**pacientis sainformacio broSura**

**oqsaviatini®5mg/ml koncentrati sainfuzio xsnaris mosamzadeblad**

**oqsaliplatini**

|  |
| --- |
| **1. farmacevtuli produqtis gansazRvreba** |

**1.1 dasaxeleba**

**oqsaviatini®**

**1.2 Semadgenloba**

**aqtiuri ingredienti:** oqsaliplatini

**Semavseblebi:** saineqcio wyali

**1.3 farmacevtuli forma:**

koncentrati sainfuzio xsnris mosamzadeblad

**1.4 Zala**

yoveli ml sainfuzio xsnaris mosamzadebeli koncentrati Seicavs 5mg oqsaliplatins.

10ml sainfuzio xsnaris mosamzadebeli koncentrati Seicavs 50mg oqsaliplatins

20ml sainfuzio xsnaris mosamzadebeli koncentrati Seicavs 100mg oqsaliplatins

40ml sainfuzio xsnaris mosamzadebeli koncentrati Seicavs 200mg oqsaliplatins

**1.5 aRwera-SefuTva**

SefuTva Seicavs gamWvirvale I tipis SuSis flakons 10, 20 an 40ml sainfuzio xsnaris mosamzadebel koncentrats bromobuTilis elastomeris sacobiT da aluminis mosatexi saxuraviT da pavientis sainformacio broSuras.

**1.6 Terapiuli klasifikacia**

antineoplaziuri agenti

**1.7 marketingis uflebis mflobeli**

vianeqs s.a. - tatoiuis quCa 146 71 nea eriTrea tel. 201 8009111

**1.8 mwarmoebeli**

vianeqs s.a. - plant c, palini, attiki.

|  |
| --- |
| **2. ra unda icodeT eqimis mier daniSnuli medikamentis Sesaxeb** |

**2.1 zogadi informacia**

oqsaliplatini aris antineoplaziuri preparati, miekuTvneba platinaze dafuZnebuli SenaerTebis axal klass, romelSic platinis atomi aris 1,2 diaminocikloheqsanTan (“DACH”) da oqsalatis jgufTan SeerTebuli.

**2.2 Cveneba**

oqsaliplatini 5 ftoruracilTan (5-FU) da folinis mJavasTan (FA) kombinaciaSi naCvenebia SemdegisTvis:

* adiuvanturi Terapia III stadiis (dukis C) kolinjis kibosTvis pirveladi simsivnis sruli rezeqciis Semdeg.
* metastazuri koloreqtaluri kibos mkurnaloba.

**2.3 ukuCveneba**

oqsaliplatini ukunaCvenebia

- oqsaliplatinis mimarT hipermgrZnobelobis mqone pacientebSi

- meZuZur qalebSi

- mielosupresiis mqone pacientebSi mkurnalobis pirvel kursamde, rogorc damtkicebulia neitrofilebis bazisuri raodenobiT <2X109/l da/an Trombocitebis raodenobiT N100X109/l

- pacientebSi periferiuli sensitiuri neiropaTiiT da funqciuri dazianebiT mkurnalobsi pirvel kursamde

- pacientebSi Tirkmlis funqciis mwvave dazianebiT (kreatininis klirensi <30ml/sT).

**2.4 specialuri gafrTxilebebi da usafrTxoebis zomebi gamoynebisas**

**2.4.1 zogadi**

|  |
| --- |
| oqsaliplatini unda gamoiyenon mxolod specializebul onkologiur departamentebSi da gamocdili onkologis meTvalyureobiT.  |

usafrTxoebis SezRuduli monacemebis gamo Tirkmlis saSualod dazianebuli funqciisas, miReba unda moxdes mxolod pacientisTvis sargeblis/riskis Sesabamisi SefasebiT.

am SemTxvevaSi saWiroa Tirkmlis funqciis regularuli monitoringi da dozis cvlileba toqsikurobis Sesabamisad.

pacientebSi, romelbsac anamnezSi aReniSNebaT alergiuli reaqcia platinis SenaerTebis mimarT saWiroa monitoringi alergiis simptomebis gamosavlenad. anafilaqsiis msgavsi reaqciis SemTxvevaSi infuzia dauyovnebliv unda Sewydes da unda daiwyos Sesabamisi simptomuri mkurnaloba. oqsaliplatinis xelaxla miReba ukunaCveneba.

oqsaliplatinis eqstravazaciis SemTxvaSi, infuzia dauyovnebvli unda Sewydes da unda daiwyos Cveulebrivi lokaluri simptomuri mkurnaloba.

saWiroa oqsaliplatinis nevrologiuri toqsikurobis frTxili monitoringi gansakuTrebiT nevrologiuri toqsikurobis mqone sxva medikamentebTan erTad. nevrologiuri gamokvleva unda Catardes yovel miRebamde da periodulad Semdgom.

pacientebSi, romlebsac uviTardebaT mwvave laringofaringealuri dizesTezia (ix. paragrafi 2.9) infuziis dros an infuziidan 2 saaTis Semdeg, oqsaliplatinis Semdgomi infuzia unda gamoiyenon 6 saaTis Semdeg.

