

გამოყენების ინსტრუქცია

augmentini 228 mg/5 ml da 457 mg/5 ml suspensia - narevi xilis aromatiT amoq̄silinis trihidrati – kaliumis klavulanati

xarixobrivi da raodenobrivi Semadgenloba

TeTri an moTeTro feris mSrali fvxvili wyalSi gansazaveblad, raTa miRebul iqnas moTeTro feris suspensia narevi xilis aromatiT.

augmentini 228 mg/5 ml suspensia: ganzavebis Semdeg TiToeuli 5 ml Seicavs 200 mg amoq̄silinis (amoq̄silinis trihidratis saxiT) da 28.5 mg klavulanis mJavas (kaliumis klavulanatis saxiT).

augmentini 457 mg/5 ml suspensia: ganzavebis Semdeg TiToeuli 5 ml Seicavs 400 mg amoq̄silinis (amoq̄silinis trihidratis saxiT) da 57 mg klavulanis mJavas (kaliumis klavulanatis saxiT).

klinikuri informacia

Cvenebebi

augmentini gamoyenebul unda iqnas antibiotikebis gamoyenebis adgilobrivi oficialuri gaidlainevisa da mgrZnobelobis Sesaxeb adgilobrivi monacemebis Sesabamisad.

augmentinis suspensia (228 mg/5 ml da 457 mg/5 ml) orjer dReSi peroralurad misaRebad naCvenebia qvemoT CamoTvliili baqteriuli infeqciebis xanmogle mkurnalobisaTvis, roca eWvia, rom maTi gamomwvevi mizezi amoq̄silinis mimarT rezistentuli beta-laqtamazas warmomq̄mneli Stamebia. sxva SemTxvevaSi ganxiluli unda iqnas mxolod amoq̄silinis gamoyeneba.

zeda sasunTqi gzebis infeqciebi (maT Soris yel-yur-cxviris), rogoricaa: morecidive tonziliti, sinusiti, Sua yuris anTeba.

qvada sasunTqi gzebis infeqciebi, rogoricaa: qronikuli bronqitis gamwvaveba, wilovani pnevmonia da bronqopnevmonia.

saSarde gzebis infeqciebi, rogoricaa: cistiti, ureTriti, pielonefriti.

kanisa da rbili qsovilebis infeqciebi, rogoricaa: celuliti, cxovelis nakbenebi.

stomatologiuri infeqciebi, rogoricaa: kbilis mZime abscesi gavrcelebadi celulitiT.

augmentinisadmi mgrZnobeloba Seicvleba geografiulad da drois mixedviT (damatebiTi informaciisaTvis ix. *farmakologiuri Tvisebebi, farmakodinamika*). Tu xelmisawvdomia, ganxilul unda iqnas adgilobrivi mgrZnobelobis monacemebi da saWiroebis SemTxvevaSi aRebul unda iqnas mikrobiologiuri nimuSebi da gakeTdes mgrZnobelobis analizi.

Sereuli infeqciebis, romlebic gamowveulia amoq̄silinis mimarT mgrZnobiare organizmebis kombinaciIT *augmentinis* mimarT mgrZnobiare beta-laqtamazas warmomq̄mnel organizmebTan, mkurnaloba SeiZleba *aumgentinis* 228 mg/5 ml da 457 mg/5 ml suspenziIT. es infeqciebi ar saWiroeben beta-laqtamazas mimarT rezistentuli sxva antibiotikis damatebas.

dozireba da miRebis wesi

dozireba damokidebulia patientis asakze, wonasa da Tirkmlis funqciaze da infeqciis simZimeze.

dozireba yvelgan mocemulia amoq̄silini/klavulanatis Semcvelobis saxiT, garda im SemTxvevebisa, roca dozireba gansazRvrulia individualuri komponentis mixedviT.

kuW-nawlavis SesaZlo autanlobis Sesamcireblad iniSneba Wamis dawyebisas. *augmentinis* absorbcia optimaluria, roca misi miReba xdeba kvebis dasawyisSi. mkurnalobam ar unda gadaaWarbos 14 dRes ganxilvis gareSe.

Terapia SeiZleba daiwyos parenteralurad da gagrZeldes SigniT misaRebi preparatiT.

suspenziisTvis *augmentinis* boTlis saxiT mowodebul SefuTvas SeiZleba Tan axldes plastmasis dozatori xelsawyo. suspenziis mosamzadeblad ix. *gamoyenebis/moxmarebis instruqciebi*.

