**broSura: informacia momxmareblisTvis**

**onda®**

**apkiani garsiT dafaruli tabletebi 8mg**

**saineqcio xsnari 4mg/2ml**

**saineqcio xsnari 8mg/4ml**

**medikamentis miRebis dawyebamde yuradRebiT waikiTxeT broSura.**

es medikamenti dageniSnaT Tqven. ar gadasceT igi sxvebs. es SeiZleba maTTvis sazano iyos im SemTxvevaSic, Tu maTi simptomebi Tqvensas gavs.

SeinaxeT broSura. SeiZleba dagWirdeT misi xelaxla wakiTxva.

damatebiTi kiTxvebis SemTxvevaSi mimarTeT eqims an farmacevts.

gverdiTi efeqtebis SemTxvevaSi mimarTeT eqims an farmacevts. es exeba im gverdiT efeqtebsac, romlebic am broSuraSi CamoTvlili ar aris. ix. paragrafi 4.

**ra aris am broSuraSi**:

1. ra aris onda da risTvis gamoiyeneba
2. ra unda icodeT ondas miRebis dawyebamde
3. rogor miiReba onda
4. SesaZlo gverdiTi efeqtebi
5. rogor inaxeba onda
6. damatebiTi informacia
7. **ra aris onda da risTvis gamoiyeneba**

onda miekuTvneba anti-emeturi medikamentebis jgufs. zogierTma farmacevtulma substanciam an mkurnalobam substanciis gamoTavisuflebiT, SeiZleba ganapirobos nivTierebis gamoTavisufleba, romelsac SeuZlia gulisrevis da Rebinebis gamowveva. onda ainhibirebs am nivTierebebis efeqts da aqedan gamomdinare axdens gulisrevis an Rebinebis prevencias.

mozrdilebi: onda saineqcio xsnari da apkiani garsiT dafaruli tabletebi naCvenebia gulisrevis da Rebinebis menejmentisTvis, rac gamowveulia citotoqsikuri qimioTerapiiT da radioTerapiiT. ondas saineqcio xsnari da Apkiani garsiT dafaruli tabltebi agreTve naCvenebia post-operaciuli gulisrevis da Rebinebis prevenciis da mkurnalobisTvis.

pediatruli populacia: onda naCvenebia qimioTerapiiT gamwoveuli gulisrevis da Rebinebis mkurnalbisTvis, 6 Tveze ufrosi asakis bavSvbSi da post-operaciuli gulsirvis da Rebinebis prevenciis da mkurnalobisTvis, 1 Tveze ufrosi asakis bavSvebSi.

1. **ra unda icodeT ondas miRebis dawyebamde**

**ar miiRoT onda**

* Tu xarT alergiuli (gaqvT hipermgrZnobeloba) ondansetronis an ondas xva ingredientebis mimarT.

hipermgrZnobelobis reaqciebi aRwerilia pacientebSi, romlebmac gamoavlines momatebuli mgrZnobeloba sxva seleqciuri 5HT3 receptorebis antagonistebisadmi.

respiratoruli movlenebis mkuranloba saWiroa simptomurad da eqimma gansakuTrebuli yuradReba unda miaqcios maT rogorc hipermgrZnobelobis reaqciebis prekursorebs.

iSviaTad, pacientebSi, romlebic iReben ondansetrons aRwerilia ekg tranzitoruli cvlilebebi QT intervalis gaxangrZlivebis CaTvliT. ama sgarda, marketingis Semdeg pacientebSi, romlebic ondansetrons iReben aRwerilia polimorfuli ventrikuluri taqikardiis SemTxvevebi (Torsades de Pointes). ondanstroni sifrTxiliT unda gamoiyenon pacientebSi, romelbsac aqvT an SeiZleba ganuviTardeT QTc gaxangrZliveba. es molenebi moicavs pacientebs eleqtrolituri darRvevebiT, kongenitaluri QT intervalis gaxangrZlivebis sindromiT an pacientebs, romelbic iReben sxv medikamentebs, romelbic iwveven QT intervalis gaxangrZlivebas.

radgan ondansetroni axangrZlivebs msxvil nawlavSi gavlis dros, qvemwvave intenstinuri obstruqciis niSnebis mqone pacintebSi miRebis Semdeg saWiroa intensiuri monitoringi.

pacientebSi, romlebic itareben adenotonzilur operacias, gulsirevis da Rebinebis ondansetroniT prevenciam SeiZleba SeniRbos faruli sisxldena. aqedan gamomdinare amgvar pacientebSi ondansetronis miRebis Semdeg saWiroa intensiuri monitoringi.