Tu viTardeba nevrologiuri simptomebi (paresTezia dizesTezia) oqsaliplatinis rekomendebuli dozireba dafuZnebuli unda iyos am medikamentebis xangrZlivobasa da simwvaveze;

- Tu simptomebi grZeldeba ramdenime dReze didxans da problemuria, oqsaliplatinis Semdgomi doza 85-dan 65 mg/m2-amde unda Semcirdes (metastazuri SemTxveva) an 75mg/m2-mde (damxmare mkurnaloba).

- Tu paresTezia funqciuri darRvevis gareSe persistirebs Semdgom ciklamde oqsaliplatinis Semdogmi doza85-dan 65 mg/m2-amde unda Semcirdes (metastazuri SemTxveva) an 75mg/m2-mde (damxmare mkurnaloba).

- Tu paresTezia funqciur dazianebasTan erTad persistirebs Semdogm cikalmde, oqsaliplatini unda moixsnas.

- Tue s simptomebi umjobesdeba oqsaliplatinis moxsnis Semdeg, Terapiis ganaxleba unda ganixilon.

pacientebs unda acnobon periferiuli sensoruli neiropaTiis simpomebis persistirebis SesaZleblobaze, mkurnalobis dasrulebis Semdeg. lokalizebuli saSualo paresTezia an paresTezia, romelmac SeiZleba imoqmedos funqciur aqtivobaze SeiZleba persistirebdes 3 wlis ganmavlobaSi mkurnalobis Sewyvetis Semdeg damxmare saSualebis SemTxvevaSi.

gastrointestinuri toqsikuroba gamovlenili rogorc gulisreva da Rebineba saWiroebs profilaqtikas da/an Terapiul antiemetur mkurnalobas (is. paragrafi 2.9).

dehidratacia, paralizuri gauavloba,. intestinuri obstruqcia, hipokaliemia, metaboluri acidozi da Tirkmlis ukmarisoba SeiZleba ganviTardes mwvave daireis/Rebinebis gamo gansakuTrebiT oqsaliplatinis 5-FU-sTan kombinaciaSi.

hemtologiuri aqtiuroba viTardeba (neitrofilebi <1.5X109/l an Trombocitebi <50X109/l) Terapiis Semdgomi kursis miReba unda gadaidos sanam hematologiuri maCveneblebi normas ar daubrundeba. saWiroa sisxlis sruli raodenobis gansazRvra Terapiis dawyebamde da yoveli momdevno kursis win.

pacientebs unda acnoboT diareis/Rebinebis, mukozitis/stomatitis da neitropenis riskis Sesaxeb oqsaliplatinis/5-ftoruracilis (5-FU) miRebis Semdeg radgan maT swrafad SeZlon mkurnal eqimTan dakavSireba Sesabamisi menejmentisTvis.

Tu viTardeba mukoziti/stomatiti neitropeniiT an mis gareSe, Semdogmi mkurnaloba unda gaidaidos sanam mukoziti/tomatiti ar iqneba 1 xarisxis an naklebi da neitrofilebis raodenoba ar miaRwevs ≥1.5X100/l-s.

oqsaliplatinis 5-ftoruracilTan (5-FU) erTad gamoyenebisas (filinis mJavas (FA)- sTan erTad an mis gareSe) rekomendebulia dozis cvlileba 5-ftoruracilTan (5-FU) dakavSirebuli toqsikurobis gamo.

Tu viTardeba me-4 xarisxis diarea. 3-4 xarisxis neitropenia (neitrofilebi<1.0X109l) 3-4 xarisxis Trombocitopenia (Trombocitebi N50X109/l) oqsaliplatinis doza unda Semcirdes 85-dan 65 mg/m2-amde unda Semcirdes (metastazuri SemTxveva) an 75mg/m2-mde (damxmare mkurnaloba). damatebiT saWiroa 5-FU dozis Semcireba.

ucnobi etiologiis respiratoruli simptomebis SemTxvevaSi rogoricaa araproduqtiuli xvela, dispnoe, xmis Caxlexa an radiologiurad vizualizebadi filtvis intfiltracia, oqsaliplatini unda Sewydes sanam momdevno pulmonologiuri kvleva ar gamoicavs filtvis intersticialur daavadebas an fibrozs (ix. paragrafi 2.9).

RviZlis anomaluri funqciuri testebis SemTxvevaSi an portuli hipertenziisas, romelic gamowveuli ar aris RviZlis metastazebiT, unda gaiTvaliswinon preparatiT gamowveuli RviZlis vaskuluri darRvevebis Zalian iSviaTi SemTxvevis potenciali.

genotoqsikuri efeqtebi aRiniSna oqsaliplatinis klinikamdel kvlevebSi. aqrdan gamomdinare mamakac pacientebs urCeven Casaxvisgan Tavi Seikavon mkurnalobidan 6 Tvis ganmavlobaSi da mkurnalobamde moaxdinon spermis konservacia radgan oqsaliplatinma SeiZleb gaoiwvios antifertiluri efewti, romelic SeiZleba Seuqcevadi iyos.

qalebi ar unda daorsuldnen oqsaliplatiniT mkurnalobis dros da unda gamoiyenon kontracefciis efeqturi meTodebi.