Cveulebrivi rekomendebuli dRiuri dozaa:

- *dabali doza*: 25/3.6 – 45/6.4 mg/kg/dReSi gayofili or dozad, msubuqidan saSualomde simZimis infeqciebis dros (zeda sasunTqi gzebis infeqciebi, rogoricaa.: morecive tonziliti, qveda sasunTqi gzebis infeqciebi da kanisa da rbili qsovilis infeqciebi);
- *maRali doza*: 45/6.4 – 70/10 mg/kg/dReSi gayofili or dozad, ufro seriozuli infeqciebis dros (zeda sasunTqi gzebis infeqciebi, mag.: Sua yuris anTeba da sinusiti, qveda sasunTqi gzebis infeqciebi, mag.: bronqopnevmonia da saSarde gzebis infeqciebi).

ar aris klinikuri monacemebi xelmisawvdomi 2 wlamde asakis bavSvebSi 45/6.4 mg/kg/dReSi met dozaze gamoyenebis Sesaxeb.

ar aris klinikuri monacemebi *augmentini* 228 mg/5 ml da 457 mg/5 ml suspenziis dozirebis rekomendaciebis Sesaxeb 2 Tvemde asakis bavSvebSi.

cxrilSi mocemulia bavSvebSi dozirebis rekomendaciebi.

2 wlis da zemoT asakis bavSvebi

| <i>augmentini</i> 228 mg/5 ml suspenzia | | |
|--|--|--|
| sxeulis wona (kg) | ufro dabali dozis intervalisaTvis (ml yovel 12 saaTSi) | ufro maRali dozis intervalisaTvis (ml yovel 12 saaTSi) |
| 12-16 | 5 | 10 |
| 17-26 | 10 | 15 |

| <i>augmentini</i> 457 mg/5 ml suspenzia | | |
|--|--|--|
| sxeulis wona (kg) | ufro dabali dozis intervalisaTvis (ml yovel 12 saaTSi) | ufro maRali dozis intervalisaTvis (ml yovel 12 saaTSi) |
| 12-16 | 2.5 | 5 |
| 17-26 | 5 | 7.5 |
| 27-35 | 7.5 | 10 |
| 36-dan <40 | 10 | 12.5 |

2 Tvidan 2 wlamde asakis bavSvebi

| <i>augmentini</i> suspenzia 457 mg/5 ml | | |
|--|--|--|
| wona (kg) | ufro dabali doza 25/3.6 mg/kg/dReSi (ml yovel 12 saaTSi) | ufro maRali doza 45/6.4 mg/kg/dReSi (ml yovel 12 saaTSi) |
| 2 | 0.3 | 0.6 |
| 3 | 0.5 | 0.8 |
| 4 | 0.6 | 1.1 |
| 5 | 0.8 | 1.4 |
| 6 | 0.9 | 1.7 |
| 7 | 1.1 | 2.0 |
| 8 | 1.3 | 2.3 |
| 9 | 1.4 | 2.5 |
| 10 | 1.6 | 2.8 |
| 11 | 1.7 | 3.1 |
| 12 | 1.9 | 3.4 |
| 13 | 2.0 | 3.7 |
| 14 | 2.2 | 3.9 |
| 15 | 2.3 | 4.2 |

Tirkmlis dazianeba

dozis koreqcia ar aris saWiro pacientebSi, romelTa kreatininis klirensi 30 ml/wT-ze metia. *augmentinis* 228 mg/5 ml da 457 mg/5 ml suspenzia ar aris rekomendebuli pacientebSi, romelTa kreatininis klirensi 30 ml/wT-ze naklebia.

RviZlis dazianeba

doza iniSneba sifrTxiliT; RviZlis funqciis monitoringi unda Catardes regularuli intervalebIT. monacemebi arasakmarisia, raTa moxdes dozirebis rekomendaciis gacema.

ukuCvenebebi

augmentini ukunaCvenebebi

- pacientebSi, romelTac aqvT beta-laqtamebis, mag.: penicilinebis da cefalosporinebis, mimarT hipermgrZnobelobis anamnezi;
- pacientebSi, romelTac aqvT *augmentinTan* asocirebuli siyviTlis/RviZlis disfunqciis anamnezi.

gafrTxilebebi da sifrTxilis zomebi

augmentiniT Terapiis dawyebamde saWiroa anamnezis guldasmIT Sekreba hipermgrZnobelobiTi reaqsiebis Sesaxeb penicilinebis, cefalosporinebis an sxva alergenebis mimarT.