*pacientebma, romlebsac aReniSnebaT iSviaTi memkvidruli problemebi, rogoricaa galaqtozas autanloba, lap laqtazas deficiti an glukoza-galaqtozas malabsorbcia, ondas tabletebi ar unda miiRon.*

**pediatruli populacia**

pacientebSi, romlebic ondasetrons iReben hepatotoqsikur qimioTerapiul agentebTan erTad RviZlis funqciis dazianebis gamosavlenad saWiroa intensiuri monitoringi.

**sxva medikamentebis miReba**

gTxovT acnobeT eqims an faramcevts Tu iRebT an bolo periodSi miRebuli gaqvT raime medikamenti, receptis gareSe gacemuli saSualebebis CaTvliT.

ar arsbobs mtkicebuleba, rom ondansetroini ainducirebs an ainhibirebs erTdroulad miRebuli medikamentebis metabolizms. specifiuri kvlevebi aCvenebs rom ar arsebobs urTierTqmedeba, rodesac ondansetroni gamoieneba alkoholTan, temazepamTan, furosemidTan, alfentanilTan, tramadolTan, morfinTan, lidokainTan, TiopentalTan an propofolTan erTad.

ondansetroni metabolizdeba RviZlSi citoqrom P450-is mravlobiTi enzimebiT: CYP3A4, CYP2D6 da CYP1A2. metaboluri enzimebis mravalferovnebisTvis, romlebsac SeuZliaT ondansetronis metabolizmi, enzimsi inhibireba an erTi enzimis aqtivobis Semcireba (mag. CYP2D6 genetikuri deficiti) Cveulebriv kompensirdeba sxva enzimiT da ar iwvevs an iwvevs mcire cvlilebas ondansetronis saerTo klirensSi da saWiro dozaSi.

fenitoini, karbamazepini da rifampicini: pacientebSi, romlebic mkurnaloben CYP3A4 induqtorebiT (mag. fenitoini, karbamazepini da rifampicini) ondansetronis oraluri klirensi gaizarda da daqveiTda sisxlSi misi koncentracia.

tramadoli: mcire kvlevebis monacemebi aCvenebs, rom ondansetronma SeiZleba Seamciros tramadolis analgezuri efeqti.

ondas gamoyenebam QT intervalis gamaxangrZlivebel saSualebebTan erTad SeiZleba gamoiwvios QT intervalis damatebiTi gaxagrZilveba. ondansetronis kardiotoqsiur preparatebTan (mag. antraciklinebi) erTad gamoyeneba SeiZleba zrdides ariTmiebis risks.

**orsuloba da ZuZuTi kveba**

orsulobis dros ondansetronis gamoyenebis usafrTxoeba dadgenili ar aris. eqsperimentuli cxovelebis kvlevebis Sefasebebi ar miuTiTebs pirdapir an arapirdapir damazianebel efeqtze embrionis an nayofis ganviTarebaze, gestaciis mimdinreobaze da peri da post-natalur ganviTrebaze. Tumca radgan cxovelebis kvlevebi yovelTvis ganmsazRvreli ar aris adamianis SemTxvevaSi orsulobis dros ondansetronis gamoyeneba rekomendebuli ar aris.

testebma aCvena, rom ondansetroni gadis laqtaciaSi myofi cxovelebis rZeSi.aqedan gamomdinare rekomendebulia ondansetornis miRebis dros qalebma Tavi Seikavon ZuZuTi kvebisgan.

**avtomobilis marTva da meqanizmebis gamoyeneba**

fsiqomotoruli testirebisas ondansetroni ar moqmedebs moqmedebis unarze da ar iwvevs sedacias. amgvar aqtivobaze damazianebeli efeqtebi mosalodneli ar aris ondansetronis farmakologiis safuZvelze.

