**doqsotili®**

**doqsorubicini**

**pacientis sainformacio CanarTi**

* 1. **samedicino preparatis dasaxeleba:** doqsotili
  2. **Semadgenloba:**

**aqtiuri nivTiereba:** doqsorubicinis hidroqloridi

Semavseblebi: natriumis qloridi, saineqcio wyali da marilmJava (pH regulirebisTvis

**1.3 samkuranlwamlo forma:** saineqcio xsnari

**1.4 aqtiuri ingredientebi:** 10mg/5ml flakoni, 20mg/10ml flakoni, 50mg/25ml, 100mg/50ml flakoni

**1.5 aRweriloba-SefuTva:**

yuTi romelic Seicavs 5ml erT SuSis flakons an yuTi romelic Seicavs 10ml erT SuSis flakons an yuTi romelic Seiacs 25ml erT SuSis flakons an yuTi romelic Seicavs 50ml erT SuSis flakons.

**1.6 farmakoTerapiuli kategoria:** citostatikuri saSualeba

**1.7 savaWro licenziis mflobeli:**

Genepharm S.A.

18th Km Marathonos Ave.,

153 51 Pallini Attiki,

Greece

**1.8 mwarmoebeli**

Genepharm S.A.

18th Km Marathonos Ave.,

153 51 Pallini Attiki,

Greece

1. **ra unda icode eqimis mier gamowerili preparatis Sesaxeb**

**2.1 zogadi informacia**

miuxedavad imisa, rom cnobilia rom antraciklinebs SeuZliaT xeli SeuSalon bioqimiuri da biologiuri funqciebis garkveul raodenobas eukariotuli ujredebis SigniT, doqsorubicinis citotoqisikuri Tvisebebis zusti meqanizmi ar aris srulad garkveuli. preparati rogorc ki SeiWreba ujredSi, umTavresad ukavSirdeba qromatins. eqperimentuli monacemebis mixedviT doqsorubicini ayalibebs kompleqss dnm-Tan planaruli (brtyeli) rgolisebri struqturis interkalaciiT, nukleotidulri fuZeebis wyvils Soris. am interkalaciis Sedegebi seriozulad arRvevs dnm sinTezs, dnm-damokidebul rnm sinTezs da proteinis sinTezs. Tumca doqsorubicinis koncentraciebi saWiroebda zegavlenis moxdenas citotoqsikur efeqtebze am meqanizmebis saSualebiT romlebic rogorc Cans gakveulwilad ufro didia vidre isini romlebic miiRweva simsivnis lokalizaciis adgilas, klinikur garemoSi. uaxlesi eqperimentuli monacemebi gviCvenebs, rom dnm interkalacia ainicirebs dnm gaxleCvas topoizomeraza-II-is saSualebiT, romelic iwvevs seriozul darRvevebs dnm mesame rigis struqturaSi. es efeqti aRiniSna wamlis iseTi koncetraciebis SemTxvevaSi, romlebic iyo klinikuri, Terapiul diapazonSi. aseve cnoblia, rom doqsorubicini CarTulia oqsidacia/reduqciis reaqciebSi: NADPH-damokidebul ujredul reduqtazebs SeuZliaT gadaiyvanon doqsorubicini semiqvinonis Tavisufal radikalebamde, romelsac Tavis mxriv SeuZlia reaqciaSi Sevides molekulur JangbadTan, raTa moaxdinos iseTi maRalreaqtiuli citotoqsikuri SenaerTebis generireba, rogoric aris superoqsidi, hidroqsilis radikalebi da wyalbadis zeJangi. Tavisufali radikalebis Camoyalibeba CarTuli iyo doqsorubicinis kardiotoqsikurobaSi. doqsorubicinis moqmedebis Semdgomi ubani SeiZleba iyos ujreduli membranis doneze: preparati SeiZleba daukavSirdes ujreduli membranis lipidebs da daazianos mTeli rigi funqciebi. doqsorubicinis citotoqsikurma aqtivobam SeiZleba gamoiwvios naxsenebi meqanizmebis nebismieri Sedegi an SeiZleba iyos sxvebic. ujreduli kinetikis kvlevebma aCvena, rom doqsorubicini aqtiuria mTeli ujreduli ciklis ganmavlobaSi, maT Soris interfazis ganmavlobaSi. swrafad proliferebadi qsovilebi, rogoric aris simsivnuri qsovilebi (magram aseve Zvlis tvini, gastrointestinuri da oraluri lorwovani garsi, Tmis folikulebi) amis gamo arian yvelaze metad mgrZnobiareebi doqsorubicinis citotqosikuri efeqtebis mimarT.

