**sarekomendacio versia**

**furceli-CanarTi: informacia momxmareblisTvis**

**doqseni 80mg/2ml koncentraci da gamxsneli sainfuzio xsnaris mosamzadeblad**

**docetaqseli**

**am preparatis gamoyenebamde yuradRebiT waikiTxeT furceli-CanarTi srulad, radgan is Seicavs TqvenTvis mniSvnelovan informacias.**

* SeinaxeT es furceli-CanarTi. SeiZleba dagWirdeT misi xelaxla wakiTxva.
* damatebiTi kiTxvebis SemTxvevaSi gTxovT rCevisTvis mimarToT eqims, hospitalis Tqvens farmacevts an Tqvens eqTans.
* Tu romelime gverdiTi efeqti xdeba seriozuli an Tu Tqven aRniSnavT gverdiT efeqtebs, romlebic CamoTvlili ar aris, mimarTeT eqims, farmacevys an eqTans. es exeba nebismier gverdiT efeqts, romelic am furcel-CanarTSi aRniSnuli ar aris.

**am furcel-CanarTSi:**

1. ra aris doqseni da risTvis gamoiyeneba.

2. ra unda icodeT doqsenis gamoyenebamde

3. rogor gamoiyeneba doqseni

4. SesaZlo gverdiTi efeqtebi

5. rogor inaxeba doqseni

6. SefuTvis Semadgenloba da damavebiTi informacia

1. **ra aris doqseni da risTvis gamoiyeneba.**

am medikamentis dasaxelebaa doqseni. es aris substancia, romelic miiReba uTxovris xis Teslebisgan. misi generikuli dasaxelebaa docetaqseli. docetaqseli miekuTvneba kibos sawinaaRmdego medikamentebis jgufs - taqsoidebs.

doqseni Tqvenma eqimma daniSna ZuZus kibos, filtvis kibos specialuri formebis (filtvis arawvrilujredovani kibo), da prostatis kibos samkurnalod:

* ZuZus Sorswasuli kibos samkurnalod doqsenisgamoyeneba SeiZleba monoTerapiis saxiT an kombinaciaSi doqsorubicintan an trastuzumabTan an kapecitabinTan.
* ZuZus kibos mkurnalobisTvis adreul stadiaze doqsenis gamoyeneba SeiZleba doqsorubicinTan an ciklofosfamidTan kombinaciaSi
* filtvis kibos samkurnalod doqseni unda gamoiyenon monoTerapiis saxiT an cisplatinTan kombinaciaSi.

- prostatis kibos mkurnalobisTvis doqseni gamoiyeneba prednizonTan an prednizolonTan kombinaciaSi.

1. **ra unda icodeT doqsenisgamoyenebamde**

**doqseni ar unda miiRoT**

* Tu alergiuli xarT (gaqvT momatebuli mgrZnobeloba) docetaqselis an doqsenis nebismieri sxva ingredientis mimarT.
* sisxlis TeTri ujredebis raodenoba Zalian dabalia.
* gaqvT RviZlis mwvave daavadeba.

**gansakuTrebuli sifrTxile gamoiCineT doqsenismiRebisas**

doqseniT yovel mkurnalobamde CagitardebaT sisxlis testireba raTa Semowmdes gaqvT Tu ara sakmarisi raodenobiT sisxlis ujredebi da RviZlis sakmarisi funqciebi, SeiZleba aRgeniSnebodeT amasTan dakavSirebuli cxeleba an infeqciebi.

doqsenisnebismir miRebamde erTi dRiT adre gTxoven miiRoT premedikacia, oraluri kortikosteroidis saxiT, rogoricaa deqsameTazoni, misi miReba unda ganagrZoT amis Semdeg erTi an ori dRis ganmavlobaSi zogierTi arasasurveli efeqtis asacileblad, romelic SeiZleba ganviTardes doqsenisinfuziis Semdeg, gansakuTrebiT rogoricaa alergiuli reaqciebi da siTxis retencia (xelebis, terfebis, fexebis SeSupeba an wonaSi mateba).

mkurnalobis ganmavlobaSi SeiZleba miiRoT sxva medikamentebic sisxlis ujredebis raodenobis SenarCunebisTvis.

**sxva medikamentebis miReba**

gTxovT acnobeT eqims an saavadmyofos farmacevts Tu iRebT an bolo dros miRebuli gaqvT sxva medikamenti, receptis gareSe gacemuli saSualebebis CaTvliT. es saWiroa radgan doqsenma an sxva medikamentma SeiZleba mosalodneli efeqti ar mogceT an SeiZleba ganviTardes gverdiTi efeqti.

