

samedicino gamoyenebis instruqcia

როფერონი® -ს
ROFERON®-A
interferoni alfa-2a

1. aRwera

1.1. wamlis Terapiuli/farmakologiuri klasi

antivirusuli da simsvnis sawinaaRmdego saSualeba

1.2. dozis forma

roferoni-a moewodeba mza saineqcio xsnaris saxiT

1.3. miRebis wesi

kanqveSa ineqcia

1.4. Tvisobrivi da raodenobrivi Semadgenloba

aqtiuri nivTiereba: interferoni alfa-2a

TiToeuli mza Sprici (erTi saineqcio doza) Seicavs 3, 4.5, 6, 9 an 18mln s.e. interferon alfa-2a-s 0,5ml-s. TiToeuli kartriji Seicavs 18 mln s.e, interferon alfa-2a-s 0,6 ml-s da gamoiyeneba Roferon®Pen-Tan erTad, saineqciod

2. klinikuri maxasiaTeblebi

2.1. Terapiuli Cvenebebi

roferoni alfa-2a° dadebiTad naCvenebia Semdegi mkurnalobebisaTvis

limfuri sistemis da sisxlmბადი sistemis simsvnuri warmonaqmnebi: balanovanujredovani leikozi; mielomuri daavadeba; kanis T- ujedovani limfoma; qronikuli mieloleikozi; Trombocitozi mieloproliferaciuli daavadebebis dros, araxojkinis limfoma avTvisebianobis dabali xarisxiT.

soliduri simsvneebi; kapoSis sarkoma SidsiT daavadebul avadmyofebSi anamnezSi oportunistuli infeqciebis gareSe;

Sors wasuli Tirkmlis karcinoma; metastazirebuli melanoma;

melanoma qirurgiuli rezeqciis Semdeg (simsvnis sisqe>1,5mm) limfuri kvanZebis dazianebis da Sors wasuli metastazebis gareSe.

virusuli daavadebebi: qronikuli aqtiuri hepatiti B mozdilebSi, romelTac gaaCniaT virusuli replikasiis markerebi, anu dadebiTi arian HBV-dnm-ze, dnm-polimerazaze an HBeAg-ze; mozdilebSi qronikuli aqtiuri hepatiti C, romlebsac SratSi aReniSnebaT antisxeulebi hepatiti C-s virusis mimarT an HCV rnm SratSi da alaninaminotransferazას აქტივობის მომატება Rვიზლის დეკომპენსაციის ნიშნების გარეშე (bavSvebis klasi A-s mixedviT); wvetiani kondiloma.

roferoni alfa-2°-s miRebis optimaluri gza, qronikuli C herpatitis mqone pacientebisaTvis, aris miReba ribavirinTan erTad. wamlebis amgvარი კომბინაცია dadebiTadaa naCvebebi pacientebisaTvis, romlebsac adre ar umkurnaliaT, da aseve im pacientebisaTvis, romlebic adre Rebulobdnen interferon alfas da Semdeg Sewyvites mkurnaloba.

2.2. doza da miReba

roferoni-a iniSneba kanqveSa ineqciis saxiT. ix. informacia kopegusis Sesaxeb, rodesac roferoni-a iniSneba ribavirinTan erTad

2.2.1. specialuri miTiTebebi dozis Sesaxeb

balanovanujredovani leikozi:

sawyisi doza Seadgens 3 mln.se dReSi kanqveSa SeyvaniT, 16-24 kviris ganmavlobaSi. preparatis autanlobis SemTxvevaSi doza mcirdeba 1,5mln. se–mde an Seyvanis jeradoba mcirdeba 3-mde kviraSi, an orive erTad .

SemnarCunebeli doza: 3mln. 3 jer kviraSi. preparatis autanlobis SemTxvevaSi doza mcirdeba 1,5 mln. se-mde 3 jer kviraSi.

mkurnalobis xangrZlivoba: 6 Tvis ganmavlobaSi, ris Semdeg eqimi gansazRvravs gaagrZelos mkurnaloba (dadebiTi efeqti) Tu Sewyvitos igi (uaryofiTi efeqti). mkurnaloba grZeldeba 20 Tve.

mielomuri daavadeba:

sawyisi dozaa 3mln. se 3 jer kviraSi. individualuri amtanianobis mixedviT, doza yovel kviras izrdeba maqsimalur tolerantul dozamde (9-18mln. se) 3 jer kviraSi.

mkurnalobis xangrZlivoba: am sqemiT mkurnaloba grZeldeba ganusazRvrelad, Tu daavadeba ar progresirebs an sanam ar ganviTardeba preparatis mimarT gamoxatuli autanloba.

kanis T-ujredovani limfoma:

preparats gaaCnia gamoxatuli efeqti avadmyofebSi progresirebadi kanis T-ujredovani limfomiT, maT Soris avadmyofebSi refraqterobiT tradiciuli Terapiis mimarT an avadmyofebSi, romlebic ar eqvemdebarebian mis Catarebas.

sawyisi doza: avadmyofebSi 18 wlis asakis zeviT, preparati iniSneba 12 kviris ganmavlobaSi, dozis TandaTanobiTi gazrdiT 18 mln. se-mde. dozis momateba xorcieldeba Semdegi sqemis mixedviT :

1-3 dRe _ 3mln. se dReSi;

4-6 dRe _ 9mln. se dReSi;

7-84 dRe _ 18 mln. se dReSi.