1. **rogor miiReba onda**

onda yovelTvis miiReT zustad eqimis daniSnulebiT. eWvis SemTxvevaSi mimarTeT eqims an farmacevts.

ondas Apkiani garsiT dafaruli tabletebi miiReba oralurad.

ondas saineqcio xsnari gamoiyeneba intramuskularulad an intravenurad.

**qimio an radioTerapiiT gamowveuli gulisreva da Rebineba:**

mozrdilebi: ondansetronis saineqcio xsnaris dozireba meryeobs 832mg-mde dReSi, SerCeva xdeba qvemoT aRniSnuli wesiT.

*msubuqi emetogenuri qimioTerapia da radioTerapia:*

pacientebSi, romlebic itareben emetogenur qimiOTerapias an radioTerapias, ondansetroni SeiZleba gamoyenebuli iyos oralurad (tabletebi) an intravenuri an intramuskuluri ineqciis saxiT.

rekomendebuli doza oraluri gamoyenebisTvis Seadgens 8mg-s 1-2sT-s uSualod mkurnalobamde.

ondansetronis rekomendebuli intravenuri an intramuskuluri doza Seadgens 8mg-s neli intravenuri an intramuskuluri ineqciis saxiT uSualod mkurnalpobamde.

pirveli 24 saaTis Semdeg dagvianebuli an gaxangrZlivebuli Rebinebisganda sacavad unda gagrZeldes oraluri mkurnaloba 8mg ondansetroniT 12 saaTSi erTxel 5 dRis ganmavlobaSi.

*maRalemetogenuri qimioTerapia:*

pacientebisTvis, romlebic itareben maRalemetogenur qimioTerapias, mag. cisplatinis maRal dozebs, ondansetroni SeiZleba gaoiyeon reqtalurad an intravenuri an intramuskuluri ineqciis saxiT.

rekomendebuli doza oraluri gamoyenebisTvis Seadgens 24mg-s 12mg deqsametazonis natriumis fosfatTan erTad, qimioTerapiamde 1-2 saaTiT adre.

ondansetronis erTjeradi 8mg doza SeiZleba gamoyenebuli iyosneli intravenuri ineqciis saxiT uSualod qimioTerapiamde, ori Semdgomi intravenuri an intramuskuluri dozebiT 8mg 2-4 saaTSi erTxel mudmivi intravenuri infuziis saxiT (1mg/sT) 24 saaTis ganmavlobaSi.

alternatiulad 32mg erTjeradi doza mudmivi intravenuri infuziis saxiT aranakleb 15 wuTis ganmavlobaSi, mkurnalobamde 1-2 saaTiT adre.

ondansetronis 8mg-ze maRali da 32mg-e mcire doza gamoiyeneba mxolod intravenurad, ganzavebuli 50-100ml marilian xsnarSi an sxva SeTavsebad sainfuzio siTxeSi, induzia grzeldeba aranakleb 15 wuTis ganmavlobaSi.

dozirebis reJimis SerCeva unda moxdes mosalodneli emetogenuri pasuxis simwvavis mixedviT.

ondansetronis efeqturoba maRalemetogenuri qimioTerapiis dros SeiZLeba gaZlierdes deqsametazonis natrium fosfatis 20mg-s intravenurad miRebiT qimioTerapiamde.

24 saaTis Semdeg dagvianebuli an gaxangrZlivebuli Rebinebisgand dasacavad unda gagrZeldes oraluri ondansetroniT mkurnaloba, doza 8mg 12 saaTSi erTxel, 5 dRis ganmavlobaSi.