**2.4.2 orsuloba**

am droisTvis ar arsebvobs informacia orsul qalebSi misi gamoyenebis usafrTxoebis Sesaxeb. cxovelebis kveleebSi aRiniSna reproduqciuli toqsikuroba. Sesabamisad, oqsaliplatini rekomendebuli ar aris orsulobisd dros da reproduqciuli SesaZleblobis mqone qalebSi, romlebic ar iyeneben kontracefciul meTodebs. oqsaliplatinis gamoyeneba unda moxdes mxolod pacientTan Sesabamisi oknsultaciis Semdeg, nayofis riskis SefasebiT da pacientis TanxmobiT.

kontracefciis Sesabamsi zomebi unda miiROn Terapiamde da misi Sewyvetidan 4 Tvis Semdeg qalbeisTvis da 6 Tvis Semdeg mamakacebisTvis.

oqsaliplatins SeiZleba qondes antifertiuluri efeqti.

**2.4.3 laqtacia**

laqtatSi gamoyofa Seswavlili ar aris. ZuZuTi kveba ukunaCvenebia oqsaliplatiniT Teapiis dros.

**2.4.4 efeqtebi avtomobilis marTvis da meqanizmebis gamoyenebis unarze**

avtomobilis marTvis da meqanizmebis muSaobis unarze efeqtebis kvlvebi ar Catarebula. Tumca oqsalipaltiniT mkurnalobam Seizleba gamoiwvios Tavbrusxvevis, gulisrevis da Rebinebis riskis gazrda da sxva nevrologiuri simptomebi, romlebic moqmedebs balansze da SeiZleba msubuqi an saSualo gavlena qondes avtomobilis marTvis da meqanizmebis gamoeynebis unarze.

**2.4.5 mniSvnelovani informacia sxva ingredientebis Sesaxeb**

**2.5 urTierTqmedeba sxva medikamentebTan da nivTierebebTan**

pacientebSi, romlebmac miiRes oqsaliplatinis 85mg/m2 doza 5-ftoruracilis (5-FU) miRebisTanave, 5-ftoruracilis (5-FU) eqspoziciis donis cvlileba ar aRiniSna.

*in vitro,* oqsaliplatinis plazmis cilebTan kavSiris mniSnvleovani cvlileba ar aRiniSna Semdegi agentebis miRebisas: eriTromicini, salicilatebi, granisetroni, paklitaqseli da natriumis valproati.

**2.6 dozireba da miRebis meTodi**

mxolod erTjeradi gamoyenebisTvis

oqsaliplatinis rekomendbeuli doza damxmare mowyobilobaSi 85mg/m2 intravenurad meordeboda yovel 2 kviraSi 12 ciklis ganmavlobaSi (6 Tve).

oqsaliplatinis rekomendebuli doza metastazuri koloreqtaluri kibos mkurnalobisTvis aris 85mg/m2 intravenurad 2 kviraSi erTxel.

dozirebis cvlileba unda moxdes tolerantobis mixedviT.

**oqsaliplatini yovelTvis unda miiROn fluoropirimidebamde mag. 5-ftoruracilis (5-FU)**

oqsaliplatini miReba 2-6 saaTiani intravenuri infuziis saxiT 250-500ml 5%-ian glukozaSi ganzavebuli (50mg/ml) raTa miRweuli iyos koncentracia 0.2mg/ml da 0.70mg/ml. 0.70mg/ml aris umaRlesi koncentacia klinikur praqtikaSi oqsaliplatinis 85mg/m2 dozisTvis.

oqsaliplatini ZiriTadad gamoiyeneba 5-ftoruracilis (5-FU)-s infuziasTan erTad. or kviriani mkurnalobis reJimSi-ftoruracilis (5-FU)–s nakadiT da mudmivi infuzia gamoiyeneboda.

gansakuTrebuli populaciebi

*- Tirkmlis dazianeba:*

oqsaliplatini Seswavlili ar aris pacientebSi Tirkmlis mwvave dazianebiT. pacientebSi Tirkmlis saSualo dazianebiT, mkurnaloba SeiZleba daiwyos Cveulebrivi sawyisi doziT. ar arsebobs dozis cvlilebis aucilebloba Tirkmlis saSualo disfunqcis mqone pacientebSi.

*- RviZlis ukmarisoba*

I fazis kvlevaSi, romelci moicavda RviZlis dazianebis sxvadasxva donis mqone pacientebs, hepato-biliaruli darRvevebis sixSire da simwvave dakavSirebuli iyo progresul daavadebasTan da RviZlis funqciis dazianebasTan. RviZlis anomaluri funqciuri testebis mqone pacientebSi klinikuri ganviTarebisas dozis cvlileba ar momxdara.