**2.2. Cvenebebi**

doqsorubicins aqvs mniSvnelovani Terapiuli pasuxi garkveuli raodenobis soliduri simsivneebis an hematologiuri avTvisebiani simsivneebis SemTxvevaSi da farTod aris gamoyenebuli Semdegi neoplazmuri daavadebebis mkurnalobaSi: ZuZus kibo, filtvis kibo, sakvercxis kibo, Sardis buStis gardamaval ujredovani kibo, neiroblastoma, vilmsis simsivne, rbili qsovilis sarkoma, osteosarkoma, mwvave limfocitur limfoblasturi leikemia, mwvave mielogenuri leikemia, ara-hojkinis limfoma, hojkinis limfoma, farisebri jirkvlis kibo.

**2.3. ukuCvenebebi**

situaciebi, romlis drosac pacientebis mkurnaloba ar SeiZleba intravenuri doqsorubiciniT, maT Soris:

persisiterebadi mielosupresia an mwvave stomatiti, romlebic gamowveulia wina citotoqsikuri mkurnalobiT; generalizebuli infeqciebi; RviZlis funqciis markirebuli darRveva; mwvave ariTmia, miokardiuli ukmarisoba, manamde gadatanili miokardiuli infarqti; manamde Catarebuli mkurnaloba antraciklinebiT maT maqsimalur kumulaciur dozamde; hipermgrZnobeloba doqsorubicinis, sxva antraciklinebis an antracenedionebis mimarT.

intravezikaluri Seyvanis ukuCveneba moicavs:

* invaziuri simsivneebi, romlebic SeiWrnen Sardis buStis kedelSi; saSarde gzebis infeqciebi; Sardis buStis anTeba
* kaTeterizaciis problemebi (magaliTad, gamowveuli masiuri intravezikaluri simsivneebiT)

**2.4. specialuri sifrTxilis zomebi**

doqsitili ar Seicavs natriums, doqsorubiciniT mkurnaloba unda ganxorcieldes eqimis mier, romelic gamocdilia qimioTerapiaSi da unda Catardes mkacri zedamxedvelobis qveS, organizmis garkveuli funqciebis monitoringiT.

sisxlis saerTo analizi: unda ganxorcieldes gansakuTrebuli yuradRebiT sisxlis TeTri ujredebis totaluri da diferencialuri raodenobis mimarT. doqsorubiciniT gamowvuli Zvlis tvinis depresia, upiratesad liekocitebis, saWiroebs frTxil hematologiur monitorings, imis gaTvaliswinebiT, rom mwvave mielosupresiam SeiZleba gamoiwvios superinfeqciebi an hemoragiebi. rekomendebuli dozebiT da soliduri simsivneebis mkurnalobis grafikiT, SeiZleba gamovlindes markirebuli leikopenia (1000/mm2 an ufro dabalia mosalodneli doqsorubicinis sruli dozebiT mkurnalobis ganmavlobaSi), Tumca aseTi leikopenia rogorc wesi gardamavlia, romelic Tavis udables wertils aRwevs mkurnalobis dawyebidan me-10-14 dRes da gamojansaRebiT romlebic mTavrdeba 21-e dRes. unda gakontroldes Trombocitebis da eriTrocitebis doneebi,. hematologiuri toqsikuroba SeiZleba saWiroebdes dozis Semcirebas an doqsorubiciniT mkurnalobis droebiT Sewyvetas an Seferxebas. RviZlis funqciis Sefaseba: imis gaTvaliswinebiT rom doqsorubicini upiratesad gamoiyofa RviZliT an naRveliT, preparatis dayovnebuli eliminacia SeiZleba gamovlindes RviZlis funqciis Semcirebis an naRvelis gaZnelebuli gamodenis SemTxvevaSi da SeiZleba ganviTardes meoradi gverdiTi efeqtebi. gaidlainebi, romlebic farTod gamoioyeneba dozis SemcirebisTvis RviZlis darRveuli funqciis dros, dafuZnebulia Sratis bilirubinis qvemoCamoTvlil doneebze:

Sratis bilirubini dozis Semcireba

1.2-3.0 mg/100 ml 50%

3.1-5.0 mg/100ml 75%

kardialuri funqcia: kardiotoqsikuroba warmoadgens antraciklinebiT mkurnalobis cnobil risks. aseTi saxis toqsikurobis yvelaze mwvave da tipiuri forma warmodgenilia dayovnebuli kardiomiopaTiiT, romelic vlindeba gazrdili sixSiriT preparatis maRali kumulaciuri dozebiT da SeiZleba gamoiwvios gulis SegubebiTi ukmarisoba. kardialuri funqcia unda Sefasdes doqsorubiciniT mkurnalobis dawyebamde da unda gakontroldes mTeli mkurnalobis ganmavlobaSi raTa Semcirdes mwvave kardialuri darRvevis riski. miuxedavad imisa, rom endomiokardialuri biofsia aRiarebulia rogorc yvelaze metad Sesabamisi diagnostikuri saSualeba antracikliniT gamowveuli kardiomiopaTiis gamosavlenad, es invaziuri kvleva rutinul safuZvelze SeiZleba advilad ver ganxorcieldes. kardialuri fuqnciis rutinuli Sefaseba doqsorubiciniT mkurnalobis ganmavlobaSi SeiZleba moicavdes eleqtrokardiogramas (ekg) da marcxena parkuWis gandevnis fraqciis Sefasebas. ekg cvlilebebi rogorc wesi miuiTebs gardamaval toqsikurobaze, magram QRS voltaJis Semcireba an sistoluri drois intervalis normalur sazRvrebs miRma gafarToeba SeiZleba miuTiTebdes tipiuri antracikliniT gamowveuli kardiomiopaTiis marcxena parkuWis gandevnis fraqciis Semcirebaze. gulis SegubebiTi ukmarisobis ganviTarebis SesaZlebloba, romelic mosalodnelia 1-2% farglebSi, 300 mg/m2 kumulaciuri doziT nelnela izrdeba 450-550 mg/m2 kumulaciur dozamde. am donis zemoT, gulis SegubebiTi ukmarisobis ganviTarebis riski izrdeba mkveTrad da ar aris rekomendebuli 550 mg/m2 kumulaciuri dozis gadaWarbeba. Tu saxezea raime damatebiTi risk-faqtori (aqtiuri an pasiuri kardiovaskularuli daavadeba, mediastinalur/perikardiuli ubnis wina an Tanmxlebi radioTerapia, manamde Catarebuli mkurnaloba antraciklinantracenedionebiT, sxva kardiotoqsikuri preparatebis imavdrouli gamoyeneba) dabali kumulaciuri dozebis SemTxvevaSi SeiZleba gamovlindes kardialuri toqsikuroba (magaliTad 400 mg/m2 kumulaciuri doza pacientebSi romlebSic xdeba Suasayaris dasxiveba). am pirobebSi, kardialuri funqciis monitoringi unda iyo Zalian mkacri da riski/sargeblis Tanafardoba doqsorubicniT mkurnalobis gagrZelebasTan dakavSirebiT kardialuri funqciis darRvevis dros unda iyos gaTvaliswinebuli. eqstravazacia: Ddoqsorubicinis eqstravazaciam intravenuri ineqciis dros SeiZleba gamoiwvios qsovilebis mwvave dazianeba da nekrozic ki. venuri nekrozi SeiZleba asve gamowveuli iyos wvril venebSi ineqciiT an erTidaigive venaSi ganmeorebiTi ineqciiT. preparatis eqstravazaciis riskis Sesamcireblad da imaSi dasarwmuneblad rom vena kargad aris Carecxili, preparatis Seyvanis Semdeg rekomendebulia preparatis Seyvana Tavisuflad gamtari fiziologiuri xsnariT Carecxili milis gavliT mas Semdeg rac Semowmdeba, rom nemsi kargad aris Cadgmuli venaSi. Tu eqstravazaciis niSnebi da simptomebi vlindeba doqsorubicnis intravenuri Seyvanisas, preparatis infuzia saswrafod unda Sewydes. eqstravazaciis marTvisTvis saswrafod unda ganxorcieldes eqimis an/da hospitalis mier sanqcirebuli RonisZiebebi. doqsorubicinma SeiZleba gaaZlieros kibos sawinaaRmdego sxva preparatebis toqsikuroba. aRiniSna ciklofosfamidiT gamowveuli hemoragiuli cistitis gamwvaveba da 6-merkaptopurinis gaZlierebuli hepatotoqsikuroba. aseve aRiniSna sxivuri TerapiiT gamowveuli toqsikurobis (miokardiumi, lorwovani garsi, kani da RviZli) mateba.

* aRmoCnda rom doqsorubicinis sistemuri klirensi Semcirebulia msuqan pacientebSi. aseTi pacientebis monitoringi unda ganxorcieldes yuradRebiT, Tu maT eZlevaT preparatis sruli doza.
* doqsorubicinma SeiZleba wiTeli Seferiloba misces Sards miRebidan erTi an ori dRis ganmavlobaSi. pacientebi gafrTxilebuli unda iyvenen, rom aseTi movlena ar gaxdes SeSfoTebis sagani.

**2.5 preparatis gamoyeneba orsulobis da laqtaciis dros**

doqsorubicinis usafrTxo gamoyeneba orsulobis dros ar aris dadgenili. Ddoqsorubicini aris embriotoqsikuri da teratogenuri virTagvebSi. is embriotoqsikuria da SeiZleba gamoiwvios aborti bocvrebSi. qalebi Svilosnobis potencialiT, romlebic iReben doqsorubicins, unda gaafrTxilon nayofisTvis miyenebuli potenciuri riskis Sesaxeb da unda daarwmunon Tavidan aicilon orsuloba mkurnalobis ganmavlobaSi. Tu doqsorubicinis gamoyeneba aucilebelia orsulobis ganmavlobaSi, unda Seafsdes mkurnalobis potenciuri sargebeli nayofze miyenebul SesaZlo riskTan SedarebiT. imis gaTvaliswinebiT, rom doqsorubicins aqvs mutagenuri potenciali, preparatma SeiZleba gamoiwvios adamianis spermatozoidis qromosomuli dazianeba. amis gamo, rogorc kacebma, ise qalebma mkurnalobis procesSi unda gamoiyenon kontracefciuli saSualebebi. doqsorubicini gamoiyofa laqtatSi, amis gamo meZuZurma dedebma unda Sewyviton Cvilebis kveba maTze miyenebuli seriozuli potenciuri safrTxis gamo.