**pediatruli populacia:**

*qimioTerapiiT gamowveuli gulisreva da Rebineba 6 Tveze ufrosi asakis bavSvebSi da mozardebSi*

qimioTerapiiT gamowevuli gulsirevis da Rebinebistvis dozis gamoTvla SeiZleba sxeulis zedapiris fartobis (BSA) an wonis mixedviT-ix. qvemoT. wonaze dafuZnebuli dozirebis Sedegebi iwvevs ufro maRal totalur dozebs BSA-dafuZnebul dozasTan SedarebiT (ix. pragrafi 2).

ondansetronis ineqcia unda ganzavdes deqstrozis 5%-ian xsnarSi an natriumis wloridis 0.9%-ian xsnarSi an sxva SeTavsebad sainfuzio siTxeSi, intravenuri infuzia unda gagrZeldes aranakleb 15 wuTis ganmavlobaSi.

ar arsebobs monacemebi kontrolirebuli klinikuri kvlevbeidan sadac ondansetroni gamoiyeneba qimioTerapiiT gamowveuli dagvianebuli an gaxangrZlivebuli gulisrevis da Rebinebis prevenciisTvis. ar arsebobs monacemebi klinikuri kvlevebidan sadac ondansetroni gamoiyeneba bavSvebSi radioTerapiiT gamowveuli gulisrevis da Rebinebis mkurnalobisTvis.

**dozireba BSA mixedviT:**

ondansetroni unda gamoiyenon uSualod qimioTerapiamde erTjeradi intravenuri doziT 5mg/m2. intravenurma dozam ar unda gadaaWarbos 8mg-s.

oraluri dozireba SeiZleba daiwyos Tormeti saaTiT gvian da SeiZleba 5 dRemde gagrZeldes (cxrili 1).

saerTo sadReRamiso dozam ar unda gadaaWarbos mozrdilebis 32mg-s.

cxrili 1: BSA-dafuZnebuli dozirebis reJimi qimioTerapiisTvis-6 Tveze ufrosi asakis bavSvebsa da mozardebSi

|  |  |  |
| --- | --- | --- |
| BSA | dRe 1 (1,2)  | dRe 2-6 (2) |
| <0.6m2 | 5mg/m2 IV 12 saaTis Semdeg 2mg sirofi | 2mg sirofi 12 saaTSi erTxel |
| ≥0,6m2 | 5mg/m2 IV 12 saaTis Semdeg 4mg sirofi an tableti | 4mg sirofi an tableti 12 saaTSi erTxel |

1 intravenurma dozam ar unda gadaaWarbos 8mg-s.

2 saerTo dozam ar unda gadaaWarbos mozrdilebis dozas 32mg-s.

dozireba wonis mixedviT:

wonaze dafuZnebuli dozireba iwvevs ufro maRali dozis gamoyenebas BSA-dafuZnebul dozirebasTan SedarebiT (ix. paragrafi 2).

ondansetroni unda gamoiyenon uSualod qimioTerapiamde erTjeradi intravenuri dozis saxiT (0,15mg/kg). intravenurma dozam ar unda gadaaWarbos 8mg-s.

4 saaTiani intervaliT SeiZleba ori intravenuri dozis micema. saerTo dRiurma dozam ar unda gadaaWarbos mozrdilebis dozas-32mg-s.

oraluri dozireba SeiZleba daiwyos Tormeti saaTiT gvian da SeiZleba 5 dRe gagrZeldes (cxrili 2).

cxrili 2: wonaze dafuZnebuli dozireba qimioTerapiisTvis 6 Tveze ufrosi asakis bavSvebsa da mozardebSi

|  |  |  |
| --- | --- | --- |
| wona  | dRe 1 (1,2) | dRe 2-6 (2) |
| ≤10kg  | 0,15mg/kg 4 saaTSi erTxel, 3 doza | 2mg sirofi 12 saaTSi erTxel |
| >10kg | 0,15mg/kg 4 saaTSi erTxel 3 doza | 4mg sirofi an tableti 12 saaTSi erTxel |

1 intravenurma dozam ar unda gadaaWarbos 8mg-s.

2 saerTo dRiurma dozam ar unda gadaaWarbos 32mg-s.

xandazmulebi:

ondansetroni kargad aitaneba 65 welze ufrosi asakis pacientebis mier, saWiro ar aris dozirebis, dozirebis sixSiris an miRebis meTodis cvlileba.