SemnarCunebeli doza: 3 jer kviraSi maqsimaluri amtani doziT, magram araumetes 18mln. s.e.

mkurnalobis xangrZlivoba: avadmyofi iRebs preparats aranakleb 8 kviris ganmavlobaSi, umjobesia _ 12 kviris, ris Semdeg eqimi gansazRvravs gaagrZelos mkurnaloba (dadebiTi efeqti) Tu Sewyvitos igi (uaryofiTi efeqti). mkurnaloba SeiZleba gagrZeldes 40 Tvis ganmavlobaSi permanentulad. mkurnalobis optimaluri xangrZlivoba dadgenili ar aris. avadmyofebi, romlebic dadebiTad reagireben Catarebul mkurnalobaze, agrZeleben mas aranakleb 12 Tvis ganmavlobaSi, raTa maqsimalurad gaizardos sruli remisiis miRwevis da misi gaxangrZlivebis albaToba.

yuradReba:

qronikuli mieloleikozi:

preparati ramdenime dRis ganmavlobaSi amcirebs Trombocitebis ricxvs, Trombohemoragiuli garTulebebis sixSires da ar gaaCnia leikozogenuri potenciali. amitom avadmyofebSi Zlieri TrombocitoziT qronikuli mieloleikozis da sxva mieloproliferaciuli daavadebebis dros, rekomendebulia preparatiT araleikozogenuri Terapiis Catareba.

rekomendirebuli doza: 18 wlisa da ufro didi asakis pacientebisaTvis 3-9mln s.e. dReSi, 8-12 kviris ganmavlobaSi qronikuli mieloleikozis dros TrombocitoziT rekomendebulia mkurnalobis Semdegi sqema dozis TandaTanobiTi momatebiT:

1-3 dRe _ 3mln. se dReSi;

4-6 dRe _ 6mln. se dReSi;

7-84 dRe _ 9 mln. se dReSi.

mkurnalobis xangrZlivoba: avadmyofebi iReben preparats aranakleb 8 kvirisa, umjobesia _ 12 kvira, ris Semdeg eqimi gansazRvrvs gaagrZelos mkurnaloba (dadebiTi efeqti) Tu Sewyvitos igi (uaryofiTi efeqti). Trombocitozi mieloproliferaciuli daavadebebis dros (qronikuli mieloleikozis garda) rekomendebulia dozis TandaTanobiTi momatebis Semdegi sqema: 1-3 dRe _ 3mln. se dReSi; 4-30 dRe _ 6mln. se dReSi. *mkurnalobis xangrZlivoba:* Trombocitebis ricxvis normis farglebSi SesanarCuneblad saWiroa kargad asatani dReRamuri doza 1-3mln. se kviraSi 2-3 jer. Tumca saWiro yoveli avadmyofisaTvis individualurad SeirCes maqsimaluri doza.

araxojkinis limfoma avTvisebianobis dabali xarisxiT:

preparatis damatebiTi daniSvnisas qimioTerapiasTan (sxivuri Terapia an mis gareSe) preparati axangrZlivebs sicocxlis unarianobas recidivis an progresirebis gareSe.

preparati iniSneba standartuli qimioTerapiis Semdeg, rogorc SemanarCunebeli Terapia (sxivur TerapiasTan an mis gareSe) doziT 3mln. se kanqveS 3 jer kviraSi 12 Tvis ganmavlobaSi. preparatiT mkurnaloba iwyeba avadmyofis mdgomareobis gaumjobesebis Semdeg, qimio- an sxivuri Terapiis Catarebidan 4-6 kviris Semdeg.

roferoni-aA iniSneba erTdroulad qimioTerapiis tradiciul sqemasTan (magaliTad, kombinacia ciklofosamidTan, prednizonTan, vinkristinTan, doqsorubicinTan) doziT 6mln. se/m² kanqveS an kunTebSi 22 dRidan 26 dRemde yoveli 28 dRiani ciklis dros. aseT SemTxvevaSi mkurnaloba iwyeba erTdroulad qimioTerapiasTan.

kapoSi sarkoma Sidsis fonze:

sawysi doza: 18 wlis asakis da zeviT avadmyofebSi, preparati iniSneba kanqveS an kunTebSi 8-12 kviris ganmavlobaSi, dozis TandaTanobiTi momatebiT 18mln.se mde, SesaZleblobis SemTxvevaSi _ 36mln. se-mde.

rekomendebulia mkurnalobis Semdegi sqema dozis TandaTanobiTi momatebiT:

1-3 dRe _ 3mln. se dReSi;

4-6 dRe _ 9mln. se dReSi;

7-9 dRe _ 18 mln. se dReSi., kargi amtanianobis SemTxvevaSi doza izrdeba 10-84 dRes 36mln.se-mde.

SemanarCunebeli doza: kanqveS an kunTebSi 3 jer kviraSi maqsimalurad asatani doziT araumetes 36mln. se-sa.

mkurnalobis xangrZlivoba: mkurnalobaze reaquiis dasadgenad saWiroa simsiwnis dinamikis dokumenturi asaxva. avadmyofebi iReben preparats aranakleb 10 kvirisa, umjobesia _ 12 kvira, ris Semdeg eqimi gansazRvrvs gaagrZelos mkurnaloba (dadebiTi efeqti) Tu Sewyvitos igi (uaryofiTi efeqti). Cveulebriv efeqti vlindeba mkurnalobidan 3 Tvis Semdeg. mkurnaloba grZeldeba zedized 20 Tve. mkurnalobis optimaluri xangrZlivoba dadgenili ar aris. klinikuri efeqtis miRebis Semdeg mkurnaloba grZeldeba simsiwnis gaqrobamde.