**2.6. preparatis zegavlena avtomanqanis an sxva meqanizmebis marTavze**

ar aris aRniSnuli raime gansakuTrebuli efeqti avtomanqanis an sxva meqanizmebis marTvaze

**2.7 SeuTavsebloba**

Tavidan unda iqnas acilebuli tute pH xsnarebTan kontaqti, vinaidan aman SeiZleba gamoiwvios doqsorubicinis hidorlizisi. ar SeiZleba doqsorubicinis Sereva heparinTan, cefalotinTan an natriumis deqsametazonis fosfatTan, imis gaTvaliswinebiT, rom es preparatebi arian qimiurad SeuTavseblebi (prepcipitatis Camoyalibeba). misi feri icvleba wiTelidan lurj-mewamulamde aminofilinis an 5-ftoruracilis SemTxvevaSi, rac warmoadgens gaxleCvis niSans. doqsorubicinis Sereva ar SeiZleba sxva citotoqsikur preparatebTan erTidaigive SpricSi kombinirebuli qimioTerapiis ganmavlobaSi.

**2.8 urTierTqmedeba sxva preparatebTan da nivTierebebTan**

doqsorubicinma SeiZleba gaaZlieros kibos sawinaaRmdego sxva mkurnalobis toqsikuroba. aRiniSna ciklofosfamidiT gamowveuli cististis gamwavaveba an 6-merkaptopurinis gaZlierebuli hepatotoqsikuroba. aseve aRiniSna radiaciuli TerapiiT gamowveuli toqsikurobis (miokardiumi, lorwovani garsi, kani da RviZli) toqsikurobis gaZliereba. Ddoqsorubicinis umTavresad gamoiyeneba sxva citotoqsikur preparatebTan erTad da SeiZleba gamovlindes damatebiTi toqsikuroba gansakuTrebiT Zvlis tvinTan/sisxlTan an gastrointestinur efeetebTan dakavSirebiT. ufro metic, doqsorubicnis gamoyeneba kibos sawinaaRmdego sxva preparatebTan erTad, romlebic arian potenciurad toqsikurebi (magaliTad, 5-ftoruracili, ciklofosfamidi, cisplatini, taqsanesi) isev rogorc sxva kardioaqtiur SenaerTebTan erTad (magaliTad, kalciumis arxebis blokerebi) saWiroebs kardialuri funqciis mkacr monitorings, mTeli mkurnalobis ganmavlobaSi. doqsorubicini eqstensiurad metabolizdeba RviZliT. Tanmmxlebi TerapiiT gamowveulma RviZlis funqciis cvlilebebma SeiZleba daazianos doqsorubicinis metbolizmi, farmakokinetika, Terapiuli efeqturoba an/da toqsikuroba. doqsorubicin-citarabinis kombinaciam gamoiwvia msxvili nawlavis lorwovani garsis hemoragia, dawyluleba an nekrozi pacientebSi romlebsac aqvT mwvave mielogenuri leikemia.

**2.9 dozireba da miRebis wesebi**

doqsorubicini aris citotoqsikuri nivTiereba, romelic rogorc wesi SeyavT kiboian pacientebSi intarvenuri ineqciiT da rodesac saWiroa intravezikaluri an intraarteriuli gziT. intravenuri Seyvanisas dozireba, rogorc wesi, iTvleba sxeulis zedapiris farTobis (mg/m) safuZvelze. doqsorubicinis dozirebis grafiki SeiZleba gansxvavdebodes Terapiuli Cvenebis mixedviT (magaliTad, soliduri simsivne an mwvave leikemia) iseve rogorc misi gamoyenebis mixedviT specifiukr reJimSi (magaliTad, erTi nivTiereba an sxva citotoqsikur nivTierebebTan kombinaciaSi an rogorc multidisciplinaruli midgomis nawili, romelic moicavs qirurgiul CarevasTan an/da radioTerapaiasTan an/da hormonul TerapiasTan kombinacias). doqsorubicinis intravenuri Seyvana unda ganxorcieldes sifrTxiliT. rekomendebulia doqsorubicinis nela Seyvana kaTeteris saSualebiT, romelic winaswar Carecxili iqneba xsnariT (izotonuri natriumis qloridi an 5% glukozis xsnari) 3-5 wuTis ganmavlobaSi. mizani aris Trombozis an perivenuri eqstravazaciis riskis Semcireba, romelmac SeiZleba gamoiwvios mwvave anTeba, vezikacia an qsovilis nekrozi. pirdapiri (uSualo) CxvletiT Seyvana ar aris rekomendebuli eqstravazaciis riskis gamo, romelic SeiZleba gamovlindes punqciuri biofsiis dros sisxlis adeqvaturi dabrunebis drosac ki.