***operaciis Semdgomi gulisreva da Rebineba:***

mozrdilebi:

postoperaciuli gulisrevis da Rebinebis prevenciisTvis ondansetronis miReba SeiZleba oralurad (tabletebi) an intravenuri an intramuskularuli ineqciis saxiT.

oraluri miRebisas rekomendebuli dozaa 16mg anesTeziamde erTi saaTiT adre an 8mg anesTeziamde erTi saaTiT adre, rasac moyveba 8mg-s ori Semdgomi doza 8 saaTSi erTxel.

alternatiulad, ondansetronis ineqcia SeiZleba gamoiyenon erTjeradi 4mg-s neli intravenuri an intramuskuluri ineqciis saxiT anesTeziis dasawyisSi.

dadgenili post-operaciuli gulisrevis da Rebinebis mkurnalobisTvis rekomendebulia 4mg-s erTejradi doza intravenuri an intramuskuluri ineqciis saxiT.

pediatruli populacia

*post-operaciuli gulisreva da Rebineba 1 Tveze ufrosi asakis bavSvebsa da mozardebSi*

post-operaciuli gulisrevis da Rebinebis prevenciisTvis pediaturl pacientebSi, romlebsac operacia utardebaT zogadi anesTeziiT, ondansetronis erTjeradi dozis miReba SeiZleba neli intravenuri ineqciis saxiT (aranakleb 30wami) 0,1mg/kg doziT maqsimum 4mg anesTeziis induqciamde an mis Semdeg.

pediatrul pacientebSi postoperaciuli gulisrevis da Rebinebis mkurnalobisTvis rodesac operacia tardeba zogadi anesTeziiT, ondansetronis erTjeradi doza SeiZleba gamoyenebuli iyos neli intravenuri ineqciis saxiT (aranakleb 30 wami) 0,1mg/kg doziT maqsimum 4mg.

ar arsebobs monacemebi ondansetronis gamoyenebaze postoperaciuli gulisrevis da Rebinebis mkurnalobisas 2 welze umcrosi asakis bavSvebSi.

kvlevebi ar Catarebula oraluri ondansetronis gamoyenebaze postoperaciuli gulisrevis da Rebinebis mkurnalobisTvis. rekomendebulia neli intravenuri ineqcia (aranakleb 15 wuTi).

xandazmulebi:

arsebobs SezRuduli gamocdileba xandazmulebSi ondansetronis gamoyenebis Sesaxeb postoperaciuli gulisrevis da Rebinebis mkurnalobisTvis, Tumca ondansetroni kargad aitaneba 65 welze ufrosi asakis pacientebSi, romlebic qimioTerapias itareben.

Tirkmlis ukmarisobiT daavadebuli pacientebi: l

saWiro ar aris dozirebis reJimis an miRebis meTodis cvlileba.

RviZlis ukmarisobiT daavadebuli pacientebi:

ondansetronis klirensi mniSvnelovnad Semcirebulia da naxevargamoyifis priodi mniSvnelovnad gaxangrZlivebulia RviZlis funqciis saSualo an mZime dazianebis mqone pacientebSi. amgvar pacientebSi ar unda gadaaWarbon intravenur an oralur 8mg dozas.

pacientebi sparteinis/debrisoqinis cudi metabolizmiT:

ondansetronis naxevardaSlis periodi ar icvleba subueqtebSi, romlebsac aqvT sparteinis da debrisoqinis cudi metabolizmi. amgvar pacientebSi ganmeorebiTi dozireba ar mogvcems eqspoziciis zogadi populaciisgan gansxvavebul dones. sadReRamiso dozirebis da siXsiris cvlileba saWiro ar aris.

**Tu miiReT saWiroze meti onda**

arsebobs ondansetronis dozis gadaWarbebis SezRuduli gamocdileba. umravles SemTxvevebSi simtomebi gavs im pacientebis niSNebs, romlebmac rekomendebuli doza miiRes. aRwerili gamovlinebebi moicavs mxedvelobis darRvevebs, mwvave yabzobas, hipotenzias da vazovagalur epizods meroe xatisxis tranzitoruli av blokiT.

ar arsebobs ondansetronis specifiuri antidote, aqedan gamomdinare dozis gadaWarbebaze eWvis SemTxvevaSi epikacis gamoyeneba naCvenebi ar aris, radgan pacients SeiZleba reaqcia ar qondes TviTon ondansetronis antiemeturi moqmedebis gamo.

**Tu dagaviwydaT ondas miReba**

Tu dagaviwydaT dozis miReba da gaqvT gulisreva da Rebineba, sxva doza miiReT rac SeiZleba male, Semdeg Cveulebriv ganagrZeT. Tu dagaviwydaT dozis miReba da ar gaqvT gulisreva an Rebineba, Semdegi dozia miiReT sqemis mixedviT.

1. **SesaZlo gverdiTi efeqtebi**

rogorc yvela medikamentma ondam SeiZleba gamowivios gverdiTi efeqtebi, Tumca isini yvelas ar uviTardeba.

Semdegi gverdiTi efeqtebi qvemoT CamoTvlilia organoTa sistemis klasis da sixSiris mixedviT. sixSire ganszRvrulia rogorc Zalian xSiri (≥1/10), xSiri (≥1/100-<1/10), naklebad xSiri (≥1/1000-<1/100), iSviaTi (≥1/10,000 da <1/1000) da Zalian iSviaTi (<1/10,000).

imunuri sistemis darRvevebi

*iSviaTi:* hipermgrZnobelobis dauyovnebeli reaqciebi, zogjer mwvave, anafilaqsiis CaTvliT.

nervuli sistemis darRvevebi

*Zalian xSiri*: Tavis tkivili.

*naklebad xSiri*: epilefsiuri gulyrebi, moZraobis darRvevebi (eqstrapiramiduli reaqciebis CaTvliT rogoricaa distoniuri reaqciebi, okulogiruli krizi da diskinezia).1

*iSviaTi*: Tavbrusxveva swrafi intravenuri Seyvanisas.

Tvalis darRvevebi

*iSviaTi:* tranzitoruli vizualuri darRvevebi (mag. mxedvelobis dabindva), ZiriTadad intravenuri miRebisas.

*Zalian iSviaTi*: tranzitoruli sibrmave ZiriTadad intravenuri miRebisas.2

gulis darRvevebi

*naklebad xSiri*: ariTmia, gulmkerdis tkivili ST segmentis derpesiiT an mis gareSe, bradikardia

vaskuluri darRvevebi

*xSiri:* siTbos SegrZneba an alebi

*naklebad xSiri*: hipotenzia.

respiratoruli, Torakaluri da Suasayris darRvevebi

*naklebad xSiri*: slokini

gastrointestinuri darRvevebi

*xSiri*: yabzoba.

lokaluri wvis SegrZneba sanTlis miRebis Semdeg.

hepatobiliaruli darRvevebi

*naklebad xSiri*: RviZlis funqciuri testebis asimptomuri momateba3/

zogadi darRvevebi da mdgomareoba Seyvanis adgilas

*xSiri:* adgilobrivi reaqciebi intravenuri ineqciis adgilas.

1 aRniSnulia persistiuli klinikuri Sedegebis mtkicebulebis gareSe

2 sibrmavis SemTxvevebis umravlesoba gaqra 20 wuTSi. pacietnebis umravlesobas miRebuli qonda qimioTerapiuli agentebi, romelbic moicavda cisplatins. tranzitoruli sibrmavis zogierTi SemTxveva aRwerili iyo rogorc kortikaluri warmoSobis.

3 es movlenebi xSirad aRiniSna pacientebSi, romlebic itarebdnen cisplatiniT qimioTerapias.

pediatruli populacia

bavSvebSi da mozardebSi gverdiTi movlenebis profile mozrdilebTan Sedarebadia.

**gverdiTi efeqtebis Setyobineba**

Tu aRgeniSnebaT gverdiTi efeqtebi, mimarTeT eqims an farmacevts. es moicavs gverdiT efeqtebs, romlebic broSuraSi CamoTvlili ar aris. gverdiTi efeqtebis Setyobineba uSualod SegiZliaT medikamentebis nacionaluri organozaciisTvis, mesogeionis gamziri 283, gr-15562, qolargosi, aTeni, tel: +30213 2040380/337, faqsi: +30210649585, veg-gverdi: <http://www.eof.gr>

gverdiTi efeqtebis SetyobinebiT gvexmarebiT medikamentis usafrTxoebis Sesaxeb meti informaciis miRebaSi.