mZime da zogjer fataluri hipermgrZnobelobis reaqsiebi (anafilaqtoiduri da mZime kanismieri gverdiTi reaqsiebi) aRiniSna pacientebSi peniciliniT Terapiis dros. es reaqsiebi ufro metad mosalodnelia ganviTardes penicilinis mimarT hipermgrZnobelobis anamnezis mqone pirebSi (*ix. ukuCvenebebi*). hipermgrZnobelobiTi reaqsiebi aseve SeiZleba progresirdes kunisis sindromamde - mZime alergiuli reaqsia, romelmac SeiZleba gamoiwvios miokardiumis infarqti. am reaqsiebis simptomebi SeiZleba moicavdes mkerdis areSi tkivils, romelic viTardeba *augmentinis* mimarT alergiul reaqsiasTan erTad (*ix. gverdiTi reaqsiebi*). alergiuli reaqsii ganviTarebis SemTxvevaSi, *augmentiniT* mkurnaloba unda Sewydes da unda daiwyos Sesabamisi alternatiuli Terapia.

mZime anafilaqsiuri reaqsiebi moiTxovs dauyovnebliv gadaudebel mkurnalobas adrenaliniT. SeiZleba aseve saWiro gaxdes Jangbadi, intravenuri (i.v.) steroidebi da sasunTqi gzebis gamavlobis aRdgena (SenarCuneba) (maT Soris intubacia).

augmentini ar unda dainiSnos, Tu eWvia infeqciur mononukleozze, radgan aRiniSna am mdgomareobasTan dakavSirebuli wiTelas msgavsi gamonayaris ganviTareba amoqsicilinis gamoyenebis Semdeg.

gaxangrZlivebulma gamoyenebam xandaxan SeiZleba gamoiwvios aramgrZnobiare organizmebis gamravleba.

fsevdomembranozuli koliti aRiniSna antibiotikebis miRebis dros da simZimis mixedviT SeiZleba cvalebadobdes msubuqidan sicocxlisavis saxifaTomde. amitom, mniSvnelovania ganxilul iqnas es diagnozi im pacientebSi, romlebsac aReniSnebaT faRaraTi antibiotikebiT mkurnalobis dros an mis Semdeg. gaxangrZlivebuli an seriozuli faRaraTis dros, an Tu patients aReniSneba muclis kolika, mkurnaloba dauyovnebliv unda Sewydes da saWiroa patientis Semdgomi gamokvleva.

proTrombinis drois gaxangrZliveba (gazrdili INR) iSviaTad aRiniSna pacientebSi, romlebic iRebden *augmentins* da peroralur antikoagulantebis. antikoagulantebis erTdroulad daniSvnisas saWiroa saTanado monitoringi. peroraluri antikoagulantebis dozis koreqcia SeiZleba saWiro iyos antikoagulaciis saWiro donis SesanarCuneblad.

RviZlis funqciis analizebis cvlilebebi aRiniSna zogierT pacientSi, romlebic iRebden *augmentins*. am cvlilebebis klinikuri mniSvneloba ucnobia, amitom *augmentini* sifrTxiliT unda iyos gamoyenebuli RviZlis disfunqciis mqone pacientebSi.

qolestazuri siyviTle, romelic SeiZleba iyos mZime, magram ZiriTadad Seqcevadi, iSviaTad aRiniSna. niSnebi da simptomebi SeiZleba ar gamovlindes mkurnalobis Sewyvetidan 6 kviramde.

Tirkmlis dazianebis mqone pacientebSi *augmentini* 228 mg/5 ml da 457 mg/5 ml suspenzia ar aris rekomendebuli.

Semcirebuli diurezis mqone pacientebSi Zalian iSviaTad aRiniSna kristaluria, upiratesad parenteraluri Terapiis dros. amoqsicilinis maRali dozebis miRebisas rekomendebulia siTxis adeqvaturi raodenobiT

miRebis da adeqvaturi diurezis SenarCuneba, raTa Semcirdes amoqsicilinis kristaluriis ganviTarebis albaToba (ix. *dozis gadaWarbeba*).

augmentinis 228 mg/5 ml da 457 mg/5 ml suspenziebi Seicaven aspartams, rac warmoadgens fenilalaninis wyaros da amitom, sifrTxiliT unda iqnas gamoyenebuli fenilketonuriis mqone pacientebSi.

urTierTqmedebebi

ar aris rekomendebuli probenecidis erTdrouli gamoyeneba. probenecidi aqveiTebs amoqsicilinis Tirkmlis milakovan sekrecias. *augmentinTan* erTdroulma miRebam SeiZleba gamoiwvios amoqsicilinis, magram ara klavulani mJavis, donis gazrda da gaxangrZliveba sisxSi.

alopurinolis kombinirebulma miRebam amoqsicilinis Terapiis dros SeiZleba gazardos kanis alergiuli reaqsiebis riski. ar aris monacemebi *augmentinisa* da alopurinolis erTdrouli gamoyenebis Sesaxeb.

rogorc wesi, sxva antibiotikebis msgavsad, *augmentinma* SeiZleba gavlena iqonios nawlavis floraze, rac iwvevs estrogenis dabal reabsorbacias da kombinirebuli peroraluri kontrceptivebis daqveiTebul efeqturobas.

literaturaSi aRwerilia saerTaSoriso normalizebuli Sefardebis momatebis iSviaTi SemTxvevebi im pacientebSi, romlebic imyofebodnen acenokumaroliT an varfariniT mkurnalobaze da daeniSnaT amoqsicilinis mkurnalobis kursi. Tu aucilebelia erTdrouli daniSvna, *augmentinis* damatebis an moxsnis dros saWiroa proTrombinis drois an saerTaSoriso normalizebuli Sefardebis monitoringi.

pacientebSi, romlebic iRebden mikofenolatis mofetils, mikofenolis mJavis aqtiuri metabolitis sisxSi koncentracia Semdegi dozis miRebamde (predozis koncentracia) Semcirda, daaxloebiT, 50%-iT peroralur amoqsicilins plus klavulani mJavis miRebis Semdeg. dozis miRebamde arsebul doneSi momxdari cvlileba SeiZleba zustad ar warmoadgendes MPA-s eqspoziciis saerTo cvlilebas.

fexmZimoba da laqtacia

fexmZimoba

cxovelebze (Tagvebsa da virTagvebSi dozebze, romlebic 10-er aWarbebs adamianis dozas) Catarebul reproduqciul kvlebebSi peroraluri da parenteraluri miRebisas *augmentins* ar gamouvlenia teratogenuli efekti. qalebSi Catarebul erT kvlevaSi, romelTac hqondaT vadamde adre, sanayofe buStis naadrevi rRveva (pPROM) gamovlinda, rom profilaqtikuri mkurnaloba *augmentiniT* SeiZleba dakavSirebuli yofiliyo axalSobilSi nekrozuli enterokolitis gazrdil riskTan. yvela sxva medikamentis msgavsad, preparati fexmZimobis dros ar unda dainisnos, Tu eqimi ar CaTvlis amas aucileblobad.

laqtacia

augmentini SeiZleba dainisnos laqtaciis dros. sensitizaciis riskis garda, rac dakavSirebulia narCeni raodenobebis gamoyofasTan dedis rZeSi, ar aris cnobili raime saziano gavlena ZuZuTi kvebze myof Cvilze.

avtomobilisa da sxva meqanizmebis marTvis unarze gavlena

gverdiTi efeqtebi avtomobilisa da sxva meqanizmebis marTvis unarze ar gamovlenila.

gverdiTi movlenebi

monacemebi gafarToebuli klinikuri kvlevebidan gamoyenebul iqna, raTa gansazRvruliyo gverdiTi efeqtebis sixSire Zalian xSiriTan iSviaTamde. sxva arasasurvebi movlenebis sixSire (rogoricaa $<1/10.000$ sixSiriT ganviTareba) ZiriTadad, ganisazRvra postmarketinguli monacemebis mixedvit da miuTitebs ufro Setyobinebis sixSires, vidre WeSmarit sixSires.

qvemoT mocemuli SeTanxmeba gamoyenebulia sixSiris klasifikaciisaTvis:

Zalian xSiri $\geq 1/10$

xSiri $\geq 1/100$ da $< 1/10$

araxSiri $\geq 1/1.000$ da $< 1/100$

iSviaTi $\geq 1/10.000$ da $< 1/1.000$

Zalian iSviaTi $< 1/10.000$

infeqciebi da invazia

xSiri: kan-lorwovanis kandidozi

sisxlixa da limfuri sistemis darRvevebi

iSviaTi: Seqcevadi leukopenia (maT Soris neutropenia) da Trombocitopenia

Zalian iSviaTi: Seqcevadi agranulocitozi da hemolizuri anemia. sisxldenis drois da proTrombinis drois gaxangrZliveba

imunuri sistemis darRvevebi

Zalian iSviaTi: angionevrozuli SeSupeba, anafilaqisia, Sratismieri daavadebis msgavsi sindromi. hipermgrZnobelobiTi vaskuliti

nervuli sistemis darRvevebi

araxSiri: Tavbrusxveva, Tavis tkivili

Zalian iSviaTi: Seqcevadi hiperaqtiuroba, aseptikuri meningiti, krunCxvebi. krunCxvebi SeiZleba ganviTardes pacientebSi, romlebsac aReniSnebaT daqveiTebuli Tirkmlis funqcia an iReben maRal dozebs.

kardialuri darRvevebi

Zalian iSviaTi: kunisis sindromi (ix. *gafrTxilebebi da sifrTxilis zomebi*)

kuW-nawlavis darRvevebi

mozdilebi:

Zalian xSiri: faRaraTi

xSiri: gulisreva Rebineba

bavSvebi:

xSiri: faRaraTi, gulisreva, Rebineba

yvela populacia:

gulisreva xSirad dakavSirebulia maRal peroralur dozebTan. Tu kuW-nawlavis reaqciebi vlindeba, maTi Semcireba SesaZlebelia *augmentinis* miRebiT kvebis dasawyisSi.

araxSiri: dispefsia

Zalian iSviaTi: antibiotikTan dakavSirebuli koliti (maT Soris fsevdomembranuli koliti da hemoragiuli koliti – ix. *gafrTxilebebi da sifrTxilis zomebi*), Savi bususebiani ena.

Zalian iSviaTad bavSvebSi aRiniSna kbilebis zedapiruli feris cvlileba. piriS Rrus kargi higiena axdens kbilebis feris cvlilebis prevencias, radgan misi mocileba SesaZlebelia kbilebis gaxexviT.

hepato-biliaruli darRvevebi:

araxSiri: AST-s da/an ALT-s donis zomieri momateba aRiniSna pacientebSi, romlebic mkurnalobdnen beta-laqtamuri klasis antibiotikebiT, Tumca am Sedegebis mniSvneloba ucnobia.

Zalian iSviaTi: hepatiti da qolestazuri siyviTle. es movlenebi aRiniSna sxva penicilinebis da cefalosporinebis miRebis dros.

RviZlismieri movlenebi upiratesad aRiniSna mamakacebSi da xandazmul pacientebSi da SeiZleba dakavSirebuli iyos gaxangrZlivebul mkurnalobasTan. es movlenebi Zalian iSviaTad aRiniSna bavSvebSi.

niSnebi da simptomebi Cveulebriv viTardeba mkurnalobis dros an mkurnalobidan xanmokle periodis Semdeg, magram zogierT SemTxvevaSi SeiZleba ar gamovlindes mkurnalobis Sewyvetidan ramdenime kviris ganmavlobaSi. es simptomebi Cveulebriv Seqcevadi xasiaTisaa. RviZlismieri movlenebi SeiZleba iyos mZime xasiaTis da ukiduresad iSviaT SemTxvevebSi aRiniSna sikvdili. TiTqmis yvela SemTxvevaSi pacientebS aReniSnebodaT mZime Tanmxlebi daavadeba an iRebden Tanmxleb medikamentebS, romlebsac RviZlismieri potenciuri efeqtebi hqondaT.

kanisa da kanqveSa qsovilis darRvevebi

araxSiri: gamonayari kanze, qavili, WinWris cieba

iSviaTi: multiformuli eriTema

Zalian iSviaTi: stivens-jonsonis sindromi, toqsikuri epidermulu nekrolizi, bulozuri eqsfoliaciuri dermatiti, mwvave generalizebuli egzantemuri pustulozi (AGEP) da wamlismieri reaqla eozinofiliTa da sistemuri simptomebiT (DRESS).

Tu aRiniSneba hipermgrZnobelobiTi dermatitis reaqla, mkurnaloba unda Sewydes.

Tirkmlisa da saSarde gzebis darRvevebi

Zalian iSviaTi: intersticialuri nefriti, kristaluria (*ix. dozis gadaWarbeba*).

dozis gadaWarbeba

SeiZleba ganviTardes kuW-nawlavis simptomebi da siTxisa da eleqtrolitebis balansis darRveva. kuW-nawlavis simptomebis mkurnaloba unda moxdes simptomurad, wylisa da eleqtrolitebis balansze yuradRebis miqceviT.

aRiniSna amoqsicilinis kristaluria, romelmac zogierT SemTxvevebSi gamoiwvia Tirkmlis ukmarisoba (*ix. gafrTxilebebi da sifrTxilis zomebi*).

augmentini cirkulaciidan SeiZleba gamodevnil iqnas hemodializis saSualebiT.

farmakologiuri Tvisebebi

farmakodinamika

aTq kodi

anomiur-Terapiuli-qimiuri (aTq) kodi: J01CR02

farmakoTerapiuli jgufi: penicilinebis kombinaciebi, beta-laqtamazas inhibitorebis CaTvlit

bevri antibiotikis mimarT rezistentoba gamowveulia baqteriuli fermentebiT, romlebic Slian antibiotiks, sanam is daiwyebis paTogenze zemoqmedebas. *augmentinis* suspenziaSi Semavali klavulanati gansazRvra am damcvelobiT meqanizms beta-laqtamazas fermentebis blokirebiT, rac organizmebs mgrZnobiare xdis amoqsicilinis swrafi baqteriduli efeqtis mimarT koncentraciebze, rac swrafad miiRweva organizmSi.

klavulanats TavisTavad susti antibaqteriuli moqmedeba gaaCnia, Tumca amoqsicilinTan erTad, rogorc es warmodgenilia *augmentinSi*, is warmoqmni farTo speqtris antibiotikur saSualebas, romelic farTod gamoiyeneba rogorc hospitaluri mkurnalobis, ise zogadi praqtikis dros.

farmakodinamikuri efeqtebi

qvemoT CamoTvili organizmebi kategorizebulia *augmentinis* mimarT maTi *in vitro* mgrZnobelobis mixedviT.

mikroorganizmebis *in vitro* mgrZnobeloba *augmentinis* mimarT

augmentinis klinikuri efeqturoba klinikur kvlevebSi aRniSnulia varskvlaviT (*).

organizmebi, romlebic ar warmoqmni beta-laqtamazas, identificirebulebi arian niSnit (†). Tu izolati mgrZnobiarea amoqsicilinis mimarT, is miCneulia *augmentinis* mimarT mgrZnobiared.

ZiriTadi mgrZnobiare saxeobebi

gram-dadebiTi aerobebe:

Bacillus anthracis

Enterococcus faecalis

Listeria monocytogenes

Nocardia asteroides

*Streptococcus pyogenes**†

*Streptococcus agalactiae**†

Streptococcus spp. (sxva beta-hemolizuri) *†

Staphylococcus aureus (meTicilinmgrZnobiare)*

Staphylococcus saprophyticus (meTicilinmgrZnobiare)*

koagulaza-uaryofiTi stafilokokebi (meTicilinmgrZnobiare)

gram-uaryofiTi aerobebi:

Bordetella pertussis
*Haemophilus influenzae**
Haemophilus parainfluenzae
Helicobacter pylori
*Moraxella catarrhalis**
Neisseria gonorrhoeae
Pasteurella multocida
Vibrio cholera

sxva:

Borrelia burgdorferi
Leptospira icterohaemorrhagiae
Treponema pallidum

gram-dadebiTi anaerobebi:

Clostridium spp.
Peptococcus niger
Peptostreptococcus magnus
Peptostreptococcus micros
Peptostreptococcus spp.

gram-uaryofiTi anaerobebi:

Bacteroides fragilis
Bacteroides spp.
Capnocytophaga spp.
Eikenella corrodens
Fusobacterium nucleatum
Fusobacterium spp.
Porphyromonas spp.
Prevotella spp.

saxeobebi, romlebisTvisac SeZenili rezistentoba SeiZleba problemuri iyos

gram-uaryofiTi aerobebi:

*Escherichia coli**
Klebsiella oxytoca
*Klebsiella pneumoniae**
Klebsiella spp.
Proteus mirabilis
Proteus vulgaris
Proteus spp.
Salmonella spp.
Shigella spp

gram-dadebiTi aerobebi:

Corynebacterium spp.
Enterococcus faecium
Streptococcus pneumoniae†*
Viridans group streptococcus

bunebrivad rezistentuli organizmebi

gram-uaryofiTi aerobebi:

Acinetobacter sp.
Citrobacter freundii
Enterobacter spp.
Hafnia alvei
Legionella pneumophila
Morganella morganii

Providencia spp.
Pseudomonas sp.
Serratia sp.
Stenotrophomonas maltophilia
Yersinia enterocolitica

sXva:
Chlamydia pneumoniae
Chlamydia psittaci
Chlamydia spp.
Coxiella burnetti
Mycoplasma spp

amoq̄silinis mimarT mgrZnobiare organizmebiT gamowveuli infeq̄ciebi emorCilebian *augmentini*T mkurnalobas, masSi amoq̄silinis Semcvelobis gamo. amoq̄silinis mimarT mgrZnobiare organizmebiT da *augmentinis* mimarT mgrZnobiare beta-laqtamazas warmomq̄mneli organizmebiT gamowveuli Sereuli infeq̄ciebis mkurnaloba unda moxdes *augmentini*T.

farmakokinetika

Sewova

augmentini 228 mg/5 ml da 457 mg/5 ml suspenziis ori komponenti, amoq̄silini da klavulanis mJava, srulad disocirebulebi arian wyalxsnarSi fiziologiur pH-ze. orive komponenti swrafad da kargad Seiwoveba SigniT miRebis dros. *augmentinis* Sewova optimizirebulia, roca misi miReba xdeba kvebis dasawyisSi.

mozdilebSi saSualo AUC maCveneblebi amoq̄silinisaTvis ZiriTadad igivea, rac *augmentini* 875/125 mg tabletis orjer dReSi dozirebis an *augmentini* 500/125 mg tabletis samjer dReSi dozirebis dros. ar aRiniSna gansxvaveba 875 mg orjer dReSi da 500 mg samjer dReSi dozirebis sqemebis dros amoq̄silinis $T_{1/2}$ an Cmax Sedarebisas amoq̄silinis gansxvavebuli dozebis miRebis Semdeg normalizaciisas. aseve, ar iqna nanaxi gansxvaveba klavulanatis $T_{1/2}$, Cmax an AUC maCveneblebis kuTxiT, Sesabamisi dozis normalizaciis Semdeg.

augmentinis dozis miRebis dros, kvebis dawyebasTan mimarTebaSi, ar aqvs amoq̄silinis farmakokinetikaze raime gamoxatuli efeq̄tebi mozdilebSi. *augmentinis* 875/125 mg tabletis kvlevaSi dozirebis dros, sakvebis miRebasTan mimarTebaSi, hqonda gamoxatuli efeq̄ti klavulanatis farmakokinetikaze. klavulanatis AUC-sTvis da Cmax-sTvis umaRlesi saSualo maCveneblebi da umciresi pirTaSorisi variabeloba miRweuli iqna *augmentinis* daniSvniT kvebis dasawyisSi im mdgomareobebTan SedarebiT, roca wamlis miReba xdeboda uzmoze an kvebis dawyebidan 30 an 150 wuTis Semdeg.

saSualo Cmax, Tmax, $T_{1/2}$ da AUC sidideebi amoq̄silinisa da klavulanatisTvis mocemulia qvemoT, roca 875 mg/125 mg amoq̄silini/klavulanis mJavis miReba xdeboda kvebis dawyebisas.

| saSualo farmakokinetikuri parametrebi | | | | | |
|---------------------------------------|-----------|--------------|-----------|----------------|-----------|
| miRebuli wamali <i>augmentini</i> 1g | doza (mg) | Cmax (mg/ml) | Tmax*(sT) | AUC (mg.sT/ml) | T1/2 (sT) |
| amoq̄silini | 875 | 12,4 | 1,5 | 29,9 | 1,36 |
| klavulanati | 125 | 3,3 | 1,3 | 6,88 | 0,92 |
| *mediana maCveneblebi | | | | | |

amoq̄silinis Sratis koncentraciebi, romlebic miiRweva *augmentini*T, msgavsia mxolod amoq̄silinis eq̄ivalenturi dozebis peroraluri miRebiT warmoq̄mnili koncentraciisa.

ganawileba.

augmentinis ori komponentis farmakokinetika Zalian hgavs erTmaneTs. rogorc klavulanats, ise amoq̄silins axasiaTebis SratSi dakavSirebis dabali doneebi; daaxloebiT 70% Tavisufali rCeba SratSi.

augmentinis dozis gaormageba iwvevs SratSi misi donis daaxloebiT gaormagebas.

arakinikuri informacia

ar aris damatebiTi Sesabamisi informacia.

farmaceutuli informacia

damxmare nivTierebebis CamonaTvali

augmentiniis mSrali fxnili suspenziisaTvis Seicavs gumis fiss, hidroqsipropilmeTilcelulozas, koloiduri siliciumis dioqsids, suqcinis mJavas, siliciumis dioqsids, aspartams da mSral aromatebs (Jolo, forToxali "1", forToxali "2" da oqrosferi sirofi).

Senaxvis vada

Senaxvis vada miTiTebulia SefuTvaze.

Senaxva

Senaxvis pirobebi detalurad mocemulia SefuTvaze.

dauSvebelia miReba SefuTvaze miTiTebuli Senaxvis vadis gasvlis Semdeg.

inaxeba mSral adgilas, originalur SefuTvaSi nestisagan dasacavad.

ganzavebis Semdeg, suspenzia Senaxul unda iqnas macivarSi (2°C - 8°C) da gamoyenebul iqnas 7 dRis ganmavlobaSi. dauSvebelia gayinva (ix. aseve *gamoyeneba da moxmareba*).

konteineris forma da Semadgenloba

augmentini suspenziis mosamzadeblad boTlebSi

gamWvirvale minis boTlebi Seicaven fxnils, romelic unda ganzavdes. boTlebs SeiZleba hqondeT aluminis Casaxraxni TavsaXuri dasaluqi rgoliT an plastmasis, bavSvisTvis usafrTxo TavsaXuri, mosaxsneli folgis sarCuliani luqiT boTlze. punqtiris xazi datanilia boTlis etiketze. boTlebs SeiZleba Tan axldes plastmasis dozatori xelsawyo.

augmentini suspenziis mosamzadeblad saSetebSi (mxolod 457 mg farmaceutuli formisaTvis)

erTjeradi gamoyenebis qaRaldis/aluminis/polieTilenis mraValSriani saSetebi, romlebic Seicaven fxnils gansazaveblad.

SeuTavsebloba

ar aris cnobili

gamoyeneba da moxmareba

augmentinis suspenzia boTlebSi

gamoyenebamde boTlebi aluminis xraxniani TavsaXuriT unda Semowmdes, rom TavsaXuris dasaluqi rgoli xeluxlebelia alternatiulad, boTlebi plastmasis bavSvisTvis usafrTxo TavsaXuriT unda Semowmdes gamoyenebamde, rom folgis sarCuliani boTlis luqi intaqtura.

gamoyenebis dros mSrali fxnili unda ganzavdes, raTa warmoiqmas SigniT misaRebi suspenzia, rogorc es mocemulia qvemoT:

- boTli unda gadmotrialdes da SeinjRres, raTa fxnili gafxvierdes;
- unda daematos wylis moculoba (miTiTebulia qvemoT). unda gadmotrialdes da SeinjRres;
- alternatiulad, boTli unda aivosos wyliT boTlis etiketze aRniSnuli niSnulis qvemoT. unda gadmotrialdes da kargad SeinjRres, Semdeg bolomde, niSnulamde unda Seivosos wyliT. unda gadmotrialdes da iseV SeinjRres;
- sruli dispersiisaTvis saWiroa 5 wuTiT dayovneba;
- TiToeuli dozis miRebis win kargad unda SeinjRres.

| <i>augmentini 228 mg/5 ml suspenzia</i> | | |
|--|--|---|
| avsebis wona (g) | wylis moculoba, romelic unda daematos gansazaveblad (ml) | ganzavebuli peroraluri suspenziis saboloo |

| | | |
|------|-----|---------------|
| | | moculoba (ml) |
| 7,7 | 64 | 70 |
| 15,4 | 128 | 140 |

| augmentini suspenzia 457 mg/5 ml | | |
|---|--|---|
| avsebis wona (g) | wylis moculoba, romelic unda daematos gansazaveblad (ml) | ganzavebuli peroraluri suspenziis saboloo moculoba (ml) |
| 6,3 | 31 | 35 |
| 12,6 | 62 | 70 |
| 25,2 | 124 | 140 |

plastmasis dozatori xelsawyo SeiZleba moTavsebuli iyos SefuTvaSi, romelic SeiZleba gamoyenebuli iqnas swori dozirebisaTvis.

gamoyenebeli suspenzia gadagdebul unda iqnas 7 dRis Semdeg.

augmentini suspenzia saSetebSi

TiToeuli erTjeradi saSeti Seicavs fvxnils *augmentini* 457 mg/5 ml suspenziis 2,5 ml dozisaTvis. gamoyenebis dros oraluri suspenziis misaRebad mSrali fvxnili unda ganzavdes qvemoT aRwerilis Sesabamisad:

- gamoyenebamde saSeti unda Semowmdes, rom xeluxlebelia;
- saSeti unda gaiWras punqtiris xazis gaswvri;
- SigTavsi unda gadmoyaros WiqaSi;
- naxevari saSeti unda gaivos wyliT;
- unda Caisxas WiqaSi. saWiroa moreva, rom gaixsnas;
- ganzavebis Semdeg dauyovnebliv unda dailios.

Tu saWiroa erTdroulad erTze meti saSetis miReba, maSin isini SeiZleba Seerios erTsa da imave WiqaSi. nebismieri gamoyenebeli samkurnalo produqti an narCeni masala unda ganadgurdes adgilobrivi moTxovnebis Sesabamisad.

yvela farmaceutuli forma ar aris warmodgenili yvela qveyanaSi.

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warmoebulia:

Glaxo Wellcome Production*

ZI de la Peyenniere

53100 Mayenne

France

glaqso velqam produqcion*

peienis industriuli zona

53100 maieni

safrangeTi

*glaqsosmiTklainis jgufis kompaniebis wevri

sasaqonlo niSani ekuTvnis an licenziIT gadacemulia gsk jgufis kompaniebze.

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