**soliduri simsivneebis mkurnaloba**

doqsorubiciniserTjeradi nivTierebis gamoyenebisas, rekomendebuli doza erT samkurnalo ciklze aris sxeulis zedapiris farTobis 60-75 mg/m2 yovel sam kviraSi erTxel.

preparats rogorc wesi aZleven erTjeradi dozis saxiT, erT ciklze. Tumca preparatis doza erT ciklze SeiZleba micemuli iqnas gayofil dozebad (magaliTad, pirvelidan mesame dRis gavliT an pirveli da me-8 dReebi). doqsorubicinis miReba kvireuli reJimiT efeqturi aRmoCnda 3-kviriani grafikis SemTxvevaSi, rekomendebuli kvireuli doza aris 10-20 mg/m2. es grafiki SeiZleba asocirdebodes Semcirebul toqsikurobasTan, gansakuTrebiT gulTan mimarTebaSi. roca doqsorubicini gamoiyeneba kibos sawinaaRmdego sxva preparatebTan kombinaciaSi, romlebsac aqvT potenciurad gadamfarveli toqsikuroba, rekomendebuli doza ciklis ganmavlobaSi meryeobs 30-60 mg/m2 diapazonSi., imis gaTvaliswinebiT rom doqsorubicini aris mielosupresiuli preparati, ciklebs Soris intervali SeiZleba gaizardos an preparatis doza Semcirdes im pacientebis SemTxvevaSi, romelTa sisxlis TeTri ujredebis (gansakuTrebiT neitrofilebis) raodenoba normaze dabalia mkurnalobis nebismieri ciklis win. dozis Semcireba aseve SeiZleba saWiro gaxdes pediatriuli an geriatriuli pacientebis SemTxvevaSi romlebsac ukve Catarebuli aqvT mkurnaloba da Zvlis tvinis rezervi SeiZleba iyos dabali RviZlis darveuli funqciis dros, rekomendebulia doqsorubicinis dozis Semcireba.

mwvave leikemiis marTvisas, Zvlis tvinis aplazia warmodgens Terapiul miRwevas da gamoiyeneba intensiuri kombinaciuri qimioTerapiis grafikebi. aseT situaciebSi, doqsorubicinis rekomendebuli doza aris sxeulis wonis 2.4 mg/kg (romelic Seesabameba sxeulis zedapiris farTobis daaxloebiT 75-90mg/m2), romlis Seyvana unda moxdes gayofil dozad, sami Tanamimdevruli dRis ganmavlobaSi (erTi cikli). Mmeore ciklis dro da doza nakarnaxebi unda iyos Zvlis tvinis da periferiuli sisxlis ujredebis mdgomareobiT. Tumca ciklebs Soris periodi unda iyos sul mcire 10 dRe.

intravezikaluri Seyvana

doqsorubicinis intravezikalurad Seyvana SeiZleba zedapiruli Sardis buStis simsivneebis samkurnalod an transureTruli rezeqciis Semdgomi recidivis riskis Semcirebis profilaqtikisTvis. Sardis buStis zedapiruli simsivneebis adgilobrivi intravezikaluri mkurnalobisTvis doqsorubicinis rekomendebuli doza aris 30-50 mg 25-50 ml fiziologiur xsnarSi TiTouel instilaciaze da optimaluri koncentracia aris daxloebiT 1.0mg/ml. rogorc ki instilacia dasruldeba, pacienti unda gadaabrunon meoTxediT yovel TxuTmet wuTSi mTlianobaSi, xsnari unda Sekavdes Sardis buStSi 1-2 saaTiani periodiT. SardiT gadaWarbebuli ganzavebis Tavidan asacileblad, pacientebs sTxoven ar dalion raime saxis siTxe instilaciamde 12 saaTiT adre (es SezRudavs Sardis produqcias daaaxloebiT 50ml/saaTamde.). instilaciis gameoreba SeiZleba intervalebiT, romelic SeiZleba meryeobdes erTi kviridan erT Tvemde, imaze damokidebulebis mixedviT mkurnaloba Terapiulia Tu profilqtikuri. doqsorubicinis sistemuri absorbcia intravezikaluri instilaciis Semdeg aris Zalian dabali.

**intraarteriuli Seyvana**

doqsorubicini aseve gamoyenebuli iqna intraarteriuli gziT Sesayvanad, raTa moexdinaT intensiuri adgilobrivi aqtivobis producireba Semcirebuli zogadi toqsikurobiT. imis gaTvaliswinebiT, rom es teqnika potenciurad saSiSia da SeiZleba gamoiwvios qsovilis farTomasStabiani nekrozi, intraarteriuli Seyvana SeiZleba ganxorcieldes mxolod im eqimebis mier, romlebsac aqvT gamocdileba am teqnikaSi.

**2.10 gamoyeneba da marTvis instruqcia**

intravenuri Seyvana: doqsorubicini rogoroc wesi SeyavT intravenurad. xsnaris ineqcia unda ganxorcieldes 3-5 wuTis ganmavlobaSi,AkaTeteris saSualebiT, fiziologiuri xsnariT Carecxvis Semdeg, mas Semdeg rac gakontroldeba, rom nemsi kargad aris Cadgmuli venaSi. es teqnika gamoiyeneba Trombozis da preparatis periferiuli eqstravazaciis riskis minimizaciisTvis, romelmac SeiZleba gamoiwvios mwvave anTeba da nekrozi da uzrunvelyofs venis Carecxvas prepartis Seyvanis Semdeg. venuri sklerozi SeiZleba gamowveuli iyos wvril venebSi ineqciiT an erTi da igive venaSi ganmeorebiTi ineqciiT. Aadgilobrivi ubnis Terapia: rigorc intravezikaluri ise intraarteriuli SeyvanisTvis ixileT 4.2 Tavi. dacviTi RonisZiebebi: mocemuli nivTierebis toqsikuri bunebis gaTvaliswinebiT mowodebulia Semdegi gaidlainebi:

aucilebelia personalis trenireba preparatis gaxsnis da marTvis Sesabamis teqnikasTan dakavSirebiT. orsulebs ekrZalebaT am preparatTan muSaoba. personali romelic muSaobs mocemul preparatTan unda atarebdes damcav tansacmels: erTjeradi gamoyenebis specialuri damcavi saTvale, winsafari, xelTaTmanebi. gamoyofili unda iqnas specialuri adgili gaxsnisTvis (upiratesad laminaruli dinebis sistemis qveS). sawarmoo adgilis zedapiri daculi unda iyos erTjeradi gamoyenebis laminirebuli, absorbirebuli qaRaldiT, yvela nivTi, romelic gamoiyeneba gaxsnisTvis, SeyvanisTvis an gasawmendad maT Soris xelTaTmanebi, unda ganadgurdes im CanTebSi, romelic gankuTvnilia mavne gadanayrebisTvis, kremaciisTvis maRal temperaturaze. kanTan da TvalebTan SemTxveviTi kontaqtisas aucilebelia dauyovnebeli Camorecxva didi raodenobiT wyliT an sapniT da wyliT an natriumis bikarbonatis xsnariT. Semdeg aucilebelia eqimis konsultacia. daRvris an gaJonvis SemTxvevaSi aucilebelia damuSaveba ganzavebuli natriumis hipoqloritiT (1 % qlorini) upiratesad absorbciiT da Semdeg wyliT CarecxviT. gamoyenebis Semdeg yvela nivTi, romelic gamoyenebuli iqna dasasufTaveblad, unda daiwvas zemoT mocemuli instruqciis mixedviT.

**2.11 dozis gadaaWarbeba**

doqsorubicinis dozis gadaWarbeba iwvevs mwvave meilosupresias (umTavresad liekopenia da Trombocitopenia), gastrointestinur toqsikur efeqtebs (umTavresad mukozitebs) da mwvave kardialur alternaciebs. mwvave Warbi dozirebis mkurnaloba moicavs hospitalizacias, intravenur antibiotikebs, granulocitebis da Trombocitebis transfuzias da gastrointestinuri da kardialuri toqsikuri movlenebis mkurnalobas. hepatopoezuri zrdis faqtorebis gamoyenebac SeiZleba iyos gaTvaliswinebuli. qronikuli dozis gadaWarbeba, roca absoluturi kumulaciuri doza aWarbebs 550 mg/m2 zrdis kardiomiopaTiis risks da SeiZleba gamoiwvios gulis SegubebiTi ukmarisoba. aseT SemTxvevebSi moicavs sagule preparatebs, periferiul vazodilatatorebs da angiotenzin-gardamqneli fermentis inhibitorebs.

**2.12 gverdiTi efeqtebi**

Zvlis tvinis/hematologiuri toqsikuroba. doza-damokidebuli, Seqcevadi leikopenia an/da granulocitopenia (neitropenia) aris doqsorubicinis Zvlis tvinis/hematologiuri toqsikurobis predominantur gamoxatuleba da warmoadgens preparatis mwvave doza-limitirebul toqsikurobas. yvelaze xSirad gamoyenebuli 3-4 kviriani Seyvanis grafikis ganmavlobaSi, leikocitebis/granulocitebis dacema rogorc wesi miiRweva wamlis Seyvanidan me-10-14 dRes. pacientebSi normaluri Zvlis tvinis regenarciis unariT, sisxlis TeTri ujredebis raodenoba, rogorc wesi, aRdgeba mesame kviris bolos. Tu gamovlinda mwvave mielosupresia, SeiZleba Zvlis tvinis daxmareba (magaliTad, periferiuli sisxlis aradiferencirebuli ujredebi an zrdis faqtorebi). aseve SeiZleba gamovlindes Trombocitopenia da anemia. doqsorubicinis Zvlis tvinis/hematologiuri toqsikurobis klinikuri Sedegebi SeiZleba moicavdes cxelebas, infeqciebs, sefsis/septicemias, septiur Soks, hemoragias, qsovilis hipoqsias an sikvdils. Tu gamovlinda febriluri neitropenia saWiroa intravenuri antibiotikebis daniSvna. meoradi mwvave mielogenuri leikemiis gamovlena pre-leikemiuri faziT an mis gareSe, iSviaTad aRiniSna pacientebSi romlebsac erTdroulad mkurnalobdnen doqsorubuciniT dnm damazianebel antineoplastikur nivTierebebTan erTad. am leikemiebs SeiZleba hqondeT mokle latenturi periodi (1-3 weli), kardialuri toqsikuroba: antracikliniT gamowveuli kardialuri toqsikuroba SeiZleba gamoixatos naadrevi (mwvave) an dayovnebuli SemTxvevebiT. doqsorubicinis naadrevi kardialuri toqsikuroba umTavresad moicavs sinusur taqikardias/an ekg anomaliebs, magaliTad araspecifikuri ST-T talRis cvlileba, Tumca aRiniSna aseve taqiariTmia, rogoric aris naadrevi parkuWovani SekumSvebi, parkuWovani taqikardia, bradikardia iseve rogorc atrioventrikuluri da atrioventrikuluri konis blokada. malignanturi kardialuri disariTmiis garda es efeqtebi ar miuTiTebs dayovnebuli kardiotoqsikurobis Semdgom ganviTarebaze, iSviaTad aqvT klinikuri mniSvneloba da umTavresad ar ganixileba rogorc doqsorubicinis mkurnalobis gverdiTi efeqtis Cvenebad. dayovnebuli kardialuri toqsikuroba warmodgenilia saxasiaTo kardiomiopaTiiT, romelic klinikurad gamoxatulia ventrikuluri disfunqciis/gulis SegubebiTi ukmarisobis simptomebiT/niSnebiT rogoric aris qoSini, filtvis SeSupeba, orTostatiuli SeSupeba (magaliTad, koWTan), hepatomegalia, asciti, filtvis efuzia, galopis riTmi. es toqsikuroba savaraudod damokidebulia doqsorubicinis kumulaciur dozaze da warmoadgens preparatis kumulaciur doza-mamilitirebel toqsikurobas. garkveuli raodenobis kvlevebis mixedviT gulis SegubebiTi ukmarisobis riski mkveTrad izrdeba kardialuri risk- faqtorebis ar arsebobisas mas Semdeg, rac miiRweva 550 mg/m2 kumulaciuri doza Tu kardialuri toqsikurobis damatebiTi risk-faqtori aris warmodgenili (aqtiuri an dominanturi kardiovaskularuli daavadeba, manamde gadatanili mediastinuri radioTerapia, sxva kardiotoqsikuri preparatebis manamde arsebuli an Tanmxlebi gamoyeneba) kardialuri toqsikuroba SeiZleba gamovlindes udables kumulaciur dozebzec. Ddayovnebuli kardiotoqsikuroba umTavresad viTardeba doqsorubiciniT mkurnalobis dros da daaxloebiT 2-3 Tvis Semdeg mkurnalobis dasrulebidan, Tumca aseve aRiniSna mogvianebiTi (mkurnalobis Sewyvetidan ramdenime Tvidan wlebamde) movlenebi. Ggulis seriozuli darRvevebi SeiZleba Tavidan iqnas acilebuli mkurnalobis ganmavlobaSi regularuli monitoringiT. aseve aRiniSna qvemwvave mdgomareobebi, rogoric aris perikarditi an miokarditi. Ggastrointestinuri toqsikuri mukoziti (umTavresad stomatiti, naklebad xSirad ezofagiti) SeiZleba gamovlindes pacientebSi, romlebsac uviTardebaT doqsorubiciniT mkurnaloba. mukozitis klinikuri manifestacia moicavs tkivils da wvis SegrZnebas, eriTemas, eroziebs wylulebs, sisxldenas da infeqciebs. stomatiti rogorc wesi Cndeba maSinve wamlis Seyvanis Semdeg da Tu mwvavea, SeiZleba ramdenime dReSi gadavides lorwovanis dawylulebaSi, TumcaRa pacientebis umravlesobas es gverdiTi efeqti exsneba mesame kviraze. aseve SeiZleba gamovlindes gulisreva, Rebineba, xandaxan diarea da abdominaluri tkivili. mwvave Rebinebam da diaream SeiZleba gamoiwvios dehidratacia. gulsirevis da Rebinebis prevencia an Semsubuqeba SesaZlebelia Sesabamisi antiemeturi TerapiiT. doqsorubicin-citarabinis kombinacam gamoiwvia msxvili nawlavis lorwovani garsis sislxlmdeni wylulebi da nekrozi pacientebSi mwvave mielogenuri leikemiiT., xSirad vlindeba kanis reaqciebi da momatebuli mfrZnobelobis reaqciebi, alopecia maT Soris wveris gazrdis Sewyveta. es gverdiTi efeqtebi rogorc wesi Seuqcevadia da yvela saxis Tmis xelaxali zrda Tavs iCens Terapiis Sewyvetidan 2-3 Tvis Semdeg. aseve SiZleba gamovlindes sisxlis mowola, kanis da frCxilis hiperpigmentacia da iradirebuli kanis momatebuli mgrZnobeloba (dasxivebis moxsnis reaqcia), urtikaria da anafilaqsia aRiniSna pacientebSi doqsorubiciniT mkurnalobis dros. am reaqciebis niSnebi da simptomebi SeiZleba varirebdes kanis gamonayaridan da qavilidan cxelebamde, ciebamde da Sokamde. aseve aRiniSna ‘xelis da fexis sindromi” (palmar-plantaruli eriTrodizesTezia an akraluri ariTema).