**5. rogor inaxeba onda**

SeinaxeT bavSvebisTvis miuwvdomel adgilas.

onda ar gamoiyenoT kolofze miTiTebuli vargisianobis vadis gasvlis Semdeg.

tabletebi: inaxeba 25°C-ze dabal temperaturaze.

saineqcio xsnari: produqtisTvis saWiro ar aris Senaxvis gansakuTrebuli pirobebi. ampula SeinaxeT originalur konteinerSi, sinaTlisgan dacvisTvis.

**6. damatebiTi informacia**

**ras Seicavs onda**

**aqtiuri nivTierebaaL**

**apkiani garsiT dafaruli tabletebi**: 8mg ondansetroni erT tabletSi.

**saineqcio xsnari**: 2mg ondansetroni ml-ze

**sxva ingredientebia**:

**Semogarsuli tabletebi 8mg**: laqtoza uwylo, mikrokristaluri celuloza, saxamebeli (1500) magniumis stearati.

garsi: hipromeloza (5CPS), titanis dioqsidi (E171), rkinis yviTeli oqsidi E172, hipromeloza 15 CPS.

**saineqcio xsnari**: limonmJavas monohidrati, natriumis citrate, atriumis qloridi, saineqcio wyali.

**ondas aRwera da SefuTvis Semadgenloba**

**apkiani garsiT dafaruli tabletebi:** kolofi Seicavs 1 blisters, 15 tablets.

**saineqcio xsnari 4mg/2ml&8mg/4ml**: kolofi Seicavs qarvisferi gamWvirvale minis 1 ampulas, plastmasis strips gamoyenebis instruqciasTan erTad.

**svaWro licenziis mflobeli:** vianeqsi s.a.,tatoius quCa 14671, nea eriTrea, tel. 210.8009111-120

**mwarmoebeli**:

**apkiani garsiT dafaruli tabletebi:** vianeqs s.a-palini, attiki

**saineqcio xsnari**: vianeqs s.a-plant a, metamorfossi, attiki

**broSuris bolo damtkicebis TariRi** 31-03-2015

**informacia jandacvis sferos profesionalisTvis**

ondas saineqcioo xsnari ar unda Seurion SpricSi sxva preparatebs da ar unda moxdes maTTan erTad infuzia. ondas saineqcio xsnari unda Seurion mxolod rekomendebul sainfuzio xsnarebs.

ar SeiZLeba ondas saineqcio ampulebis avtoklavireba.

**intravenur siTxeebTan SeTavsebadoba:**

ondas saineqcio xsnari unda Seerios mxolod rekomendebul sainfuzio xsnarebs. kargi farmacevtuli praqtikis mixedviT, intravenuri xsnari unda momzaddes infuziis dros. Tumca naCvenebia, rom ondas saineqcio xsnari stabiluria 7 dRis ganmavlobaSi oTaxis temperaturaze (25°C-ze dabla) fluorescentuli naTebis qveS an macivarSi Senaxvisas Semdeg sainfuzio xsnarebTan erTad:

* natriumis qloridis 0,9%-iani intravenuri w/v sainfuzio xsnari
* glukozis 5%-iani intravenuri xsnari w/v
* manitolis 10%-iani intravenuri xsnari w/v
* ringeris intravenuri sainfuzio xsnari
* kaliumis qloridis 0,3% w/v da glukozis 5%-iani w/v intravenuri sainfuzio xsnari.

ondansetronis SeTavsebadobis kvlevebi Catarda polivinilqloridis sainfuzio flakonebSi da sistemebSi. adeqvaturi stabiluroba SenarCunebuli iyo polieTilenis sainfuzio flakonebis an 1 tipis minis flakonebis gamoyenebisas.

ondansetronis xsnari Sereuli natriumis qloridis 0,9%-ian w/v an glukozis 5%-ian w/v xsnarSi stabiluri iyo polipropilenis SpricebSi,

miiCneva, rom ondansetrinis saineqcio xsnari sxva sainfuzio siTxeebTan Serevisas stabiluria polipropilenis SpricebSi.

SeniSvna: produqtis unda Seinaxon Sesabamis aseptiuri pirobebSi rodesac saWiroa Senaxvis vadis gaxangrZliveba.

**sxva preparatebTan SeTavsebadoba:** ondas miReba SeiZLeba intravenuri infzuiiT 1mg/sT, sinfuzio flakonis an tumbosgan. Semdegi preparatebis gamoyeneba SeiZleba ondasTan erTad Y tipis sistemiT rodesac ondansetronis koncentracia Seadgens 16=160mikrogram/ml-s (mag. 8mg/500ml da 8mg/50ml):

**cisplatini:**

koncentracia 0,48mg/ml-mde (mag. 240mg 500ml-Si), erTi-8 saaTis ganmavlobaSi.

**5-fluoruracili:**

koncentracia 0,8mg/ml-mde (2.4g 3 litrSi an 400mg 500ml-Si) gamoiyeneba minimum saaTSi 20ml siswrafiT (500mg 24 saaTSi). 5-fluoruracilis ufro maRalma koncentraciam SeiZLeba gamoiwvios ondansetronis daleqva. 5-fluoruracilis infuzia SeiZleba Seicavdes 0,045% w.v magniumis qlorids sxva Semavseblebze damatebiT.

**karboplatini:**

0,18mg/ml -9,9mg/ml (90mg 500mlSi -990mg 100ml-Si) koncentracia gamoiyeneba 10 wuTis –1 saaTis ganmavlobaSi.

**etopozidi:**

0,14mg/ml-0,25mg/ml (72mg 500ml-Si -250mg 1 litrSi) koncentracia gamoiyeneba 30wuTis-1 saaTis ganmavlobaSi.

**ceftazidimi:**

250-2000mg doza ganzavebuli gamoxdil saineqcio wyalSi, rogorc rekomendebulia mwarmoeblis mier (mag. 2,5ml 250mg-sTvis da 10ml 2g ceftazidimisTvis), intravenuri nakadiT ineqcia grZeldeba daalxiebiT 5 wuTi.

**ciklofosfamidi:**

100mg-1g doza ganzavebuli gamoxdil saineqcio wyalSi 10mh/5ml ciklofosfamidTan erTad mwarmoeblis rekomendaciis Sesabamisad, intravenuri nakadiT ineqcia grZeldeba daaxloebiT 5 wuTi.

**doqsorubicini:**

10-100mg ganzavebuli gamoxdil saineqcio wyalSi 10mg/5ml doqsorubicinTan erTad mwarmoeblis rekomendaciis mixedviT, intravenuri nakadiT ineqcia grZeldeba daaxloebiT 5 wuTi.

**deqsametazoni:**

deqsametazonis natriumis fosfati 20mg SeiZLeba gamoyenebuli iyos rogorc neli intravenuri ineqcia 2-5 wuTis ganmavlobaSi Y-tipis sainfuzio sistemiT 8 an 32mg ondansetronTan erTad (ganzavebul 50-100ml SeTavsebad sainfuzio siTxeSi) daaxloebiT 15 wuTis ganmavlobaSI.

deqsametazonis natriumis fosfats da ondansetrons Soris SeTavsebadoba naCvenebia ori preparatis erTi sistemiT SeyvaniT 32mkg-2m5mg/ml koncentraciiT deqsametazonis natriumis fosfatisTvis da 8mkg-1mg/ml koncentraciiT ondansetronisTvis.

**gacemis meTodi**

**tabletebi:** mxolod eqimis receptiT. mkurnaloba unda daiwyos saavadmyofoSi da SeiZleba mis gareT gagrZeldes eqimis meTvalyureobis qveS.

**saineqcio xsnari**: mxolod eqimis receptiT. mxolod saavadmyofoSi gamoyenebisTvis.

**aTeni, 2016 wlis 12 dekemberi**

Targmani Seesabameba originals, mTargmneli: