

გამოყენების ინსტრუქცია

samkurnalo produqtis saxelwodeba

klotrimazoli, 10 mg/g, kremi

raodenobrivi daxarixobrivi Semadgenloba

klotrimazoli, 10 mg/g, kremi

1 grami kremi Seicavs 10 mg klotrimazols.

damxmare nivTierebebi

Semadgenloba	komponentebi (g)
moqmedi nivTiereba klotrimazoli 100%*	1.00
sxva komponentebi	
cetostearilis spirti	11.50
oqtildodekanoli	10.00
polisorbati 60	1.50
sorbitanstearati	2.00
sinTezuri spermaceti (cetilis eTerebis cvili)	3.00
benzilis spirti	1.00
gamoxdili wyali	70.00
sul	100.00

SeniSvna:

*klotrimazolis miTiTebuli raodenoba Seesabameba uwylo sawyisi nivTierebis 100%-s da unda gamoiTvalos sawyis nivTierebaSi moqmedi nivTierebis da wylis realuri Semcvelobis gaTvaliswinebiT, miRebuli gansxvaveba unda dakoreqtirdes gamoxdili wylis raodenobiT.

farmacevtuli forma

klotrimazoli, 10 mg/g, kremi

rbili, TeTri feris, erTgvarovani konsistenciis masa

an

rbili, TeTri feris, erTgvarovani kremi benzilis spirtis suniT.

klirikuri monacemebi

gamoyenebis Cvenebebi

klotrimazoli, 10 mg/g, kremi

gankuTvnilia adgilobrivi mkurnalobisaTvis:

- yvela saxis dermatomikozebi, romlebic gamowveulia obisa da sxva saxeobis sokoebiT (mag.: Trichophytonspecies, maT Soris dermatofitozi (rubrofitia);
- Candida-Ti da sxva mgrZnobiare gamomwvevebiT gamowveuli sokovani infeqciebi, mag.: Staphylococcida Bacteroides, gardaLactobacilli;
- aRniSnuli sokoebiT meoradi inficirebis Sedegad ganviTarebuli kanis daavadebebi;
- safenis dermatiti, romelic garTulebulia kandidoziT, vulvitiT da balanitiT;
- qatosebri liqeni;
- eriTrazmebi.

miRebis wesi da dozebi

klotrimazoli, 10 mg/g, kremi

kremi daitaneba sufTa da mSral kanis dazianebul ubanze (dabanili unda iqnas neitraluri pH-is mqone sapniT). terfze datanisas fexi gulmodgined unda iqnas dabanili, gamSrali da mxolod amis Semdeg unda moxdes garegani gamoyenebis kremis wasma TiTebis Soris.

Tu mkurnalobis dawyebidan 7 dRis Semdeg simptomebi ar umjobesdeba, saWiroa mimarTva samedicino daxmarebis aRmosaCenad.

miRebis meTodi

klotrimazoli, 10 mg/g, kremi

gankuTvnilia garegani gamoyenebisaTvis.

mozrdilebi da 12 welze ufrosi asakis bavSvebi

klotrimazoli, 10 mg/g, kremi

kremi daitaneba kanis dazianebul ubanze or-samjer dReSi.

recidivis profilaqtikisaTvis mkurnaloba unda gagrZeldes infeqciis yvela simptomis gaqrobidan aranakleb 2 kviris ganmavlobaSi.

mkurnalobis savaraudo xangrZlivoba:

- dermatofituri infeqciebi: aranakleb erTi Tve
- kandidozuri infeqciebi: aranakleb ori kvira

Tu mkurnalobis dawyebidan 7 dRis Semdeg simptomebi ar umjobesdeba, saWiroa mimarTva samedicino daxmarebis aRmosaCenad.

bavSvebi

klotrimazoli, 10 mg/g, kremi

saWiro klinikuri monacemebi ar arsebobs.

xandazmulebi

saWiro klinikuri monacemebi ar arsebobs.

RviZlis ukmarisoba

saWiro klinikuri monacemebi ar arsebobs.

Tirkmlis ukmarisoba

saWiro klinikuri monacemebi ar arsebobs.

ukuCvenebebi

klotrimazoli ukunaCvenebia:

- klotrimazolis an preparatis sxva romelime damxmare nivTierebis mimarT hipermgrZnobelobis SemTxvevaSi.

gansakuTrebuli miTiTebebi da sifrTxilis zomebi gamoyenebisas

klotrimazoli, 10 mg/g, kremi

Tavidan unda iqnas acilebuli TvalSi moxvedra. dauSvebelia gadaylapva. aucilebelia yvela potenciurad inficirebuli ubnis erTdroulad damuSaveba.

urTierTqmedeba

klotrimazoli, 10 mg/g, kremi

kontracefciuli saSualebepi

laboratoriuli kvlevebi aCvenebis, rom erTdroulma gamoyenebam SeiZleba gamoiwvios lateqsis Semcveli kontrceptivebis dazianeba. Sesabamisad, kontrceptivebis efeqturoba SeiZleba daqveiTdes. aseT SemTxvevaSi rekomendebulia kontracefciis alternatiuli meTodebis gamoyeneba aRniSnuli preparatis gamoyenebis Semdeg aranakleb 5 dRis ganmavlobaSi.

orsuloba da laqtacia

reproduqciuli funqcia

klotrimazolis reproduqciul funqciaze gavlenis Sesaxeb kvlevebi adamianebSi ar Catarebula, Tumca cxovelebze Catarebulma kvlevebma ar aCvena preparatis gavlena reproduqciul funqciaze.

orsuloba

monacemebi klotrimazolis gamoyenebis Sesaxeb orsul qalebSi SezRuduli raodenobiTaa. klotrimazolis kvlevebma cxovelebSi daadastures preparatis reproduqciuli toqsikuroba maRali dozebiT peroraluri Seyvanisas (ix. paragrafi “preklinikuri monacemebi”). klotrimazolis dabali dozebiT sistematuri gamoyenebisas, ar aris mosalodneli saziანo gavlena, reproduqciul toqsikurobasTan dakavSirebuli, adgilobrivi gamoyenebis Semdeg. klotrimazolis gamoyeneba orsulobis dros SesaZlebelia mxolod eqimis meTvalyureobis qveS.

laqtacia

arsebuli monacemebiT, romelic miRebulia farmakodinamikuri/ toqsikologiuri kvlevis Sedegad cxovelebze, dadasturda klotrimazolis/metabolitebis gamoyofa dedis rZeSi intravenuri Seyvanis Semdeg (ix. paragrafi “prelinikuri monacemebi”). kanze gamoyenebis dros farmakokinetikurma kvlevis aCvenes, rom adamianebSi klotrimazoli minimalurad Seiwoveba sixlis mimoqcevaSi kanTan kontakTis adgilidan an kanis anTebiTi adgilidan (ix. farmakokinetika”).

ar unda gamoiricxos riski bavSvebisTvis, romlebic imyofebian ZuZuTi kvebaze ZuZuTi kvebis Sewyvetis an klotrimazoliT mkurnalobis moxsnis/SeCerebis Sesaxeb gadawyvetilebis miReba unda moxdes bavSvisTvis ZuZuTi kvebis sargeblobis an dedisTvis mkurnalobis sargeblobis gaTvaliswinebiT.

gavlana satransporto saSualebebis da sxva meqanizmebis marTvis unarze

samkurnalo preparati ar axdens aranair gavlenas avtomobilis an meqanizebuli saSualebebis marTvis unarze, an msgavsi gavlena ar aris mxedvelobaSi misaRebi.

gverdiTi movlenebi

kllinikuri kvlevis monacemebi

saWiro klinikuri monacemebi ar arsebobs.

registraciis Semdgomi monacemebi

qvemoT mocemulia wamlis arasasurveli gverdiTi reaCiebi MedDRA klasifikaciit organoTa sistemebis klasebisa da ganviTarebis sixSiris mixedvit.

gverdiTi movlenebis sixSire ganisazRvrebaze Semdegnairad:

Zalian xSiri $\geq 1/10$

xSiri $\geq 1/100$ -dan $1 < 10$ -mde

araxSiri $\geq 1/1000$ -danda $1 < 100$ -mde

iSviaTi $\geq 1/10000$ -dan $1 < 1000$ -mde

Zalian iSviaTi $< 1/10000$

sixSire ucnohia (sixSiris Sefaseba ver xerxdeba arsebuli monacemebis safuZvelze)

imunuri sistemis darRvevebi

sixSire ucnohia: alergiuli reaCiebi (iseTi simptomebiT, rogoricaa: WinWris cieba, qoSini, hipotonia da gulis wasvla).

kanisa da kanqveSa qsovilis darRvevebi

sixSire ucnohia: qavili, gamonayari, buStukebi, kanis aqercvla, diskomforti/tkivili, SeSupeba, wva, gaRizianeba, eriTema.

dozis gadaWarbeba

simptomebi da niSnebi

dozis gadaWarbebis simptomebi: Tavbrusxveva, gulisreva, Rebineba.

mkurnaloba

preparatis SemTxveviT gadaylapvisas aucilebelia simptomuri mkurnalobis standartuli zomebis miReba.

Semdgom mkurnalobas unda hqondes klinikuri Cveneba an unda Catardes erovnuli toqsikologiuri centris, aseTis arsebobis SemTxvevaSi, rekomendaciebis mixedviT.

farmakologiuri Tvisebebi

farmakodinamikuli Tvisebebi

farmakoTerapiuli jgufi

klotrimazoli, 10 mg/g, kremi

adgilobrivi gamoyenebis sokos sawinaaRmdego preparetebi, imidazolisa da triazolis warmoebulebi.

aTq kodi:

klotrimazoli, 10 mg/g, kremi

D01AC01

moqmedebis meqanizmi da farmakodinamikuri efeqtebi

klotrimazoli Trgunavs mikroorganizmebis zrdasa da gayofas da koncentraciis mixedviT SeiZleba hqondes fungistaturi an fungiciduri moqmedeba. klotrimazolis moqmedebis meqanizmi moicavs ujreduli membranis ganvladobis cvlilebas, romelic gamowveulia ergosterolis sinTezis darRveviT, aseve sokos ujredebis kedlebSi fosfolipidebis SeboWvas.

klotrimazoli Trgunavs cilebis, cximebis, dnm-is da polisaqaridebis sinTezs, azianebs ujredul nukleinis mJavebs da aCqarebs kaliumis gamoyofas. aseve SeiZleba daTrgunos damJangveli da peroqsidazuli fermentebi da trigliceridebis da fosfolipidebis biologiuri sinTezi sokos ujredSi. maRali koncentraciebiT gamoyenebisas klotrimazoli iwvevs ujreduli membranის dazianebas iseTi meqanizmebiT, romlebic ar aris damokidebuli sterolebis sinTezze. klotrimazoli xels uSlis Candida albicans-is blastosporebis gardaqmnas sokos invaziur formebad. ujreduli membranის aqtivობის cvlileba iwvevs ujredebis sikvdils da damokidebulia preparatis mikroorganizmebze zemoqmedebaze.

moqmedebis speqtri

klotrimazoli xasiaTdeba sokos sawinaaRmdego da antimikrobuli moqmedebis farTo speqtriT. preparati Trgunavs ganviTarebas da anadgurebs:

- dermatofitebs (Epidermophyton floccosum, Microsporumcanis, Trichophyton mentagrophytes, Trichophyton rubrum);
- safuara sokoebis (Candida sp., Cryptococcus neoformans);
- dimorful sokoebis (Coccidioides immitis, Histoplasma capsulatum, Paracoccidicoides brasiliensis).

aseve, antimikrobuli moqmedeba gaaCnia zogierTi gram-dadebiTi baqteriebis mimarT.

sokos sawinaaRmdego moqmedebasTan erTad klotrimazoli gavlenas axdens gram-dadebiT mikroorganizmebze (Streptococci/Staphylococci/ Gardnerella vaginalis) da gram-uaryofiT mikroorganizmebze (baqteroidebi). preparati ar axdens gavlenas Lactobacilli-ze.

in vitro pirobebSi klotrimazoli Trgunavs korinobaqteriebisa da gram-dadebiTi kokebis gamravlebas, garda enterokokebisa, substratis 0.5-10 mkg/ml koncentraciebiT Seyvanisas.

in vitro pirobebSi klotrimazolma gamoavlina fungistaturi da fungiciduri moqmedebis farTo speqtri. misi gavlena dermatofitebis micelebze (Trichophyton, Microsporum, Epidermophyton) grizeofulvinis moqmedebis analogiuria da misi efeqti safuara sokoebze (Candida) polienebis moqmedebis analogiuria (amfotericini B da nistatini).

1 mkg/ml-ze dabali koncentraciebiT klotrimazoli Trgunavs Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum da Microsporum canis umetesi Stamebis ganviTarebas.

3 mkg/ml koncentraciebiT is Trgunavs umetesi sxva gamomwvevebis ganviTarebas: Pitorosporum orbiculare, Aspergillus fumigatus, Candida-s ojaxi maT Soris, Candida albicans, Staphylococcus aureus, Streptococcus pyogenis zogierTi Stamebi, aseve, Proteus vulgaris da Salmonella-szogierTi Stamebi. klotrimazoli moqmedebs Sporotrix, Cryptococcus, Cefalosporium da Fusarium-is winaaRmdeg.

Zalian iSviaTad gvxdaba sokoebi, romlebic rezistentulebi arian klotrimazolis mimarT, maT miekuTvneba mxolod Candida guilliermondi-is Stamebi.

dReisTvis ar arsebobs monacemebi sokoebis rezistentobis Sesaxeb, romlebic mgrZnobiareebi arian klotrimazolis mimarT, Candida albicans da Trichophyton mentagrophytes-isdas Semdeg. ar aRiniSna klotrimazolis mimarT mdgradoba C. albicans-is Stamebs Soris, romlebic rezistentulebi iyvnen polienuri antibiotikebiT mkurnalobis mimarT qimiuri mutaciis Semdeg.

farmakokinetikuri Tvisebebi

Sewova da ganawileba

klotrimazoli, 10 mg/g, kremi

kanze datanis Semdeg farmakokinetikuri kvlevebis Sedegebis mixedviT, adamianebsi klotrimazoli minimalurad Seiwoveba sixlis mimoqcevasi kanTan kontakqtis adgilidan an anTebiTi ubnidan. klotrimazolis miRebuli pikuri koncentraciebi plazmasi gazomvadi donis qvemoTaa da Seadgens 0.001 mkg/ml-s, rac miuTitebs, rom adgilobrivi gamoyenebisas klotrimazoli ar iwvevs gazomvad sistemur efeqtebs an gverdiT movlenebs.

metabolizmi da gamoyofa

klotrimazoli metabolizdeba RviZiSi araaqtur nivTierebad da gamoiyofa SardTan da ganavalTan erTad.

klinikuri gamokvlebebi

ar exeba aRniSnul preparats.

preklinikuri usafrTxoebis monacemebi

preklinikuri kvlebebis monacemebis safuZvelze ar aris dadgenili preparatis raime safrTxe adamianebSi gamoyenebisas farmakologiuri usafrTxoebis, mravaljeradi gamoyenebisas toqsikurobis, genotoqsikurobis, kancerogenobis da reproduqciul funqciaze an nayofis ganviTarebaze toqsikuri gavlenis standartuli kvlebebis safuZvelze.

klotrimazolis sxvadasxva dozirebis formebs adgilobrivi da sistemuri amtanoba Sefasda ZaRlebsa da maimunebze Catarebul kvlebebsi intravaginaluri Seyvanisas da kurdRlebSi kanismieri qvemwvave toqsikurobis kvlebebsi. arc erT am kvlevaSi ar gamovlinda mkurnalobasTan dakavSirebuli adgilobrivi an sistemuri gverdiTi efeqtebis mtkicebulebebi.

klotrimazolis peroraluri toqsikuroba kargad aris Seswavlili.

klotrimazolis erTjeradi peroraluri Seyvanisas eqsperimentul cxovelebsi gamovlinda susti an zomieri xasiaTis toqsikuroba LD50 sidideebiT: 761 - 923 mg/kg sxeulis wonis TagvebisaTvis, 95 - 114 mg/kg sxeulis wonis axalSobili virTxebisaTvis da 114 - 718 mg/kg sxeulis wonis zrdsruli virTxebisaTvis, >1000 mg/kg sxeulis wonis bocvrebisaTvis da >2000 mg/kg sxeulis wonis ZaRlebisa da katebisaTvis.

virTxebsa da ZaRlebze Catarebuli ganmeorebiTi peroraluri dozebis kvlebebsi aRmoCnda, rom RviZli warmoadgens mTavar samizne organos toqsikurobisaTvis. amaze miuTiTebS Sratsi transaminazebs aqtivobis momateba da RviZlis vakuolizaciisa da cximovani depozitebis gaCena virTxebSi 50 mg/kg dozidan qronikul (78-kvirian) kvlebebsi da ZaRlebSi 100 mg/kg dozidan subqronikul (13-kvirian) kvlebebsi.

klotrimazoli kargad aris Seswavlili mutagenobis in vitro da in vivo analizebsi da ar aRmoCenila mutagenobis potencialis raime niSani. klotrimazolis peroraluri dozirebis 78-kvirianma kvlevam virTxebSi ar gamoavlina kancerogenuli efeqti.

virTxebis fertilobis kvlebebsi FB30 jgufis virTxebi peroralurad iRebden klotrimazolis 50 mg/kg-mde sxeulis wonis 10 kviris ganmavlobaSi Sewyvilebamde da an Sewyvilebis 3-kviriani periodis ganmavlobaSi (mxolod mamrebisaTvis) an mdedrebisaTvis orsulobis me-13 dRemde, an 4 kviramde mSobiarobis Semdeg. axalSobilebis gadarCena daqveiTebuli iyo jgufSi, sadac iRebden 50 mg/kg-s sxeulis wonis. klotrimazoli, dozebamde 25 mg/kg sxeulis wonis, ar axdenda STmomavlobis ganviTarebis darRvevas. klotrimazoli yvela dozebze ar axdenda gavlenas fertilobaze.

Tagvebze, bocvrebsa da virTxebze kvlebebsi ar gamovlinda teratogenuli efeqtebi peroralur dozebze 200, 180 da 100 mg/kg, Sesabamisad.

kvlevam, sadac 3 virTxas laqtaciis periodSi intravenurad ukeTdeboda 30 mg/kg klotrimazoli, aCvena, rom preparatis sekrecia rZeSi 10-20-er ufro meti iyo plazmasTan SedarebiT Seyvanidan 4 saaTis Semdeg, romelic Semdgom daqveiTda 0.4-eradamde 24 saaTis Semdeg.

vaginaluri gamoyenebis Semdeg klotrimazolis SezRuduli absorbciiis gaTvaliswinebiT (daaxloebiT 3%-10%), ar aris mosalodneli safrTxe klotrimazolis vaginaluri gamoyenebisas.

farmaceutuli maxasiaTeblebi

Senaxvis vada

3 weli

Senaxvis pirobebi

inaxeba 25°C-zedabal temperaturaze. dauSvebelia gayinva.

gacemis wesi:

ფარმაცევტული პროდუქტის ჯგუფი III, გაიცემა რეცეპტის გარეშე.

SefuTvis forma da Semcveloba

kremit moTavsebulia 20 g aluminis gravirebul tubSi, romelic Signidan dafarulia laqit, aqvs membrana da xraxniani polietilenis an polipropilenis Tavsaxuri.

individualuri SefuTva Seicavs 1 tubs, romelic samedicino gamoyenebis instruqiasTan erTad moTavsebulia muyaos kolofSi.

SeuTavsebloba

saWiro klinikuri monacemebi ar arsebobs.

mwarmoebeli

mwarmoebeli (xarisxis kontrolis gamcemi)

<<delfarm poznan s.a.>>/

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samkurnalo produqtis savaWro licenciis mflobelis saxelwodeba da misamarTi

<<glaqsosmiTklain eqsforT limiTid, gaerTianebuli samefo >> /

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