SeniSvna:

Sors wasuli Tirkmlis ujrედovani kibo:

avadmyofebSi simsiwnis recidiviT an metastaziT saukeTeso Terapiuli efeqti aRiniSneba preparatis didi dozebiT daniSvnisas (36mln. se dReSi) monoTerapiis saxiT an preparatis zomieri dozebi (18mln. se 3 jer kviraSi) kombinaciaSi vinblastinTan, monoTerapiasTan SedarebiT, zomieri dozebiT 3 jer kviraSi. avadmyofebSi, romlebic iReben preparatis mcire dozebs (2mln. se/m²) dReSi efeqti ar aRiniSneba. preparatis kombinacia vinblastinTan iwvevs msubuqi da zomieri leukopeniis sixSiris momatebas da granulocitopenias, monoTerapiasTan SedarebiT.

a) *monoTerapia roferon-a-Ti:*

sawyisi doza: kanqveS an kunTebSi 8-12 kviris ganmavlobaSi, dRiuri dozis TandaTanobiTi momatebiT 18mln. se-mde, SesaZleblobis SemTxvevaSi _ 36mln.se-mde. rekomendebulia dozis momateba Semdegi sqemiT:

1-3 dRe _ 3mln. se dReSi;

4-6 dRe _ 9mln. se dReSi;

7-9 dRe _ 18 mln. se dReSi., kargi amtanianobis SemTxvevaSi doza izrdeba me-10-84 dRes _ 36mln.se-mde dReSi.

SemanarCunebeli doza: kanqveS an kunTebSi maqsimalurad asatani doziT araumetes 36mln. se.

mkurnalobis xangrZlivoba: avadmyofebi iReben preparats aranakleb 8 kvirisa, umjobesia _ 12 kvira, ris Semdeg eqimi gansazRvravs gaagrZelos mkurnaloba (dadebiTi efeqti) Tu Sewyvitos igi (uaryofiTi efeqti). mkurnaloba grZeldeba zedized 16 Tve. mkurnalobis optimaluri xangrZlivoba dadgenili ar aris.

b) roferoni-a A+ vinblastini:

pirvel kviras roferoni-aA iniSneba doziT 3mln. s.e. 3 jer kviraSi, meore kviras _ 9mln. se 3 jer kviraSi, Semdeg _ 18mln. se 3 jer kviraSi. am periodis ganmavlobaSi vinblastini SeyavT intravenurad doziT 0,1mg/kg 3 kviraSi erTxel.

Tu 18 mln s.e. doza samjer kviraSi autanelia, maSin igi SeiZleba Semcirdes 9 mln s.e.-mde, samjer kviraSi

mkurnaloba grZeldeba minimum 3 Tvis ganmavlobaSi, maqsimum 12 Tvemde an daavadebis progresirebamde. sruli dadebiTi pasuxisas pacientebis mkurnaloba SeiZleba SeuwydeT sami Tvis Semdeg

melanoma qirurgiuli rezeqciis Semdeg:

adiuvanturi Terapia roferon-a-s mcire dozebiT avadmyofebSi limfuri kvanZebis dazianebiT da Soreuli metastazebis gareSe melanomis rezeqciis Semdeg (simsivnis moculoba >1,5mm) axangrZlivebs maT sicocxles recidivis gareSe.

rekomendirebuli doza: 3mln. se 3 jer kviraSi, 18 Tvis ganmavlobaSi, da unda daiwyos qirurgiuli operaciis Semdeg araumetes 6 kviris Semdeg.

metastazuri melanoma:

rekomendirebuli doza: 18mln. se kviraSi, an pacientisaTvis asatani maqsimaluri doza, sul mcire 12 kviris ganmavlobaSi.

mkurnalobis rekomendirebuli xangrZlivobaa aranakleb 12 kvira, ris Semdeg eqimi gansazRvravs gaagrZelos mkurnaloba (dadebiTi efeqti) Tu Sewyvitos igi (uaryofiTi efeqti). mkurnaloba grZeldeba zedized 24 Tve.

qronikuli virusuli hepatiti B:

rekomendirebuli doza: Cveulebriv iniSneba 4,5-9 mln. 3 jer kviraSi, 4-6 Tvis ganmavlobaSi. SemdgomSi dozis regulireba xdeba wamlis mimarT pacientis tolerantobis mixedviT. Tu mkurnalobis dawyebidan 3-4 TveSi mdgomareobis gaumjobeseba ar SeiniSneba, SesaZloa ganxilul iqnas mkurnalobis Sewyvetis sakiTxi.

hepatiti B-s mqone 2 wlisa da ufro didi asakis bavSvebSi preparati doziT 7,5mln s.e./m² usafrTxo da efeqturia

qronikuli virusuli hepatiti C:

kombinirebuli Terapia roferon-a-Ti da ribaviriniT:

interferon-alfa-2a-s efeqturoba izrdeba misi kombinaciis dros ribavirinTan. mxolod roferoni-a pacientebis unda mieceT im SemTxvevaSi, Tuki isini ver eguebian ribvirins an es wamali ukunaCvenebia maTTvis

roferon-a-s dozirebis reJimi: 3 mln. s.e. 3 jer kviraSi 6 Tvis ganmavlobaSi.

kombinirebuli Terapi roferon-a-Ti da ribaviriniT aranamkurnaleb avadmyofebSi: roferon-a-s dozirebis reJimi 4,5mln. se 3 jer kviraSi 6 Tvis ganmavlobaSi.

klinikuri cdebiT mirebuli monacemebi interferoni lfa-2°-sa da ribavirinis kombinirebuli Terapiis sesaxeb, efuzneba 6-Tviani mkurnalobis sedegebs. magram, pacientis individualuri maxasiaTeblebidan gamomdinare (mag. genotipi) qronikuli C hepatitis standartuli mkyrnalobis xangrZliovobaa 6-dan 12 Tvemde.

ribavirinis rekomendirebul dozasTan dakavSirebiT, ix. instruqciebi kopegusis Sesaxeb *monoTerapia roferon-A –Ti:*

sawyisi doza: 3-6mln. s.e. 3 jer kviraSi 3 Tvis ganmavlobaSi.