zegavlena ineqciis adgilze: eriTematozuli aWreleba infuzirebuli venis gaswvriv ar aris xSiri da SeiZleba win uZRodes adgilobriv flebitebs da Tromboflebitebs, flebitebis/Tromboflebitebis riskis minimizeba SeiZleba Seyvanis procedurze dakvirvebiT. SeiZleba gamovlindes flebosklerozi gansakuTrebiT maSin doqsorubicini ganmeorebadad SeyavT wvril venaSi. perivenuri preparatis eqstravazaciis dros vlindeba adgilobrivi tkivili, mwvave celuliti da qsovilis nekrozi.

sxva gverdiTi efeqtebi: sxva gverdiTi movlenebi moicavs: uZlureba/gadaRla, okularul toqsikurobas (koniunqtiviti, cremldena) da hiperurikemia, romelic SeiZleba gamovlindes purinis eqstensiuri katabolizmis Sedegis saxiT romrlic Tan axlavs maRali qimiuir mgrZnobelobis axalwarmonaqmnebis prepartebiT gamowveul ujredebis swraf sikvdils (simsivnis daSlis sindromi). Hhidratacia, Sardis gatutovneba da alopurinolis Seyvana daexmareba hiperurikemiis gverdiTi efeqtebis prevencias an minimizacias. aseve SeiZleba gamovlindes amenorea da doqsorubiciniTmkurnalobam SeiZleba gamoiwvios azoospermia spermaSi. Ddoqsorubicinis Seyvanam intravezikaluri gziT SeiZleba gamoiwvios qimiuri cistiti da Sardis buStis SekumSva.

**2.13 ra unda icodeT dozis gamotoebis SemTxvevaSi**

ar aris warmodegenili

**2.14 ra unda icodeT Senaxvis vadebTan dakavSirebiT**

Senaxvis vada miTiTebulia pirvelad da meoreul SefuTvaze. vadis amowurvis SemTxvevaSi preparati ar gamoiyenoT.

**2.15 Senaxvis specialuri pirobebi**

inaxeba 2-8°C-ze, sinaTlisgan da bavSvebisgan dacul adgilze.

1. **informacia preparatebis racionalurad gamoyenebis Sesaxeb**

preparati gamowerilia TqvenTvis eqimis mier mxolod Tqveni specifikuri samedicino mdgomareobis gamo. Aar unda gadasceT sxva pirebs an gamoiyenoT sxva daavadebis samkurnalod, sanam ar miiRebT eqimis an farmacevtis konsultacias. Tu gaqvT raime saxis SekiTxvebi im preparatTan dakavSirebiT, romlebsac iRebT an gindaT ukeT iyoT informirebuli Tqveni samedicino mdgomareobis Sesaxeb, ar daayovnoT konsultaciis aReba eqimisgan an farmacevtisgan. informacia imis Sesaxeb aris Tu ara preparati usafrxo da efeqturi, gaTvalisiwinebuli unda iyos instruqciis mixedviT, romelic Tqven mogawodes. Tqveni janmrTelobis da usafrTxoebisTvis yuradRebiT unda waikiTxoT yvelanairi informacia im preparatTan dakavSirebiT, romelic gamogiweres. Aar SeinaxoT preparatebi saabazano OoTaxSi, vinaidan sicxem da nestma SeiZleba daazianos preparati da gaxados saziano Tqveni janmrTelobisTvis.

ar SeinaxoT preparatebi romlebic aRar gWirdebaT an Senaxvis vadis gasvlis Semdeg.

yvela preparati SeinaxeT usafrTxo, bavSvebisTvis miuRwevel adgilze.

1. **recepti**

mocemuli preparati gaicema eqimis receptiT

Targmani Seesabameba originals, mTargmneli: