierebebis bunebasTan dakavSirebiT ar absorbirdeba kuW-nawlavis traqtSi; aqtiuri nivTierebebis gamoTavisuflebis Semdeg inertuli matrica gamoiyofa nawlavis saSualebiT.

zemoqmedeba satransporto saSualebebis marTvis da meqanizmebTan muSaobis unarze satransporto saSualebebis marTva ukunaCvenebia.

gamoSvebis forma

300 mg nawlavSi xsnadi garsiT dafaruli tabletebi.

10 tableti pvq/pe/pvdq/al blisterSi. 10 blisteri gamoyenebis instruqciasTan erTad muaos kolofSi.

Senaxvis pirobebi

preparati inaxeba araumetes 25°C temperaturaze.

preparati SeinaxeT bavSvebisaTvis miuwvdomel adgilze.

vargisobis vada

3 weli.

preparati ar gamoiyeneba SefuTvaze miTiTebuli vargisobis vadis gasvlis Semdeg.

gacemis piroba

gaicema receptiT.

iuridiuli piri, romelzec gacemulia saregistracio mowmoba

sanofi vintrop industria, safrangeTi.

mwarmoebeli

- 1) sanofi vintrop industria, 1 ru de la vierJ, ambares-e-lagravi, 33565, karbon-blan sedeqsi, safrangeTi.
- 2) sanofi-aventis s.a., stra. s-35 (la batloria-hostalrik, km 63, 09), riels I viabrea, 17404, Jerona, espaneTi.

momxmarebelTa pretenziebi waradgineT ruseTSi misamarTze:

ss ~sanofi ruseTi~: 125009, q. moskovi, tveris q. 22.

telefoni: (495) 721-14-00; faqsi: (495) 721-14-11.

baraTi pacientisTvis, romelic iRebs valprois mJavis Semcvel preparats/ kontracefcia da orsuloba. ra unda icodeT*?

- valprois mJavis Semcveli preparetebi warmoadgens epilefsiis da bipolaruli aSlilobis samkurnalo efeqtian saSualebas.
- orsulobis periodSi valprois mJavis Semcveli preparetebis miRebam SeiZleba seriozuli ziani miayenos momaval bavSvs.
- yovelTvis mudmivad gamoiyeneT kontracefcis efeqturi meTodi valprois mJavis Semcveli preparetebiT mkurnalobis kursis ganmavlobaSi.
- mimarTeT eqims sul mcire weliwadSi erTxel.
- gamoyenebamde gaecaniT samedicino gamoyenebis instruqias.
- arasdros SewyvitoT valprois mJavis Semcveli preparetebis miReba eqimTan konsultaciis gareSe, vinaidan am SemTxvevaSi Tqveni mdgomareoba SeiZleba gauaresdes.
- Tu gegmavT daorsulebas, ar SewyvitoT valprois mJavis Semcveli preparetebis miReba damoukideblad da kontracefcuiri saSualebebis miReba Tqvens eqimTan konsultaciis gareSe.
- Tu fiqrobt, rom xarT orsulad, dauyovnebliv mimarTeT mkurnal eqims.
- mostxoveT Tqvens mkurnal eqims detaluri informacia preparatis Sesaxeb.

*** informacia exeba Svilosnobis potencialis mqone yvela gogonas da qals, romelic iRebs valprois**

mJavis Semcvel preparebs. SeinaxeT es informacia, raTa gadaikiTxoT saWiroebis SemTxvevaSi.