Tu SratSi alaninaminotransferazas normalizeba mkurnalobis sam Tvis Semdeg ar dafiqsdira, ganxileba mkurnalobis Sewyvetis sakiTxi.

pacientebs, romlebic kargad eguebian an nawiobroiv an srulad dadebiTi pasuxi aqvT roferon-a-Ti mkurnalobze, magram uaryofiTi pasuxi aqvT Sewyvetaze, SeuZliaT ganaaxlon mkurnaloba an miiRon am swamlis ufro didi doza

wvetiani kondiloma:

1-3se 3-jer kviraSi, 1-2 Tvis ganmavlobaSi.

2.3. winaaRmdegCveneba:

roferon-a ukunaCvenebia Semdeg SemTxvevebSi:

-momatebuli mgrZnobeloba preparatis da masSi Semavali komponentebis mimarT;

-gulis arsebuli an gadatanili daavadebebi; preparatis pirdapiri kardiotonur moqmedebaze miTiTeba ar arsebobs, Tumca SesaZlebelia, rom mwwave, damoukideblad gamqrali toqsiuri efeqtebi (magaliTad, sxaulis temperaturi momateba, cxeleba), romlebic xSirad aRiniSneba preparatiT mkurnalobis dros, iwveven gulis daavadebebis gamwwavebas;

-Tirkmelebis da RviZlis funqciis mZime darRvevebi da sisxlmjadi sistemis mieloiduri zrdis mxriv mZime darRvevebi;

-krunCxvebi an centraluri nervuli sistemis funqciis darRveva;

-qronikuli hepatiti gamoxatuli dekompensaciiT an RviZlis cirozi;

-qronikuli hepatiti, Tu avadmyofebi iReben an adre iRebdenen imunodepresantebs, gamonaklisia steroidebiT xanmokle mkurnaloba;

-qronikuli mieloleikozi, Tu avadmyofs gaaCnia HLA- identuri naTesavi da mas unda Cautardes an axlo momavalSi mosalodnelia Zvlis tvinis alogenuri transplantacia;

-kombinirebuli Terapiis Catareba ribavirinTan _ ix. winaaRmdegCveneba ribavirinis gamoyenebisas.

2.4. gafrTxileba da sifrTxilis zomebi:

2.4.1. zogadi

roferoni-a-s daniSvna saWiroa eqimis meTvalyureobis qveS, romelsac gaaCnia mkurnalobis gamocdileba Sesabamisi CvenebiT. aucilebelia avadmyofis informireba rogorc mkurnalobis upiratesobaze, aseve mosalodneli gverdiTi movlenebis Sesaxeb.

RviZlis, Tirkmelebis da Zvlis tvinis funqciis msubuqi da zomieri darRvevis dros aucilebelia maTi funqciis monitoringi.

RviZlis funqcia: preparati sifrTxiliT iniSneba avadmyofebSi qronikuli hepatitiT Tanmxlebi autoimunuri daavadebebiT.

Tu preparatiT mkurnalobis dros ganviTarda RviZlis sinjebis mxriv paTologiuri cvlilebebi, saWiroa maTi monitoringi an preparatis moxsna.

Zvlis tvinis supresia: gansakuTrebuli sifrTxiliT preparati iniSneba avadmyofebSi mZime mielosupresiiT, radganac preparati Trgunavs zurgis tvinis funqcias, rac iwvevs leukopenias (gansakuTrebIT granulocitebis), Trombocitopenias da iSviaTad hemoglobinis koncentraciis Semicrebas. es ganapirobebs infeqciis gazrdis risks an sixxldenias. aucilebelia am avadmyofebze dawesdes monitoringi da regularulad Catardes sixxlis analizis kontroli.

infeqciebi: imis gamo, rom cieba SeiZleba dakavSirebuli iyos gripis sindromTan interferoniT mkurnalobisas, yuradReba unda mieqces sxva mwvave ciebebsac, gansakuTrebIT neutropeniis mqone pacientebSi. seriozuli infeqciebi (virusuli, baqteriuli, sokovani) aRiniSna alfa interferonebiT, maT oris roferon-a-Ti mkurnalobisas. aseT dros dauyovnebliv unda inas dawyebuli antiinfeqciuri mkurnaloba da ganxiluli unda iqnas roferoniT mkurnalobis Sewyvetis sakiTxi.

fsiqiatria: mwvave fsiqiatრიuli gverdiTi movlenebi SeiZleba gamouvlines pacientebis, romlebic mkurnaloben interferonebiT, maT Soris roferon-a-Ti. depresia, suicidis mcdelobebi, SeiZleba aReniSnos pacientebis, romlebsac anamnezSi hqondaT an ar hqondaT fsiqiatრიul daavadebebi. amitom, roferon-a didi sifrTxiliT da yuradRebiT unda mieces depresiis mqone pacientebis, raTa ar ganviTardes msgavsi gverdiTi movlenebi, am wamliT mkurnaloba ki dauyovnebliv unda Sewydes depresis simptomebis warmoSobisTanave.