- *xandazmuli pacientebSi*

mwvave toqsikurobis zrda ar aRiniSna, rodesac oqsaliplatini gamoiyeneobda 5- ftoruracilTad (5-FU) erTad 65 welze ufrosi asakis pacientebSi. Sedegad dozis specialuri adaptacia xandazmulebSi saWiro ar aris.

miRebis meTodi

oqsaliplatini gamoiyeneba intravenuri infuziis saxiT.

oqsaliplatinis gamoyeneba ar saWiroebs damatebiT hidratacias.

oqsaliplatinis 250-500ml 5%-ian glukozaSi ganzavebuli (50mg/ml) xsnari aranakleb 0.2mg/ml koncentraciiT ganzavebuli unda iyos centralur venur xazSI an periferiul venaSi 2-6 saaTis ganmavlobaSi. oqsaliplatinis infuzia unda miiROn folinis mJavasTan erTad da yovelTvis win unda uswrebdes 5-ftoruracilis (5-FU) miRebas.

eqstravazaciis SemTxvevaSi, miReba dauyovnebliv unda Sewydes.

instruqciebi gamoyenebisTvis

oqsaliplatini unda ganzavdes gamoyenebamde. mxolod 5%-iani glukoza (50mg/ml) unda gamoiyenon saunfuzio xsnaris ganzavebisTvis.

rogorc sxva potenciuri toqsikuri SenaerTebis SemTxvevaSi, sifrTxile unda daicvan osqaliplatinis xsnaris momzadebisas.

instruqcia SenaxvisTvis

am citotoqsikuri agentis Senaxva jandacvis profesionalis mier saWiroebs usafrTxoebis zomas momxmareblis da misi garemocvis dacvis uzrunvelsayofad.

|  |
| --- |
| citotoqsikuri agentebis saineqcio xsnarebis momzadeba unda moxdes treining gavlili perosnalis mier, romelsac aqvs am medikamentebis gamoyenebis codna, raTa garantirebuli iyo sproduqtis dauzianebloba, garemos dacva da gansakuTrebiT personalis usafrTxoeba saavadmyofos politikis Sesabamisad. saWiroa am miznisTvis Senaxuli mosamzadebeli adgili. am adgilas akrZalulia moweva, Wama an daleva. personals unda qondes Sesabamisi Senaxvis masala, aRsaniSnavia grZelsaxeloiani xalaTebi, damcavi niRbebi, qudebi, niRbebi, sterikuri xelTaTmnebi, damcavi dasafareblebi samuSao adgilas, mnarCenebis Sesagrovebeli konteinerebi da CanTeba. pacientebisgan datovebuli eqskrementebi da amonaRebi masa unda ganadgurdes sifrTxiliT. orsuli qalebi unda gaafrTxilon citotoqsikuri agentebis Sesaxeb. nebismieri gatexili konteineris SemTxvevaSi unda daicvan igive usafrTxoebis zomebi rogorc dabinZurebuli narCeni masalisas. dabinZurebuli narCenebi unda moTavsdes Sesabamisad daniSnul rigidul konteinerebSi, qvemoT ix. paragrafi “ganadgureba”. Tu oqsiplatinis koncentraci an sainfuzio xsnari kontaqtSi modis kanTan, sasawrafid intensiurad dauibaneT wyliT. Tu oqsaliplatinis koncentrati an sainfuzio xsnari kontaqtSi modis lorwovan garsebdan saswrafod da intensiurad daibaneT wyliT.  |

***specialuri usafrTxoebis zomebi gamoyenebisas***

*-* ar gamoiyenoT aluminis Semcveli saineqcio aRWurviloba.

- ar gamoiyenoT ganuzavebeli.

- gamxsnelis saxiT dasaSvebia mxolod glukozis 5%-iani xsnaris gamoyeneba (50mg/ml). ar ganazavoT natriumis qloridiT an qloris Semcveli xsnarebiT.

- ar SeurioT sxva medikamentebis sainfuzio flakonSi da ar gamoiyenoT infuziis erT sistemaSi.

- ar SeurioT tute preparatebs an xsnarebs, gansakuTrebiT 5-ftoruracils (5-FU), folinis mJavas preparatebs (FA), romelic Semavseblis saxiT Seicavs trometamols da sxva preparatebis trometamolis marilebs. tute preparatebi an xsnarebi uaryofiTad imoqmedebs oqsaliplatinis stabilurobaze.

***folinis mJavasTan (FA) erTad gamoyenebis instruqcia (kalciumis folinatis an dinatrium folinatis saxiT).***

oqsaliplatini 85mg/m2 IV infuzia 250-500ml 5%-ian glukozis xsnarSi 950mg/ml) gamoiyeneba igive dros rodesac folinis mJavas IV infuzia (FA) 5%-ian glukozis xsnarSi 950mg/ml) 2-6 saaTis ganmavlobaSi Y xazis gamoyenebiT romelic dauyovnebliv idgmeva infuziis adgilamde. ori preparati ar unda Seurion igive sainfuzio flakonSi. folinis mJava ar unda Seicavdes trometamols Semavseblis saxiT da ganzavenuli unda iyos mxolod glukozis 5%-iani izotonuri xsnariT (50mg/ml), arasdros ar unda Seurion tute xsnarebs an natriumis qlorids an qloris Semcvel xsnarebs.