**orsuloba, laqtacia da fertiloba**

nebismieri medikamentis miRebamde rCeva kiTxeT eqims an farmacevts.

doqseni,**ar unda gamoiyenoT** orsulobis dros Tu amas ar gadawyvets eqimi.

am medikamentiT mkurnalobis dros ar unda daorsuldeT da unda gamoiyenoT kontracefciis efeqturi meTodi, radgan doqseni, SeiZleba sazino iyos bavSvisTvis. Tu mkurnalobis dros daorsuldebiT, dauyovnebliv unda mimarToT eqims.

ZuZuTi kvebis dros doqseniTar unda imkurnaloT.

Tu xarT mamakaci da doqseniT mkurnalobTgirCeven, rom mkurnalobis dros da misi dasrulebidan 6 Tvis ganmavlobaSi Casaxvisgan Tavi SeikavoT da mkurnalobamde gaiaroT konsultacia spermis konservaciasTan dakavSuirebiT, radgan docetaqselma SeiZleba imoqmedos mamakacis fertilobaze.

**avtomobilis marTva da meqanizmebis gamoyeneba**

ar arsebobs mizezi, romlis gamoc doqsenis kursis dros (miRebisas) avtomobilis marTvisgan Tavi unda SeikavoT, im SemTxvevis garda rodesac grZnobT Tavbrusxvevas da sakuTar TavSi eWvi geparebaT.

1. **rogor gamoiyeneba doqseni**

doqsens daginiSnavT Tqveni eqimi.

**Cveuli doza**

doza damokiebuli iqneba wonaze da zogad mdgomareobaze. eqimi gamoTqlis Tqveni sxeulis zedapiris farTobs kvadratul metrebSi (m2) da gansazRvravs saWiro dozas.

**miRebis meTodi**

doqsenis miReba moxdeba venaSi infuziiT (intravenurad). infuzia daaxloebiT gagrZeldeba erTi saaTi da gakeTdeba saavadmyofoSi.

**miRebis sixSire**

infuzia Cveulebriv CagitardebaT 3 kviraSi erTxel.

eqimma SeiZleba Secavlos doza da miRebis sixSire, sisxlis analizis, zogadi mdgomareobis da doqsenze pasuxis mixedviT.

acnobeT eqims, gansakuTrebiT, diareis, piris simSralis, dabuJebis, Cxvletis da Cqmetis SegrZnebis, cxelebis SemTxvevaSi da miawoeT mas Tqveni sisxlis analizis Sedegebi.

amgvari informacia mas saSualebs miscems gadawyvitos saWiroa Tu ara dozis Semcireba. am medikamentis gamoyenebis Sesaxeb damatebiTi kiTxvebis SemTxvevaSi mimarTeT eqims an saavadmyofos faramcevts.

**4. SesaZlo gverdiTi efeqtebi**

rogorc yvela medikamentma, doqsenma SeiZleba gamoiwvios gverdiTi efeqtebi, Tumca isini yvelas ar uviTardeba.

Tqveni eqimi ganixilavs maT TqvenTan erTad da gangimartavT potenciur riskebs da mkurnalobis sargebels.

mxolod doqsenis gamoyenebisas yvelaze xSirad aRwerili gverdiTi efeqtebia: sisxlis wiTeli an TeTri ujredebis raodenobis daqveiTeba, alopecia, gulisreva, Rebineba, piris simSrale, diarea da daRliloba.

doqsenis gverdiTi movlenebis simwvave SeiZleba gaizardos rodesac misi gamoyeneba xdeba sxva qimioTerapiul agentebTan erTad.

saavadmyofoSi infuziis dros SeiZleba ganviTardes Semdegi alergiuli reaqciebi (aRiniSneba 10-idan 1-ze met SemTxvevaSi)

* alebi, kanis reaqciebi, qavili
* gulmkerdSi SeboWiloba, sunTqvis gaZneleba
* cxeleba an wva
* zurgis tkivili
* sisxlis dabali wneva.

SeiZleba ganviTardes ufro mwvave reaqciebi

saavadmyofos personali mkurnalobis dros intensiurad daakvirdeba Tqvens mgomareobas. dauyovnebliv acnobeT maT Tu SeniSnavT raime gverdiT efeqts.

doqsenis infuziebs Soris SeiZleba ganviTardes Semdegi reaqciebi da maTi sixSire SeiZleba varirebdes miRebuli medikamentebis mixedviT:

**Zalian xSiri (aRiniSneba 10-idan 1-ze met SemTxvevaSi):**

* infeqciebi, sisxlis wiTeli (anemia) an TeTri ujredebis (romlebic mniSvnelovania infeqciebTan brZolisTvis) da Trombocitebis raodenobis Semcireba
* cxeleba: am SemTxvevaSi dauyovnebliv unda mimarToT eqims
* alergiuli reaqciebi rac aRwerilia zemoT
* madis dakargva (anoreqsia)
* uZiloba
* saxsrebSi da kunTebSi dabuJebis, Cxvletis da Cqmetis SegrZneba
* Tavis tkivili
* gemos SegrZnebis darRveva
* Tvalis anTeba an momatebuli cremldena
* limfuri drenaJis darRvevis gamo gamowveuli SeSupeba
* sunTqvis ukmarisoba
* cxviridan gamonadeni, yelis da cxviris anTeba; xvela
* cxviridan sisxldena
* piris RruSi wyluebi
* kuWis mxriv darRvevebi, gulisrevis, Rebinebis, diareis CaTvliT, yabzoba
* muclis tkivili
* saWmlis monelebis darRveva
* xanmokle Tvmis cvena (umravles SemTxvevebSi aRdgeba Tmis normaluri zrda)
* xelis da fexis gulebis siwiTle da SeSupeba, ramac SeiZleba gamoiwvios kanis aqercvla (agreTve SeiZleba ganviTardes xelebis, saxis an sxeulis midamoSi)
* frCxilebis feris cvlileba, romlebic SeiZleba moZvres
* kunTebis daWimuloba da tkivili, zurgis an Zvlis tkivili
* menstrualuri ciklis Secvla an ar arseboba
* xelebis, terfebis, fexebis SeSupeba
* daRliloba an gripis msgavsi simptomebi
* wonaSi mateba an kleba.

**xSiri (aRiniSneba 10-idan 1-ze nakleb, magram 100-dan 1-ze met SemTxvevaSi):**

* oraluri kandidozi
* dehidratacia
* Tavbrusxveva
* smenis darRveva
* sisxlis wnevis daqveiTeba; araregularuli an swrafi guliscema
* gulis ukmarisoba
* ezofagiti
* piris simSrale
* ylapvis gaZneleba an ylapvis dros tkivili
* hemoragia
* RviZlis enzimebis momateba (aqedan gamomdinare saWiroa sisxlis regularuli testireba)

**nakleba xSiri (aRiniSneba 1000-dan 1-ze met, magram 100-idan 1-ze nakleb SemTxvevaSi):**

* gulis wasvla
* ineqciis adgilze kanis reaqciebi, flebiti (venis anTeba) an SeSupeba
* msxvili da wvrili nawlavis anTeba, intestinuri perforacia
* sisxlis Trombebi.

gverdiTi efeqtebis SemTxvevaSi mimarTeT eqims, saavadmyofos farmacevts an eqTans.

1. **rogor inaxeba doqseni**

**SeinaxeT bavSvebisTvis miuwvdomel adgilze.**

doqsenis miReba ar SeiZleba kolofze da flakonebze miTiTebuli vargisianobis vadis gasvlis Semdeg.

ar SeinaxoT 25°C-ze maRal an 2°C-ze dabal temperaturaze.

SeinaxeT originalur SefuTvaSi, sinaTlisgan dacvisTvis.

flakonis pirveli gaxnis Semdeg produqti unda gamoiyenon dauyovnebliv.

**momzadebis Semdeg**

mikrobiologiuri TvalsazrisiT, momzadebuli an gansazavebeli xsnari unda gamoiyenon momzaebisTanave.

Tu dauyovnebliv gamoyeneba ar xdeba, Senaxva aris momxmareblis pasuxismgebloba, 2-8oC temperaturaze. sanam ar moxdeba momzadeba validuri da aseptikur pirobebSi, drom ar unda gadaaWarbos fizioqimiuri stabilurobis vadas.

gansazavebeli xsnaris qimiuri da fizikuri stabiluroba gamovlenilia 8 saaTis ganmavlobaSi 2°C da 8°C-ze an 25°C–ze dabal, oTaxis temperaturaze Senaxvisas.

**sainfuzio xsnari**

mikrobiologiuri TvalsazrisiT glukozis 5%-ian an NaCI 0,9%-ian xsnarTang anzavebis Semdeg sainfuzio xsnaris gamoyeneba unda moxdes dauyovnebliv. Tu dauyovnebliv gamoyeneba ar xdeba, Senaxva momxmareblis pasuxismgeblobaa 2-8oC temperaturaze sanam ar moxdeba momzadeba validuri da aseptikur pirobebSi, drom ar unda gadaaWarbos fizioqimiuri stabilurobis vadas.

gansazavebeli xsnaris qimiuri da fizikuri stabiluroba gamovlenilia 4 saaTis ganmavlobaSi 25°C –ze dabal oTaxis temperaturaze Senaxvisas

**6. damatebiTi informacia**

**ras Seicavs doqsenis koncentratis flakoni:**

* aqtiuri nivTierebaa docetaqseli. doqseniskoncentratis yoveli flakoni Seicavs 80mg/2ml docetaqsels. konentratis yoveli ml Seicavs 40mg docetaqsels.
* sxva ingredientebia polisorbati 80 da limonmJava.

**ras Seicavs gamxsnelis flakoni:**

gamxsnelis yoveli flakoni Seicavs 6ml 12% uwylo eTanolis xsnars saineqcio wyalSi ganzavebuls (13% w/w 95%-iani eTanolis eqvivalenturi).

**doqsenisaRwera da SefuTvis Semadgenloba**

doqseni 80mg/2ml koncentrati sainfuzio xsnaris mosamszadeblad aris gamWvirvale, yviTeli an yavisferi-yviTeli xsnari.

yoveli kolofi Seicavs:

* erTi erTjeard doziani flakoni koncentratiT da
* erTi erTjerad doziani flakoni gamxsneliT.

**savaWro licenziis mflobeli:**

**VIANEX S.A.,** Tatoiou Street 18th km National Road Athens Lamia, 14671 Nea Erythrea

Greece

**mwarmoebeli**:

**VIANEX S.A. -Plant C’**

16th km Avenue Marathonos, Pallini

**instruqciis bolo damtkiceba moxda 09/2013.**

Semdgomi informacia gankuTvnilia xolod samedicino sferos profesionalisTvis.

**momzadebis gaidlaini doqsenis 80mg/2ml sainfuzio xnsaris mosamsadebeli koncentratis da doqsenis gamxsnelisTvis**

*mniSvnelovania proceduris sruli Sinaarsi winaswr waikiTxoT doqsenis gansazavebeli xsnaris an sainfuzio xsnaris momzadebamde.*

**1. Semadgenloba**

doqseni 80mg/2ml sainfuzio xsnaris mosamzadebeli koncentrati aris gamWvirvale, blanti, yviTeli an yavisferi-yviTeli siTxe, Seicavs 40mg/ml docetaqsels (uwylo) polisorbat 80-Si da limonmJavaSi. doqsenis gamxsneli aris 12% w/w uwylo eTanolis xsnari saineqcio wyalSi ganzavebuli (13% w/w 95%-iani eTanolis eqvivalenturi).

**2. SefuTva**

doqseni gamodis erTjerad-doziani flakonebiT.

yoveli kolofi Seicavs doqsenis erT flakons (80mg/2ml) da erT gamxsnelis flakons.

doqsenis flakonebis Senaxva unda moxdes 2°C - 25°C temperaturaze, sinaTlisgan dacul adgilze.

doqseni ar unda gamoiyenon kolofze da flakonebze miTiTebuli vargisobis vadis gasvlis Semdeg.

**2.1 doqseni 80mg/2ml flakoni**

* doqseni 80mg/2ml flakoni aris gamWvirvale I tipis SuSis flakoni, lurji TavsaxuriT
* doqseni 80mg/2ml flakoni Seicavs docetaqselis xsnars polisorbat 80-Si 40mg/ml koncentraciiT.
* doqseni 80mg/2ml yoveli flakoni Seicavs 2ml 40mg/ml docetaqselis xsnaris polisorbat 80-Si (Sevsebuli moculoba: 94.4mg/2.36ml).

es moculoba gansazRvrulia doqsenis SemuSavebisas siTxis danakargis kompensaciisTvis winaswari Serevis dros (ix. paragrafi 4) aqafebis, kedlebTan adheziis da “mkvdari-moculobis” gamo. Warbi avseba uzrunvelyofs, rom doqsenis Tanmxlebi xsnaris mTeli flakonis ganzavebis Semdeg minimalurad gamoiyos 8ml 10mg/ml docetqselis moculoba, rac Seesabameba 80mg/2ml flakonze miTiTebul raodenobas.

**2.2 doqseni xsnari 80mg/2ml flakonisTvis**

* gamxsneli doqsenis 80mg/2ml flakonisTis aris 10ml gamWvirvale I tipis SuSis flakoni lurji TavsaxuriT
* gamxsnelis yoveli flakoni Seicavs 6ml 12% w/w uwylo eTanolis xsnars saineqcio wyalSi (avsebis moculoba: 7.33ml). es mocloba ganisazRvra da dadginda doqsenis 80mg/2ml flakonis avsebis moculobis mixedviT. gamxsnelis flakonis sruli SigTavsis doqsenis 80mg/2ml-ze damateba uzrunvelyofs 10mg/ml docetaqselis Serevamdel koncentracias.
1. **rekomendaciebi usafrTxo SenaxvisTvis**

doqseni aris antineoplaziuri agenti da rogorc potenciurad toqsikuri sxva SenaerTebis SemTxvevaSi, sifrTxilea saWiro misi xsnaris Senaxvis da mozadebis dros. rekomendebulia xelTaTmanebis gamoyeneba.

Tu xdeba doqsenis koncentracis, gansazavebeli xsnaris an sanfuzio xsnaris kanTan kontaqti, dauyovnebliv CamoibaneT sapniT da wyliT.

Tu xdeba doqsenis koncentracis, gansazavebeli xsnaris an sanfuzio xsnaris lorwovan garsebTan kontaqti, dauyovnebliv CamoibaneT wyliT.

1. **momzadeba intravenuri gamoyenebisTvis**

**4.**1 **doqsenis gansazavebeli xsnaris momzadeba (10mg docetaqseli/ml)**

**4.1.1** Tu flakonebi macivarSi inaxeba, doqsenis kolofebis saWiro raodenoba daayovneT oTaxis temperaturaze (ara umetes 25°C-ze) 5 wuTis

ganmavlobaSi.

**4.1.2** nemsiani Spricis gamoyenebiT aseptikurad amoiReT doqsenis flakonis gamxsneli nawilobriv misi gadabrunebiT

**4.1.3** Spricis mTeli SigTavsi moaTavseT doqsenis Sesabamis flakonSi.

**4.1.4** moaSoreT Sprici da SeurieT, brunvebis minimum 45 wamis ganmavlobaSi gameorebiT. ar SeanjRrioT.

**4.1.5** gansazavebeli flakoni oTaxis temperaturaze dadgiT 5 wuTis ganmavlobaSi (ara umetes 25°C-ze), SeamowmeT, rom xsnari iyos homogenuri da gamWvirvale (aqafeba normaluria 5 wuTis ganmavlobaSi, SemadgenlobaSi polisorbat 80-is arsebobis gamo).

gansazavebeli xsnari Seicavs 10mg/ml docetaqsels da unda gamoiyenon momzadebisTanave. Tumca qimiuri da fizikuri stabiluroba gamovlinda 8 saaTis ganmavlobaSi, 2-8°C –ze an oTaxis - araumetes 25°C temperturaze.

**4.2 sainfuzio xsnaris momzadeba**

**4.2.1** pacientisTvis saWiro dozis misaRebad SeiZleba aucilebeli iyos erTze meti gansazavebeli flakoni. pacientisTvis saWiro dozis mixedviT mg-ze gaangariSebiT, aseptikurad amoiReT gansazavebeli moculoba, romelic Seicavs 10mg/ml docetaqsels Seasabamisi raodenobiT flakonebidan graduirebuli, nemsiani Spricis gamoyenebiT. magaliTad, 140mg docetaqselis dozas daWirdeba 14ml gansazavebeli xsnari.

**4.2.2** saWiro gansazavebeli moculoba CaasxiT 250ml sainfuzio flakonSi, romelic Seicavs 5%-ain glukozis xsnars an natriumis qloridis 9mg/ml (0.9%) xsnars. Tu saWiroa 200mg docetaqselze meti doza, gamoiyeneT didi moculobis sainfuzio sistema, ise rom docetaqselis koncentraciam ar gadaaWrbos 0.74mg/ml-s.

**4.2.3** sainfuzio paketi an flakoni xeliT aurieT qanaobiT.

**4.2.4** doqsenissianfuzio xsnari unda gamoiyenon 4 saaTis ganmavlobaSi da aseptikurad unda miiRon 1 saaTiani infuziis saxiT, oTaxis temperaturaze (ara umetes 25°C-ze) da normaluri ganaTebis pirobebSi.

**4.2.5** rogorc yvela parenteruli produqti, doqsenisgansazavebeli xsnari da sainfuzio xsnari vizualurad unda daTvalierdes gamoyenebamde, nawilakebis Semcveli xsnarebi unda ganadgurdes.

**5. ganadgureba**

ganzavebis da miRebisTvis gamoyenebuli mTeli masala unda ganadgurdes standartuli procedurebis Sesabamisad.

გაცემის წესი:

ფარმაცევტული პროდუქტის ჯგუფი II, გაიცემა ფორმა №3 რეცეპტით