oftalmologia: iseve rogorc sxva interferonebis miRebis SemTxvvaSi, SesaZloa warmoiSvas retinauri srteriis an venis trombozi, papiloedema, ramac SeiZleba mxedvelobis dakargva gamoiwvios am wamliT mkurnalobisas. amitom, Tu pacienti am mxriv raime garTulebas, an mxedvelobis daqveiTebas uCivis, unda seumowmdes Tvalebi mkurnalobis dawyebamde, radgan amgvარი garTulebebi SesaZloa sxva garemoebebiTac iyos gamowveuli. es rekomendirebulia diabetis an maRali wnevis pacientebisaTvisac. axali oftalmologiuri garTulebebis warmoSobis an gauaresebis SemTxvevaSi, patients roferon-a-Ti an roferon/ribaviriniT mkurnaloba unda Seuwydes

hipermgrZnobeloba: seriozuli, mwvave hipermgrZnobelobiTi reaqciebi (mag. urtikaria, angioedema, anafilaqsisi) iSviaT SemTxvevebSi gamovlinda alfa interferonebiT, maT Soris interferoni alfa-2-iT mkurnalobisas. Tu aseTi reaqciebi progresirdeba roferon-a-Ti an roferon/ribaviriniT mkurnalobisas, maSin mkurnaloba dauyovnebliv unda Sewydes da dainiSnos Sesabamisi Teropia. gamonayaris SemTxvevaSi mkurnalobis Sewyveta aucilebeli ar aris

endokrinuli funqcia: pacientebis, romlebic mkurnaloben roferon-a-Ti, iSviaT SemTxvevebSi SeiZleba aReniSnoT hiperglicemia. simptomatur pacientebis unda SeumowmdeT glukozis Semcveloba sixlSi, da Sesabamisad unda warimarTos maTi mkurnaloba. Saqriani diabetis mqone pacientebis SeiZleba dasWirdeT antidiabeturi reJimis koreqcia.

autoimunuri funqcia: Aalfa-interferonebiT Lmkurnalobis dros zog SemTxvevebSi pacientebis aReniSnaT sxvadasxva antisxeuilebis ganviTareba. interferoniT Terapiisasa autoimunuri daavadebebis klinikuri gamovlinebebi ufro xSirad gv xvdeba imunuri darRvevebisadmi midrekilebis mqone pacientebSi.

alfa-interferonebis gamoyeneba iSviaT SemTxvevebSi asocirebulia fsorizis gamwvavebasTan. avadmyofebSi transpalantaciis Semdeg (magaliTad, Tirkmelebis an Zvlis tvinis) medikamentozuri immunosupresia SesaZleblia iyos naklebad efeqturi, radganac interferons gaaCnia mastimulirebeli moqmedeba imunur sistemaze. sxva interferonebis msgavsad, roferonis-a-s miRebis fonze aRwerilia transplantantis mocilebis reaqcia.

2.4.2. avtomanqanis marTvisa da meqanizmebTan muSaobis SesaZleblobebi

preparatis dozirebis reJimis da avadmyofis individualuri mgrZnobelobis mixedviT, roferon alfas SeuZlia imoqmedos yuradRebis koncentraciaze avtomobilis marTvisas da meqanizmebTan muSaobisas.

2.4.3. urTierTqmedeba sxva preparebTan da urTierTqmedebis sxva formebi

alfa-interferons SeuZlia gamoiwvios aRdgeniT metaboluri procesebis darRveva sistema citoqrom P450–s RviZlis mikrosomuli fermentebis aqtivobis SemcirebiT. es gasaTvaliswinebelia preparatis erTdrouli daniSvnisas im saSualebebTan, romlebic metabolizms ganicdian am gziT. aRwerilia Teofilinis klirensis Semcireba maTi erTdrouli daniSvnisas.

interferonebi aZliereben adre an masTan erTdroulad daniSnuli neirotoksiuri, hematotoksiuri an kardiotoksiuri preparebis moqmedebas. urTierTqmedeba Sesazlebelia centraluri moqmedebis preparebis erTdrouli daniSvnisas.

kombiniirebuli Terapiis Catareba ribavirinTan _ ix. urTierTqmedeba ribavirinis gamoyenebisas C hepatitis mqone pacientebSi.

2.5. gamoyeneba specialur popoulaciebSi

2.5.1. orsuloba

mamakacebi da qalebi preparatis gamoyenebisas unda iyenebdnen kontracpciis saimedო meTodebs. orsulobis periodSi preparatis daniSvna warmoebs im SemTxvevaSi, Tu misi sargeblanoba aRemateba mosalodnel risks. Tumca kvleva ar adasturebs preparatis teratogenur efeqts, ar aris gamoricxuli, rom man uaryofiTad imoqmedos nayofze. rodesac makaka-rezusSi preparati iniSneboda didi dozebiT, romelic aRemateba klinikaSi rekomendebul dozebs, mniSvnelovnad izdeboda abortebis raodenoba. ucnobia, gadadis Tu ara preparati dedis rZeSi. ZuZuTi kvebis Sewyveta an preparatis moxsna am periodSi wydeba dedis mdgomareobidan gamomdinare.

benzilis spirti, romelic Sedis preparatis SemadgenlobaSi Semavsebelis saxiT, Sesazloa gadis placentur bariers. preparatis daniSvnisas uSualod mSobiarobis win an sakeisro kveTis win, aucilebelia gaTvaliswinebuli iqnas misi zemoqmedeba dRenaklul axalSobilebze.

roferoni-a ribavirinTan EerTad, orsul qalebs ar unda mieces. orsuli qalebisa da maTi partniorebisaTvis am wamliTa da ribaviriniT kombiniirebuli Terapia dauSvebelia efeqturi kontracpciis saSualebebis gamoyenebis gareSe. ix. gafrTxilebis zomebi ribavirinis gamoyenebisas da qronikuli C hepatitis mqone pacientebSi.

2.5.2. laqtacia

cnobili ar aris, gamoiyofa Tu ara roferoni-a dedis rZeSi. amitom, gadawyvetileba imis sesaxeb, gaugzeldes Tu seuwydes mezuZur dedas am wamliT mkurnaloba miiReba imis gaTvaliswinebiT, Tu ramdenad mniSvnelovania es wamali dedisaTvis.

2.6. gverdiTi movlenebi:

qvemoT moyvanil gverdiT movlenebs adgili hqondaT avadmyofebSi sxvadasxva avTvisebiani simsvnuri daavadebebiT, romlebic refraqterulni iyvnen wina mkurnalobis mimarT an imyofebodnen daavadebis bolo stadiaSi, aseve avadmyofebSi qronikuli hepatiti B-Ti da qronikuli hepatiti C-Ti. ixileT agreTve `gvrediTi efeqtebi~ kopegusis gamoyenebis instruqciebSi

2.6.1. klinikuri kvlevebi

zogadi simptomebi: sixSire: gripismagvari sindromi (moTenTiloba, sxeulis temperaturis momateba, cxeleba, umadoba, kunTebis, Tavis da saxsrebis tkivili, oflianoba). aRniSnuli movlenebi mcirdeba an gaivlis paracetamolის erTdrouli daniSvnisas da maTi gamoxatuleba mkurnalobis periodSi preparatis dozis Semcirebisas sustdeba, Tumca mkurnalobis gagrZelebisas SesaZloa ganviTardes Zilianoba, sisuste da moTenTiloba.

kuW-nawlavis traqtis mxriv: xSirad: onkologiuri avadmyofebis 1/3-Si viTardeba anoreqsia, naxevarSi _ gulisreva. sakmaod xSirad _ Rebineba, gemos Secvla, piris simSrale, sigamxdre, diarea, susti an zomieri xasiaTis muclis tkivili. iSviaTad _ yabzoba, meteorizmi, peristaltikis gaZliereba, gulZmarva, wylulovani daavadebis gamwvaveba, sicocxlisaTvis arasaxifaTo sisxldena kuW-nawlavis traqtidan, RviZlis funqciis mZime darRvevebi.

RviZlia funqciaebi: (ix. qveTavi laboratoriuili cvlilebebi).

centraluri nervuli sistemis mxriv: xandaxan _ sistemuri da arasistemuri Tavbrusxveva, mxedvelobis darRveva, fsiqiuri mdgomareobis gauareseba, gulmaviwyoba, depresia, Zilianoba, cnobierebis dabindva, qceviTi darRvevebi (SiSi, nerviuloba) da Zilis darRveva. iSviaTad – suiciduri ideebi, suicidis mcdeloba, suicidi; Zlieri Zilianoba, krunCxvebi, koma, Tavis tvinis sisxlis mimoqcevis darRveva, tranzitoruli impotencia.

mxedelobiTi darRvevebi: zogjer: mxedvelobis gaZneleba. *iSviaTad:* iSemiuri retinopaTia. *Zalze iSviaTad:* retinopaTia, maT Soris retinaluri hemoragia da e.w. ”bambis-magvari laqebi” baduraze (cotton-wool spots), papiloedema, retinaluri arteriebis da venebis Trombozi, optikuri neiroptia.

periferiuili nervuli sistema: zogjer: paresTeziebi, kidurebis dabuJeba, neiroptia, qavili, tremori.

gul-sisxlZarRvTa da sasunTqi sistema: xSirad: onkologiuri avadmyofebis 1/5-Si aRiniSneba tranzitoruli arteriuili hipo- da hipertenzia, SeSupeba, cianozi, ariTmia, taqikardia da tkivili gulmkerdSi. *iSviaTad:* xvela, qoSini, filtvebis SeSupeba, pnevmonia, gulis SegubebiTi ukmarisoba, gulis da sunTqvis gaCereba, miokardiumis infarqti. avadmyofebSi hepatitiT B darRvevebi gul-sisxlZarRvTa sistemis mxriv aRiniSneba Zalian iSviaTad.

kani, kanis danamatebi, lorwovani garsebi: xSirad: avadmyofTa 1/5-Si aRiniSneba msubuqi da zomieri Tmis cvena, romelic mkurnalobis Sewyvetis Semdeg atarebs gardamaval xasiaTs. iSviaTad: herpesuli gamonayaris gamwvaveba tuCebze, gamonayari, qavili, kanis da lorwovani garsebis simSrale, gamonadeni da sisxldenebi cxviridan, fsoriazis gamwvaveba an manifestacia.

Tirkmelebi da Sardgamomyofi sistema: iSviaTad: Tirkmelebis funqciis gauareseba, Tirkmelebis ukmarisoba (ZiriTadad, onkologiur avadmyofebSi Tirkmelebis daavadebiT an erTdrouli mkurnaloba nefrotoqsiuri preparebiT), electrolituri darRvevebi, gansakuTrebiT anoreqsiis an organizmis dehidrataciis dros, proteinuria, ujreduli elementebis momateba Sardis naleqSi, azotis Sardovanas momateba sisxliSi, kreatininis da SardmJavas koncentraciis momateba SratSi (*ix. qveTavi laboratoriuili cvlilebebi*).

sxva: iSviaTad: hiperglikemia, reaqlia ineqciis adgials, autoimunuri paTologia (vaskuliti, arTriti, hemolizuri anemia, farisebri jirkvlis funqciis darRveva, mglurasmsgavsi sindromi). *Zalian iSviaTad:* usimptomო hipokalcemia. makaka-rezusebSi didi dozebis daniSvnisas, romelic aRemateba klinikaSi gamoyenebul dozebs, aRiniSneba menstrualuri ciklis tranzitoruli darRveva, maT Soris menstruaciis periodis gaxangrZliveba. am monacemebis mniSvneloba adamianisaTvis dadgenili ar aris.

kombinirebuli Terapiis Catareba ribavirinTan _ ix. gafrTxilebis zomebi kopegusis gamoyenebis instruqciebSi da qronikuli C hepatitis mqone pacientebSi.

iSviaT SemTxvevebSi, rodesac interferoni, roferon-a-s CaTvliT, gamoiyeneba kopegusTan kombinaciaSi, SeiZleba warmoiSvas pancitopenia, Zalze iSviaTad ki – aplastikuri anemia

2.6.1.1. laboratoriuili cvlilebebi

RviZlis funqciis darRveva: xandaxan: alaninaminotransferazas, tutovani fosfatazas, laqtatdehidrogenazas, bilirubinis koncentraciis momateba, rac saWiroebs dozis koreqcias. iSviaTad: transaminazebis aqtivobis cvalebadoxa B hepatitis dros, rac mowmobs avadmyofis klinikuri mdgomareobis gaumjobesebaze; Zalian iSviaTad _ RviZlis funqciis mZime darRveva, RviZlis ukmarisoba.

sisxlbadi sistema: sakmaod xSirad _ tranzitoruli leukopenia (ar iTxovs dozis Semcirebas), avadmyofebSi mielosupresiiT _ Trombocitopenia, hemoglobinis koncentraciis Semcireba. xandaxan _ hemoglobinis da hematokritis koncentraciis Semcireba. mZime hematologiuri cvlilebebis aRdgena sawyis maCveneblebamde aRiniSneba 7-10 dRis Semdeg mkurnalobis Sewyvetidan.

2.6 postmarketinguli gamocdileba

sxva interferonebis msgavsad, pacientebSi, romlebic iRebden roferons-a, aRwerilia transplantantis mocilebis reaqciebi.

2.7. Warbi doza

monacemebi preparatis Warbi dozirebis Sesaxeb ar moipoveba, Tumca interferonis didi dozebis ganmeorebiTi gamoyenebisas aRiniSneba Rrma leTargia, moTenTiloba, prostracia da koma. aseTi avadmyofebi eqvemdebarebian hospitalizacias da Sesabamisi Terapiis Catarebas.

3. farmakologiuri Tvisebebi da efeqtebi

3.1.1. moqmedebis meqanizmi

roferoni-a-s antivirusuli moqmedeba ganpirobabilia ujredesSi rezintentobis inducirebiT virusuli infeqciebis mimarT. igi agreTve iwvevs imunuri sistemis sapauxo reaqqis modulirebas, romelic mimarTulia virusebis neutralizaciisaken an maT mier dainficirebuli ujredesSi ganadgurebaze.

3.1.2. klinikuri/efeqturobis kvlebebi

adamianis simsvnur ujredesSi, romlebic damuSavebulia preparatiT (ujredesSi HT-29), sarwmunod mcirdeba dnm-s, rnm-s da cilis sinTezi. laboratoriuilad dadgenilia, rom preparats gaaCnia antiproliferaciuli moqmedeba adamianis simsvneebze da Trgunavs adamianis simsvnis zogierTi qsenotransplantatis zrdas ~titvel~ TagvebSi. bunebriv pirobesebSi preparatis antiproliferaciuli aqtivoba Seswavlilia iseT simsvneebze, rogoricaa sarZeve jirkvlis karcinoma da brma nawlavis da ganivi kolinjis adenokarcinoma, aseve winamdebare jirkvlis. misi antiproliferaciuli aqtivoba cvalebadoxs.

balanovanujredovani leukozisa da SidsTan dakavSirebuli kapoSis sarkomas mqone pacientebSi, roferon-a-s SeuZlia mniSvnelovnad Seamciros kibos ganviTareba an moaxdinos daavadebis stabilizeba. es wamali aseve efeqturad moqmedebis progresirebadi mielomas SemTxvevaSi

roferon-a-s efeqturoba vlindebamielogenuri leukemias filadelfiis pozitiuri qromosomas qronikuli fzis pacientebSi, warmoqmniis ra 60%-ian hematologikur remisias, mixedavad wina mkurnalobis Sedegisa. aseT pacientTa or mesameds sruli hematologiuri pasuxi daudginda mkurnalobis dawyebidan 18 TveSi. amasTan, citotoqsikuri qimioTerapiisagan gansxvavebiT, interferoni alfa-2° 40 Tveze meti xniTaa mdgradi citogenurad.

interferoni-a axangrZlivebs dadebiT efeqts qimioTerapiasTan erTad kombinirebuli mkurnalobisas (radioTerapiiT an mis gareSe), dabali xarixsis avTvisedianobis xojkinis limfomas mqone pacientebSi, aseve kompensirebadi qronikuli B da C hepatitis mqone pacientebSi da condilomata acumiata-s mkurnalobisas.

3.2. farmakokinetikuri Tvisеbebi

3.2.1. absorbcia

kunTebSi an kanqveS Seyvanis Semdeg preparatis bioSeRwevadoba Seadgens 80%-s. preparatis 36mln. se doziT kunTebSi Seyvanis Semdeg misi maqsimaluri koncentracia SratSi meryeobs 1500-dan 2580pg/ml-mde (saSualod 2020 pg/ml), xolo kanqveS Seyvanis Semdeg _ 1250-dan 2320pg/ml-mde (saSualod 1730pg/ml) da AaRiniSneba Sesabamisad 3,8 da 7,3 saatIs Semdeg.

3.2.2. ganawileba

preparatis gamoyenebisas doziT 3 -dan 198 mln. se –mde farmakokinetika adamiანიSi atarebs xazovan xasiaTs. 36mln. se intravenuri Seyvanisas janmrTel moxaliseebSi moculobis ganawileba wonasworul mdgomareobaSi meryeobs 0,22-dan 0,75l/kg-mde (saSualod 0,40l/kg). rogorc janmrTel moxaliseebSi, aseve avadmyofebSi metastazirebuli kiboTi aRiniSneboda SratSi interferoni alfa-2a –s individualuri meryeoba.

3.2.3. metabolizmi

metabiolizmi da eliminacia

alfa-interferonis eliminaciis ZiriTadi gza Tirkmlismieri metabolizmia. RviZlismieri metabolizmi da eliminacia naRveliT warmoadgens gamoyofis naklebad mniSvnelovan gzas. janmrTelebSi naxevargamoyofis periodi 36mln. se interferoni alfa-2a-s intravenuri infuziis Semdeg Seadgens 3,7-8,5 saatS (saSualod 5.1 saaTi), saerTo klirensi _ 2,14-3,62 ml/wT/kg-ze (saSualod 2,79 ml/wT/kg).

3.2.4. eliminacia

ix. 3.2.3. metabolizmi

3.2.5. farmakokinetika specialur populaciebSi

interferoni alfa-2a –s erTjeradad kunTebSi Seyvanis Semdeg avadmyofebSi metastazirebuli kiboTi da qronikuli B hepatitiT farmakokinetikuri maCveneblebi igivea, rac janmrTel moxaliseebSi. 198 mln. se erTjeradi Seyvanis Semdeg aRiniSneba dozadamokidebuli Sratismieri koncentraciis gazrda. interferoni alfa-2a –s ganawileba da eliminacia misi 2 jer dReSi Seyvanisas doziT 0,5-36mln. se, an erTxel dReSi _ doziT 1-54mln. se, an 3 jer kviraSi doziT 1-136mln. se, 28 dRis ganmavlobaSi ar icvleba.

28 dReze meti xnis ganmavlobaSi dReSi 1-jer an metad i.v. gamoyenebisas aRiniSneba 2-4-jer Sratismieri koncentraciis gazrda zogierT metastazirebuli kiboTi daavadebul pacientebSi, vidre erTjeradi dozebiT gamoyenebisas. Tumca mravaljeradi gamoyeneba ganawileba da eliminacia parametrebs ar cvlis arsebuli kvlevebis monacemebiT.

meti informacia ribavirinis farmakokinetikis Sesaxeb ixileT kopegusis gamoyenebis instruqciaSi.

3.3. wina-klinikuri usafrTxoeba

3.3.1. zemoqmedeba ganayofierebaze

ix. orsuloba da gamoyeneba gansakuTrebul jgufebSi

3.3.2. teratogenuroba

ix. orsuloba da gamoyeneba gansakuTrebul jgufebSi

4. farmaceutuli maxasiaTeblebi

eqsipientebi: amoniumis acetati, natriumis qloridi, benzilis spirti, polizorbati 80, yinulovani ZmarmJava, natriumis hidroqsidis xsnari. saineqcio wyali.

4.1. Senaxva

mza Spricebi da kartrijebi

dauSvebelia preparatis gamoyeneba paketze miTiTebuli vargisianobis vadis gasvlis Semdeg. 2-8⁰C temperaturaze, sinaTlisagan dacul adgilze. ar gayinoT

4.2. gansakuTrebuli miTiTebebi preparatis mopyrobis Sesaxeb:

kartrijebi

mravaljeradi kartrijebi gankuTvnilia mxolod erTi avadmyofisaTvis. maTi gamoyeneba xorcieldeba Spric-kalamis saxiT _ `roferoni-peni~. Spric-kalamTan da kartrijTan erTad gamoiyeneben nems `penfaini~. Tumca SesaZlebelia zogierTi sxva nemsis gamoyeneba. yoveli ineqciisaTvis iyeneben axal sterilur Sprics. kartrijis gamoyeneba xorcieldeba 30 dRis ganmavlobaSi pirveli dozis amoRebis Semdeg. kartrijis pirveli gamoyenebis TariRi unda aRiniSnos mis etiketze da igi webdeba kolofze Spric-kalamiT.

`roferon-penis~ gamoyenebis vrceli instruqcia aris Spric-kalamis SefuTvaSi.

gamoyenebuli mza Spricebis/kartrijebis ganadgureba:

mkacrad unda davicvaT Semdegi miTiTebebi:

- ar gamoviyenoT ganmeorebiT gamoyenebuli nemsi/mza Sprici
- gamoyenebuli nemsi/mza Sprici movaTavsoT Sesabamis konteinerSi
- SevinaxoT bavSvebisgan dacul adgilas
- gamoyenebuli nemsi/mza Sprici ar unda moxvdes saojaxo nagavSi
- ganadgureba unda moxdes lokaluri moTxovnebis Sesabamisad/an jandacvis muSakis konsultaciis mixedviT.

binaze gamoyenebis SemTxvevaSi saWiroa patients miwodos Sesabamisi konteineri.

gamoyenebeli an vadagasuli preparatis ganadgureba

garemoSi da gamdinare wyalSi preparatis moxvedra unda maqsimalurad aviridoT. Tu xelmisawvdomia Tqvens regionSi, gamoiyeneT specialuri “Sesagrovebeli sitemebi”.

4.3. SefuTva:

roferion-a xsnari, 3 mln s.e./0,5ml mza SpricSi 1

roferion-a xsnari, 4,5 mln s.e./0,5ml mza SpricSi 1

roferion-a xsnari, 6 mln s.e./0,5ml mza SpricSi 1

roferion-a xsnari, 9 mln s.e./0,5ml mza SpricSi 1
roferion-a xsnari, 18 mln s.e./0,5ml mza SpricSi 1
roferion-a xsnari, 18 mln s.e./0,6ml kartrijSi i 1

SeinaxeT bavSvebisaTvis xelmiuwvdomel adgilze

2010 wlis ivnisis versia

Spricebi:

damzadebulia F. HOFFMANN-LA ROCHE Ltd-s mier, bazeli, Sveicaria

kartrijebi:

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