***instruqciebi 5-ftoruracilTan (5-FU) erTad gamoyenebisas***

oqsaliplatini yovelTvis unda gamoiyenon ftororopiridinebamde anu 5-ftoruracilamde (5-FU).

oqsaliplatinis gamoyenebis Semdeg garecxeT sistema da Semdeg gamoiyeneT 5-fluoriracili (5-FU).

oqsaliplatinTan preparatebis kombinaciis Sesaxeb damatebiTi informaciisTvis ix. produqtis maxasiaTeblis Sesabamisi Sejameba.

***koncentrati sainfuzio xsnaris mosamzadeblad***

vizualurad daaTvaliereT gamoyenebamde. unda gamoiyenon mxolod gamWvirvale, nawilakebis gareSe xsnarebi.

samedicino produqti gankuTvnilia mxolod erTjeradi gamoyenebisTvis. nebismieri gamouyenebli koncentrati unda ganadgurdes (ix. qvemoT “ganadgureba”).

***ganzaveba infuziamde***

gadmoireT koncentratis saWiro raodenoba flakonidan da ganazaveT 250ml an 500ml glukozis 5%-ian xsnarSi 950mg/ml) an gamoiyeneT oqsaliplatinis koncentracia 0.2-0.7mg/ml da 0.7mg/ml; koncentraciis meryeoba, rodesac gamovlinda oqsaliplatinis fiziko-qimiuri stabiluroba iyo 0.2mg/ml-2.0mg/ml.

gamoiyeneT intravenuri infuziis saxiT.

5%-ian glukozis xsnarSi ganzavebis Semdeg (50mg/ml), qimiuri da fizikuri stabiluroba gamovlinda 48 saatis ganmavlobaSi 2-8°C-ze da 24 saaTis ganmavlobaSi 25°C-ze.

mikrobiologiuri TvalsazrisiT, sainfuzio preparati unda gamoiyenon dauyovnebliv.

Tu gamoyeneba ar xdeba dauyovnebliv, Senaxvis dro da pirobebi momxmareblis pasuxismgeblobaa da Cveulebriv ar unda gadaaWarbos 24 saaTs 2-8°C-ze sanam ar moxdeba Sesabamis kontrolirebul da aseptiur pirobebSi ganzaveba.

gamoyenebamde vizualurad daaTvaliereT. unda gaoiyenon mxolod sufTa xsnarebi nawilakebis gareSe.

samedidino produqti gankuTvnilia mxolod erTjeradi gamoyenebisTvis. nebismieri gamouyenebeli sainfuzio xsnari unda ganadgurdes (ix. qvemoT “ganadgureba”).

**arasodes** ar gamoiyenoT ganzavebisTvis natriumis qloridi an qloris Semcveli xsnarebi.

oqsaliplatinis sainfuzio xsnaris SeTavsebadoba Semowmebulia pvq safuvelze damzadebul sistemebSi.

***infuzia***

oqsalipltinis gamoyeneba ar moiTxovs prehidratacias.

oqsaliplatinis 250-500ml glukozis 5%-ian xsnarSi (50mg/ml) ganzavebuli saxiT Seyvana unda moxdes aranakleb 0.2mg/ml koncentraciis centralur venaSi an periferiul venur kaTeterSi 2-6 saaTis ganmavlobaSi. rodesac oqsaliplatini gamoiyeneba 5-ftoruracilTan erTad (5-FU), oqsaliplatinis infzuia mas unda uswrebdes.

***ganadgureba***

samedicino produqtis, agreTve ganzavebis da gamoyenebisTvis gamoyenebuli masala unda ganadgurdes saavadmyofos standartuli procedurebis mixedviT, citotoqsikuri agentebisTvis da saSiSi narCeni masalis ganadgurebis kanonebis Sesabamisad.

**2.7 dozis gadaWarbeba**

ar arsebobs oqsaliplatinis cnobili antidoti. dozis gadaWarbebis SemTxvevaSi mosalidnelia gverdiTi movlenebis gamwvaveba. unda daiwyos hematologiuri parametrebis monitoringi da saWiroa simptomuri mkurnaloba.

**2.8 ra unda icodeT dozis gamotovebis SemTxvevaSi**

ucnobia.

**2.9 gverdiTi efeqtebi**

oqsaliplatinis yvelaze xSiri gverdiTi efeqtebi 5-ftoruracilTan (5-FU) /folinis mJavasTan (FA) kombinaciaSi iyo gastrointestinuri (diarea, gulsireva, Rebineba da muoziti), hematologiuri (neitropenia, Trombocitopenia) da nevrologiuri (mwvave da dozis kumulaciiT gamowveuli periferiuli sensoruli neiropaTia). saerTo jamSi es gverdiTi movlenebi ufro xSiri da mwvave iyo oqsaliplatinis da 5-ftoruracilis FU) / folinis mJavasTan (FA) kombinaciaSi gamoyenebisas vidre mxolod 5-ftoruracilis FU) / folinis mJavis (FA) miRebisas.

qvemo cxrilSi aRwerili sixSire miRebulia metastazuri SemTxvevebis da damxmare SemTxvevebis klinikuri kvlevebisas (moicavda 416 da 1108 pacients oqsaliplatins+5-ftoruracili (FU) / folinis mJavasTan (FA) mkurnalobis xazSi) da post marketinguli gamocdilebidan.

cxrilSi mocemuli sixSireebi gansazRvrulia Semdegnairad: Zalian xSiri (≥1/10), xSiri (≥1/100 <1/10), nakelabd xSiri (≥1/1000, <1/100), iSviaTi (≥1/10000, <1/1000), Zalian iSviaTi (<1/10000), ucnobi (Sefaseba SeuZlebelia arsebuli monacemebiT).

Semdogmi detalebi mocemulia cxrilis Semdeg.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **MedDRA organoTa sistemis klasi** | **Zalian xSiri** | **xSiri** | **naklebad xSiri** | **iSviaTi** |
| ***infeqciebi da invaziebi\**** | -infeqcia |  |  |  |
| ***sisxlis da limfuri sistemis darRvevebi\**** | **-** anemia-neitropenia-Trombocitopenia-lekopenia-limfopenia | **-**riniti-zemo respiratoruli traqtis infeqcia-febriuluri neitropenia/neitropeniuli sefsisi |  | **-**avtoimunuri Trombocitopenia-hemolizuri anemia |
| ***imunuri sistemis darRvevebi\**** | **-**alergia/alergiuli reaqciebi+ |  |  |  |
| ***metabolizmis da kvebis darRvevebi*** | **-**anoreqsia-glkemiuri anomaliebi-hipokaliemia-natriemiis anomaliebi | **-**dehidratacia | **-**metaboluri acidozi |  |
| ***fsiqiuri darRvevebi*** |  | **-**depresia-insomnia | **-**nevrozuloba |  |
| ***nervuli sistemis darRvevebi\**** | **-**periferiuli sensoruli neiropaTia-sensoruli darRvevebi-disgevzia-Tavis tkivili | **-**Tavbrusxveva-motoruli nevriti-meningizmi |  | **-**dizarTria |
| ***Tvalis darRvevebi*** |  | **-**koniunqtiviti-vizualuri darRvevebi |  | **-**mxedvelobis simaxvilis tranzitoruli Semcireba-mxedvelobsi velis darRvevebi-optikuri nevriti-mxedvbelobis tranzitoruli dakargva, Seqcevadi mkurnalobis Sewyvetis Semdeg |
| ***yuris da labirinTis darRvevebi*** |  |  | **-**ototoqsikuroiba | **-**siyrue |
| ***vaskuluri darRvevebi*** | **-**epistaqsisi | **-**hemoragia-siwiTle-Rrma venebis Trombozi-filtvis embolizmi |  |  |
| ***respiratoruli, Torakaluri da mediastinuri darRvevebi*** | **-**dispnoe-xvela | **-**slokini |  | -filtvis intersticialuri daavadeba, zogjer letaluri-filtvis fibrozi\*\* |
| ***gastrointestinuri darRvevebi\**** | **-**gulisreva-diarea-Rebineba-stomatiti/mukoziti-muclis tkivili-yabzoba | **-**dispefsia-gastroezofagaluri refluqsi-reqtaluri hemoragia | **-**gauvaloba-nawlavis obstruqcia | **-**koliti *Clostridium difficile-*Ti gamowveuli diarea  |
| ***kanis da kanqveSa qsovilis darRvevebi*** | **-**kanis darRvevebi-alopecia | -kanis eqsfoliacia (xelebis da fexebis sindromi)-eriTematozuli gamonayaru-gamonayari-hiperhidrozi-frCxilebis darRvevebi |  |  |
| ***ZvalkunTovani, SemaerTebeli qsovilis da Zvlis darRveebi*** | **-**zurgis tkivili | **-**arTralgia-Zvlis tkivili |  |  |
| **Tirkmlis da saSarde gzebis darRvevebi** |  | -hematuria-dizuria-miqturiasixSiris anomalia |  |  |
| ***zogadi darRvevebi da mdgomareoba Seyvanis adgilas***  | **-**daRLiloba-cxeleba++-asTenia-tkivili-ineqciis adgilis reaqciebi++ |  |  |  |
| ***gamokvlevebi*** | -RviZlis enzimebis momateba-sisxlSi tute fosfatazas monateba-sisxlSi bilirubinis momateba-sisxlSi laqtatdehidrogenazas momateba-wonis momateba (damatebiTi xazi) | **-**kreatininis momateba-wonaSi kleba (metastazuri kibos mkurnaloba) |  |  |

\*\* detaluri paragrafi ix. qvemoT

\*\* ix. paragrafi 2.4

+xSiri alergiuli reaqciebi rogoricaa kanis gmaonayari (gansakuTrebiT urtikaria), koniunqtiviti, riniti.

xSiri anafilaqsiuri reaqciebi, bronqospazmis, gulmkerdis tkivilis, angioedemis, hipotenziis da anafilaqsiuri Sokis CaTvliT.

++ Zalian xSiri: cxeleba, kankali (tremori), infeqciiT (febriluri neitropeniiT an mis gareSe) an SesaZloa imunologiuri meqanizmiT gamowveuli.

+++aRwerilia ineqciis adgilis reaqciebi lokaluri tkivilis siwiTlis, SeSupebis da Trombozis CaTvliT. eqstravazaciam SeiZleba agreTve gmaoiwvios adgilobrivi tkivili da anTeba, romelci SeiZleba mwvave iyos da gamoiwvios garTulebebi nekrozis CaTvliT, gansakuTrbiT rodesac oqsaliplatinis infuzia xdeba periferiul venaSi.

**sisxlis da limfuri sistemis darRvevebi**

**sixSire pacientze (%), xarisxis mixedviT**

|  |  |  |
| --- | --- | --- |
| oqsaliplatini/5-FU/FA 85mg/m2 2 kviraSi erTxel | metastazis xazi | damxmare xazi |
|  | yvela xarisxi | 3 xarisxi | 4 xarisxi | yvela xarisxi | 3 xarisxi | 4 xarisxi |
| anemia | 82.2 | 3 | **<1** | 75.6 | 0.7 | 0.1 |
| neitropenia | 71.4 | 28 | 14 | 78.9 | 28.8 | 12.3 |
| Trombocitopenia | 71.6 | 4 | <1 | 77.4 | 1.5 | 0.2 |
| febriluri neitropenia | 5.0 | 3.6 | 1.4 | 0.7 | 0.7 | 0.0 |
| neitropeniuli sefsisi | 1.1 | 0.7 | 0.4 | 1.1 | 0.6 | 0.4 |

**imunuri sistemis darRvevebi**

**alergiuli reaqciebis sxSire pacientebis mixedviT (%), xarisxis mixedviT**

|  |  |  |
| --- | --- | --- |
| oqsaliplatini/5-FU/FA 85mg/m2 2 kviraSi erTxel | metastazis xazi | damxmare xazi |
|  | yvela xarisxi | 3 xarisxi | 4 xarisxi | yvela xarisxi | 3 xarisxi | 4 xarisxi |
| alergiuli reaqciebi/alergia | 9.1 | 1 | 1 | 10.3 | 2.3 | 0.6 |

**nervuli sistemis darRvevebi**

oqsaliplatinis dozis SemzRudavi toqsikuroba nevrologiuria. igi mociavs sensorul perifeirul neiropaTias, romelic xasiaTdeba kidurebis dizesTeziiT da/an paresTeziiT krampebiT an maT gareSe, xSirad gamowveulia siciviT. es simptomebi viTardeba namkuranlebi pacientebis 95%-Si. am simpzomebis xangrZlivoba, romelic Cveulrbvi regress ganicdis mkunralobs kursebs Soris, izrdeba mkurnalobis ciklis raodenobis matebasTan erTad.

tkivilis da/an funqciuri darRvevebis ganviTareba simptomebis xangrZlivobis mixedviT dozis cvlilebis an mkurnalobis moxsnis Cvenebaa.

funqciuri darRveebi moicavs natifi moZraoebis Sesrulebis siZneleebs da warmaodgens sensoruli dazianebis SesaZlo Sedegs. persistentuli simptomebis ganviTarebis riski kumulaciuri dozisTvis 850mg/m2 (10 cikli) daaxloebiT 10%-s Seadgens da 1020mg/m2-isTvis (12 cikli) daaxloebiT 20%-s/

am SemTxveevbis umravlesoba, nevrologiuri niSnebi da siptomebi umjobesdeba an srulad qreba mkurnalobis Sewyvetis Semdeg.

msxvili nawlavis kibos damxmare xazSi, mkurnalobis Sewyvetidan 6 Tvis Semdeg pacientebis 87%-Si ar aRiniSneboda an fiqsirdeboda msybuqi simptomebi. 3 wliani dakvirvebis Semdeg, pacientebis daaxloebiT 3% aReniSneboda saSualo intensivobis persistirebuli lokaluri paresTezia (2.3%) an paresTezia romelic SeiZleba gavlenas axdendes funqciur saqmianobaze (0.5%).

aRwerilia mwvave neirosensoruli gamovlineba. is iwyeba gamoenebidan ramdenime saaTis ganmavlobaSi da xSirad Cndeba sicivisadmi eqspoziciisas. Cveulebriv warmodgenilia rogorc paresTezia, dizesTezia da hipoesTezia. faringolaringealuri dizesTeziis mwvave sindromi viTardeba pacientebis 1-2%-Si da xasiaTdeba disfagiis an dispnoes/SexuTvis SegrZnebiT, respiratoruli distresis mtkicebulebis (cianozi an hipoqsia) an laringoqspaznis an bronqospazmis gareSe (ar aRiniSneba stridori an qoSini). Tumca antihistaminebi da bronqodilatatorebi gamoiyeneba am SemTxvevaSi simptomebi swrafad ukuqcevadia mkurnalobis ar arsebobis SemTxvevaSic. infuziis gaxangrZliveba sasargebloa am sidromis SemcirebisTvis. sxva simptomebi moicavs ybis szmazms/kunTis spazms/kunTis uneblie SekumSvebs/kunTis TrTolvas/mioklonias/koordinaciis anomaliebs/wonasworobis anomaliebs/ataqsias/balansis darRveevbs, yelis an mkerdis SeboWilobas/zewolas/diskomforts/tkivils. damatebiT, SeiZleba kranialuri nervis disfuncia an ganviTardes izolirebuli movlenebi rogoricaa fTozi, diplopia, afonia/disfonia/xmis CaxleCa zogjer saxmo iogebis dambla. enis anomaluri SegrZneba an dizarTria, zogjer aRwerili rogorc afazia, samwvera nervis nevralgia/saxis tkivili/Tvalis tkivili, mxedvelobis simaxvilis daqveiTeba, mxedvelobis velis darRvevebi.

sxva nevrologiuri simtpmebi rogforicaa dizarTria, myesis Rrma refleqsis dakargva da lermitis niSani aRwerilia oqsaliplatiniT mkurnalobis dros. aRwerilia optikuri nevritis izolirebuli SemTxvevebi.

**gastrointestinuri darRvevebi**

**sixSire pacientebis mixedviT (%), xarisxis mixedviT**

|  |  |  |
| --- | --- | --- |
| oqsaliplatini/5-FU/FA 85mg/m2 2 kviraSi erTxel | metastazis xazi | damxmare xazi |
|  | yvela xarisxi | 3 xarisxi | 4 xarisxi | yvela xarisxi | 3 xarisxi | 4 xarisxi |
| gulisreva | 69.9 | 8 | **<1** | 73.7 | 4.8 | 0.3 |
| diarea | 60.8 | 9 | 2 | 56.3 | 8.3 | 2.5 |
| Rebineba | 49.0 | 6 | 1 | 47.2 | 5.3 | 0.5 |
| mukoziti/stomatiti | 39.9 | 4 | <1 | 42.1 | 2.8 | 0.1 |

naCvenebia Zlieri antiemeturi saSualebebiT profilaqtika da/an mkurnaloba

dehidratacia, paralizuri gauvaloba nawlavis obstruqcia, hipokaliemia, metaboluri acidozi da TIrkmlis dazianeba SeiZleba gamowveuli iyos mwvave diareiT/RebinebiT gansakuTrebiT oqsaliplatinis 5-ftoruracilTan (5-FU) kombinaciaSi.

**hepato-biliaruli darRvevebi**

*Zalian iSviaTi (<1/10\000):*

RviZlis sinosoiduri obstruqciis sindromim agreTve cnobili rogorc RviZlis venur-okluziur daavadeba an paTologoiuri gamovlinebebi dakavSirebuli RviZlis darRvevebTan, RviZlis purpuras, kvanZOvani regeneraciuli hiperplaziis, perisinosoidaluri fibrozis CaTvliT, klinikuri amovlineba SeiZleba iyos portuli hipertenzia da/am transaminazebis donis momateba.

**Tirkmlis da saSarde gzebis darRvevebi**

*Zalian iSviaTi (<1/10\000):*

mwvave tubularuli mekrozi, mwvave intersticialuri nefriti da Tirkmlis mwvave ukmarisoba.

**2.10 vargisianobis vada**

miTiTebulia gare an SigniTa SefuTvaze.

medikamenti ar gamoiyenoT am vadis gasvlis Semdeg.

**2.11 specialuri usafrTxoebis zomebi SenaxvisTvis**

ar gayinoT.

flakoni SeinaxeT kolofSi sinaTlisgan dacvisTvis.

5%-ian glukozis xsnarSi (50mg/ml) ganzavebis Semdeg, qimiuri da fizikuri gamoyenebis stabiluroba naCvenebia 48 saaTis ganmavlobaSi 4-8°C-ze an 24 saaTis ganmavlobaSi +25°C-ze.

**2.13 pacientis sainformacio broSuris bolo reviziis TariRi**

16-3-2012

|  |
| --- |
| **3. informacia medikamentebis racionaluri gamoyenebis Sesaxeb** * eqimma es medikamenti daginiSnaT Tqven mxolod specifiuri samedicino problemisTvis. arasdros gadasceT igi sxvebs da ar gamoiyenoT sxva daavadebebisTvis eqimTan konsultaciamde.
* Tu mkurnalobis ganmavlobaSi aRgeniSnebaT problema, dauyovnebliv anocbeT eqims an farmacevts.
* Tu gaqvT kiTxvebi medikamentis Sesaxeb an gWirdebaT damatebiTi informacia samedicino problemis Sesaxeb, gaiareT eqimis an farmacevtis konsultacia.
* medikamenti miiReT eqimis instruqciis mixedviT raTa iyos efeqturi da usafrTxo.
* Tqveni janmrTelobis da usafrTxoebisTvis gTxovT waikiTxeT sruli informacia medikamentis Sesaxeb.
* medikamentebi ar SeinaxoT abazanis karadebSi radgan sicxe da temperatura SeiZleba mas azianebdes da es mavne iyos Tqveni janmrTelobisTvis.
* ar SeinaxoT arasaWiro medikamentebi vargisianobis vadis gasvlis Semdeg.
* yvela medikamenti SeinaxeT bavSvebisTvis miuwvdomel adgilas.
 |

**4. gacemis wesi**

SezRuduli samedicino recepti: mxolod saavadmyofoSi gamoyenebisTvis.

Targmani Seesabameba originals, mTargmneli: