

**enjeriqsi -B
B hepatitis (rdnm) sawinaaRmdego vaqcina (adsorbirebuli)
saineqcio suspenzia**

Tvisobrivi da raodenobrivi Semadgenlobavaqcinis 10 mkg doza

1 doza (0.5 ml) Seicavs:

B hepatitis zedapiruli antigeni^{1,2} 10 mikrogrami¹adsorbirebuli aluminis hidroqsidze, hidratirebulisul: 0.25 miligrami Al³⁺²warmoqmnilia safuaris ujredebSi (*Saccharomyces cerevisiae*) rekombinanatuli dnm-is teqnologiiTvaqcinis 20 mkg doza

1 doza (1 ml) Seicavs:

B hepatitis zedapiruli antigeni^{1,2} 20 mikrogrami¹adsorbirebuli aluminis hidroqsidze, hidratirebulisul: 0.50 miligrami Al³⁺²warmoqmnilia safuaris ujredebSi (*Saccharomyces cerevisiae*) rekombinanatuli dnm-is teqnologiiT

vaqcina Zlier gawmendilia da akmayofilebs WHO-s moTxovnebs B hepatitis sawinaaRmdego rekombinantuli vaqcinebis mimarT. mis warmoebaSi ar aris gamoyenebuli adamianuri warmoSobis nivTierebebi.

mRvrie TeTri suspenzia.

Senaxvisas SeiZleba aRiniSnos wvrili, TeTri naleqi gamWvirvale, ufero supernatantiT.

klinikuri informacia**Cvenebebi**

enjeriqsi-B naCvenebia aqtiasi imunizaciisaTvis B hepatitis virusis (HBV) infeqciis winaaRmdeg, romelic gamowveulia yvela cnobili qvetipiT yvela asakis pirSi, romlebic iTvlebian, rom imyofebian HBV-Ti inficirebis riskis qveS. mosalodnelia, rom enjeriqsi-B-Ti imunizacia aseve axdens D hepatitis prevencias, radgan D hepatitis (delta agentiT gamowveuli) ar viTardeba B hepatitis virusis infeqciis gareSe.

mosalodnelia, rom B hepatitis winaaRmdeg imunizacia xangrZlivi drois ganmavlobaSi amcirebs ara mxolod am daavadebis SemTxvevebs, aseve, mis qronikul garTulebebs, rogoricaa qronikuli aqtiasi B hepatitis da B hepatitTan asocirebuli cirozi.

B hepatitis **dabali gavrcelebis** arealSi imunizacia gansakuTrebiT rekomendebulja im pirebSi, romlebic miekuTvnebian infeqciis maRali riskis mqone jgufeks (ix. qvemoT), Tumca yvela axalSobilis da mozardis sayovelTao imunizacia xels uwyoobs B hepatitis kontrols populaciaSi.

B hepatitis **saSualo da maRali gavrcelebis** arealSi, sadac populaciis umetesoba imyofeba HBV-s ganviTarebis riskis qveS, saukeTeso strategiaa yvela axalSobilis, Cvilis, bavSvisa da mozardis, aseve, infeqciis gazrdili riskis mqone jgufeks Semavalni mozrdilebis sayovelTao imunizacia.

jmo-s, aSS-s imunizaciis praqtikis sakonsultacio komitetis (ACIP) da amerikis pediatrTa akademiis rekomendaciebis mixedviT, axalSobilebis da/an mozardebis vaqcinacia warmoadgens optimalur strategias yvela qveyanaSi B hepatitis gasakontroleblad.

infeqciis gazrdilis riskis qveS myofi jgufEBI:
 sameedicino personali;
 pacientebi, romlebic xSirad moixmaren sisxlis produqtebs;
 dawesebulebebis personali da rezidentebi;
 pirebi, romlebic imyofebian maRali riskis qveS maTi seqsualuri qcevis gamo;
 saineqcio narkotikuli saSualebebis arakanonieri momxmareblebi;
 HBV-s maRali endemurobis regionebSi mogzauri pirebi;
 axalSobilebi, romelTa dedebi arian HBV-s matareblebi;
 pirebi HBV-s maRali endemurobis regionebidan;
 namglisebrujredovani anemiis mqone pacientebi;
 pacientebi, romlebic arian organos gadanergvis kandidatebi;
 sayofacxovrebo kontaqtebi nebismier zemoT CamoTvlil jgufTan da mwvave an qronikuli HBV
 infeqciis mqone pacientebTan;
 RviZlis qronikuli daavadebis (Rqd) mqone pirebi an pirebi, romlebic imyofebian Rqd-s riskis qveS
 (mag.: C hepatitis virusis matareblebi, alkoholizmiT daavadebuli pirebi);
 sxva (policieblebi, mexanZreebi, SeiaraRebuli Zalebis warmomadgenlebi da nebismieri piri, romelic
 samuSaos an cxovrebis stilis gamo, SeiZleba aRmoCndes HBV-Ti inficirebis riskis qveS).

dozireba da miRebis wesi

- **dozireba**

20 mkg doza vaqcina. 20 mkg doza (1 ml suspenziaSi) gankuTvnilia 20 wlis da zemoT asakis pirebisaTvis.

10 mkg doza vaqcina. 10 mkg doza (0.5 ml suspenziaSi) gankuTvnilia axalSobilebisaTvis, CvilebisaTvis da 19 wlis asakis CaTvliT bavSvebisaTvis.

Tumca, 20 mkg vaqcina aseve SeiZleba gamoyenebul iqnes 11-dan 15 wlis CaTvliT asakis pirebSi 2-doziани sqemiT im SemTxvevebSi, roca B hepatitis infeqciis ganviTarebis riski dabalia vaqcinaciis kursebs Soris da roca garantirebulia vaqcinaciis sruli kursis Catareba (ix. paragrafi "farmakodinamika").

pirveladi imunizaciis sqemebi

- yvela piri:

0, 1 da 6 Tveze vaqcinaciis sqema iZleva optimalur dacvas me-7 Tveze da warmoqmnis antisxeulebis maRali titrs. gaZlierebuli sqemiT imunizaciisas 0, 1 da 2 Tveze, dacva viTardeba ufro swrafad da mosalodnelia sqemis ukeTesi Sesruleba. am sqemis mixedviT, meoTxe doza keTdeba me-12 Tveze xangrZlivi dacvis uzrunvelsayofad, radgan mesame dozis Semdeg titri ufro dabalia, vidre 0, 1, da 6 Tviani sqemis Semdeg. CvilebSi am sqemis dros nebadarTulia B hepatitis vaqcinis gakeTeba sxva sabavSvo vaqcinebTan erTad.

- 20 wlis da meti asakis pirebi:

gamonalklis SemTxvevebSi mozrdilebSi, roca saWiroa swrafi dacvis ganviTareba, mag.: pirebi, romlebic mogzauroben maRali endemurobis regionebSi da romlebic iwyeben B hepatitis winaaRmdeg vaqcinaciis kurss gamgzavrebamde erTi TviT adre, SeiZleba gamoyenebul iqnas 0, 7 da 21 dReze sami kunTSida ineqciis sqema. am sqemis gamoyenebis dros meoTxe doza rekomenedebulia pirveli dozidan 12 Tvis Semdeg (ix. paragrafi "farmakodinamika" serokversiis koeficientebi).

- 11 wlidan 15 wlis CaTvliT asakis pirebi:

20 mkg vaqcina SeiZleba gakeTdes 11 wlidan 15 wlis CaTvliT asakis pirebSi 0, 6 Tviani sqemiT. Tumca, am SemTxvevaSi B hepatitis infeqciebis winaaRmdeg dacva miiRweva mxolod meore dozis Semdeg

(ix. paragrafi “farmakodinamika”). amitom, es sqema gamoyenebul unda iqnes mxolod maSin, roca vaqcinaciis kursis periodSi B hepatitis infeqciis ganviTarebis dabali riskia da roca garantirebulia ordoziani vaqcinaciis kursis Catareba. Tu orive piroba ar aris daculi (mag.: pacientebi, romlebic itareben hemodializs, maRal endemur regionebSi mogzaurebi da inficirebul pirebTan axlo kontaqti), gamoyenebul unda iqnes 10 mkg vaqcinis samdoziani an gaZlierebuli sqema.

- Tirkmlis ukmarisobis mqone pacientebi, maT Soris 16 wlis da zemoT asakis pacientebi, romlebic itareben hemodializs:

pirveladi imunizaciis sqema Tirkmlis ukmarisobis mqone pacientebSi, maT Soris pacientebSi, romlebic itareben hemodializs, aris oTxi ormagi doza (2×20 mkg) arCeul dRes, 1 Tves, me-2 Tves da me-6 Tves pirveli dozis TariRidan. imunizaciis sqema adaptirebuli unda iyos imgvarad, rom anti-HBs antisxeulis titri darCes damakmayofilebeli damcvelobiTi donis - 10 mse/ml toli an ufro maRali.

- Tirkmlis ukmarisobis mqone pacientebi, maT Soris 15 wlis asakis CaTvliT pacientebi, romlebic itareben hemodializs, axalSobilebis CaTvliT:

Tirkmlis ukmarisobis mqone pacientebs, maT Soris pacientebs, romlebic itareben hemodializs, daqveiTebuli aqvT imunuri pasuxi B hepatitis vaqcinebis mimarT. gamoyenebul unda iqnas enjeriqsi-B 10 mkg-is 0, 1, 2 da 12 Tviani an 0, 1, 6 Tviani sqema. mozrdilebSi arsebuli gamocdilebis safuZvelze, antigenis maRali doziT vaqcinaciam SeiZleba gaaumjobesos imunuri pasuxi. yuradReba unda mieqces serologjur analizs vaqcinaciis Semdeg. vaqcinis damatebiTi dozebi SeiZleba saWiro iyos, raTa SenarCundes damcvelobiTi anti-HBs done ≥ 10 mse/l.

- dadasturebuli an saeWvo kontaqti HBV-sTan:

im SemTxvevebSi, rodesac ukanasknel periodSi iyo kontaqtiH HBV-sTan (mag.: dabinZurebuli nemiST Cxvleta), enjeriqsi-B-s pirveli doza unda gakeTdes B hepatitis imunoglobulinebTan (HBIG) erTad, romelic unda gakeTdes gansxvavebul saineqcio adgilas (ix. “urTierTqmedebebi”). am dros rekomenedebulia 0, 1, 2 – 12 Tviani imunizaciis sqema.

- axalSobilebi, romelTa dedebi arian HBV-is matareblebi:

enjeriqsi-B-Ti (10 mkg) imunizacia am axalSobilebSi unda daiwyos dabadebisTanave da ori imunizaciis sqemidan unda gakeTdes erT-erTi: 0, 1, 2, da 12 Tviani an 0, 1 da 6-Tviani sqema. Tumca pirveli sqema iZleva ufro swraf imunur pasuxs. Tu SesaZlebelia, HBIG unda gakeTdes enjeriqsi-B-sTan erTdroulad, oRond sxva saineqcio adgilas, raTa gaizardos damcvelobiTi efeqturoba.

imunizaciis es sqemebi misadagebul unda iqnas imunizaciis adgilobriv praqtkasTan, romelic iTvaliswinebs rekomenedebuli asakisaTvis ssvadasxva sabavSvo vaqcinebs.

busteruli doza

busteruli dozis saWiroeba janmrTel pirebSi, romlebmac Caitares pirveladi vaqcinaciis sruli kursi, ar aris dadgenili. Tumca zogierTi oficialuri vaqcinaciis programebi Seicavs rekomenedacis busteruli dozis Sesaxeb da es mosazreba gasaTvaliswinebelia.

pacientebSi, romlebic itareben hemodializs an daqveiTebuli aqvT imunuri sistema, busteruli doza rekomenedebulia, raTa antisxeulebis done SenarCundes ≥ 10 mse/ml doneze.

busteruli dozis Sesaxeb monacemebi xelmisawvdomia. busteruli doza iseve kargad gadaitaneba, rogorc pirveladi vaqcinaciis kursi.

- **miRebis meTodi**

enjeriqsi-B keTdeba intramuskularulad deltoidur kunTSi mozdilebsa da bavSvebSi, an barZayze anterolateralurad axalSobilebSi, Cvilebsa da patara bavSvebSi. gamonaklisis saxiT, vaqcina SeiZleba gakeTdes kanqveS pacientebSi, romlebsac aRenisnebaT Trombocitopenia an sisxlis Sededebis darRvevebi.

enjeriqsi-B ar unda gakeTdes dundulebSi an intradermalurad, radgan SeiZleba gamoiwwios daqveiTebuli imunuri pasuxi.

ukuCvenebebi

enjeriqsi-B ar keTdeba vaqcinis romelime komponentis mimarT dadgenili hipermgrZnobelobis SemTxvevaSi, an Tu aRiniSna hipermgrZnobelobis niSnebi enjeriqsi-B -Ti wina vaqcinaciis dros. aiv infeqcia ar ganixileba B hepatitis vaqcinaciis ukuCvenebad.

gafrTxilebebi da sifrTxilis zomebi

sxva vaqcinebis msgavsad, enjeriqsi-B-Ti vaqcinacia unda gadaidos im pirebSi, romlebsac aRenisnebaT mwwave mZime cxelebiT mimdinare daavadeba. mcire infeqciebis arseboba ar warmoadgens imunizaciis ukuCvenebas.

B hepatitis xangrZlivi inkubaciuri periodis gamo SesaZlebelia, rom imunizaciis momentSi arsebobdes aragamovlenili infeqcia. aseT SemTxvevaSi vaqina ver moaxdens B hepatitis infeqciis prevencias. vaqina ar axdens sxva paTogenebiT gamowveuli RviZlis infeqciebis prevencias, rogoricaa A hepatitis, C hepatitis da E hepatitis virusebi.

imunuri pasuxi B hepatitis vaqcinis mimarT dakavSirebulia sxvadasxva faqtorebTan. es faqtorebi moicavs ufro did asaks, mamrobiT sqess, Warb wonas, Tambaqs mowevis Cvevasa da vaqcinaciis meTods. pirebSi, romlebsac ar uviTardebaT saTanado pasuxi B hepatitis vaqclinebis mimarT (mag.: 40 welze meti asaki da a.S.), ganxilul unda iqnas damatebiTi dozebi.

Tirkmlis ukmarisobis mqone pacientebSi, maT Soris, romlebic itareben hemodializs, aiv inficirebul pacientebSi da daqveiTebuli imunuri sistemis mqone pirebSi adeqvaturi anti-HBs antisxeulebis titri SeiZleba ver SenarCundes pirveladi imunizaciis kursis Semdeg da amitom aseTi pacientebi saWiroeben vaqcinis damatebiT dozebs (ix. paragrafi “dozireba” – Tirkmlis ukmarisobis mqone pacientebi, maT Soris, romlebic itareben hemodializs).

sxva saineqcio vaqclinebis msgavsad, Sesabamisi samedicino mkurnaloba da meTvalyureoba unda iyos swrafad SesaZlebeli vaqcinis gakeTebis Semdeg iSviaTi anafilaqsiuri reaqciebis ganviTarebis SemTxvevaSi. sinkope (gulis wasvla) SeiZleba ganviTardes vaqcinaciis Semdeg an vaqcinaciamec, rogorc fsiqogenuri reaqcia nemsiT ineqciaz. mniSvnellovania, procedura Catardes iseT adgilas, raTa ar ganviTardes travma gulis wasvlis Sedegad.

enjeriqsi-B ar keTdeba dundula kunTebSi an intradermalurad, radgan SeiZleba gamoiwwios daqveiTebuli imunuri pasuxi.

enjeriqsi-B araviTar SemTxvevaSi keTdeba intravaskularulad.

sxva vaqclinebis msgavsad, damcvelobiTi imunuri pasuxi SeiZleba ar ganviTardes yvela acril pirSi (ix. paragrafi “farmakodinamika”).

apnoes potenciuri riski da 48-72 saaTiani respiratoruli monitoringi gaTvaliswinebul unda iqnas pirveladi imunizaciis dros Zalian dRenaklul axalSobilebSi (≤ 28 gestaciuri kviraSi dabadebulebi) da gansakuTrebiT, romlebsac aRenisnebaT respiratoruli moumwifeblobis anamnezi. radgan vaqcinaciis sargebeli maRalia axalSobilebis am jgufSi, vaqcinacia ar unda SeCerdeis an dayovndes.

urTierTqmedebebi

enjeriqsi-B-s da HBIG-s standartuli dozis erTdrouli gakeTeba ar iwvevs anti-HBs antisxeulebis titris daqveiTebas, Tu maTi Seyvana xdeba sxvadasxva saineqcio adgilas.

enjeriqsi-B SeiZleba gakeTdes DTP, DT da/an poliomielitis sawinaaRmdego vaqclinebTan erTad, Tu is kargad esadageba qveynis jandacvis uwyebis mier rekomendebul imunizaciis sqemas.

enjeriqsi-B SeiZleba erTdroulad gakeTdes wiTela-ybayura-wiTuras vaqcinebTan, *Haemophilus influenza* b vaqcinasTan, A hepatitis vaqcinasTan da BCG-sTan erTad.

enjeriqsi-B SeiZleba erTdroulad gakeTdes adamianis papilomavirusis (HPV) vaqcinasTan (Cervarix) erTad.

enjeriqsi-B-s erTdroulma gakeTebam Cervarix-Tan erTad ar aCvena klinikurad mniSvnellovani urTierTqmedeba HPV antigenebis mimarT antisxeulebis pasuxze. anti-HBs antisxeulebis saSualo geometriuli koncentracia dabali iyo erTdrouli gakeTebisas. Tumca, am dakvirvebis klinikuri mniSvneloba ar aris cnobili, radgan seroproteqciis koeficientebi ucgleli darCa. pirebis proporsia, romlebSic anti-HBs ≥ 10 mse/ml-ze, iyo 97.9% erTdrouli vaqcinaciis da 100% - mxolod enjeriqsi-B -Ti vaqcinaciis.

sxvadasxva saineqcio vaqcinebi yovelTvis unda gakeTdes gansxvavebul adgilebSi.

B hepatitis sawinaaRmdego vaqcinebis Secvla

enjeriqsi-B SeiZleba gamoyenebul iqnas pirveladi imunizaciis kursis dasasruleblad, romelic daiwoy plazmisgan warmoebuli an genuri inJineriiT warmoebuli B hepatitis sxva vaqciniT, an busteruli dozis saxiT SeiZleba gakeTdes im pirebSi, romlebsac pirveladi imunizaciis kursi CautardaT plazmisgan warmoebuli an genuri inJineriiT warmoebuli B hepatitis sxva vaqcinebiT.

ორსულობა da laqtacia

ორსულობა

adeqvaturi monacemebi adamianebsi fexmZimobis dros gamoyenebis Sesaxeb da cxovelebsi adeqvaturi reproduciuli kvlevebi ar aris xelmisawvdomi.

Tumca, sxva inaqtivirebuli virusuli vaqcinebis msgavasd, ar aris mosalodneli, rom vaqcinam saziano gavlena iqonios nayofze. enjeriqsi-B fexmZimobis dros gamoyenebul unda iqnes mxolod absoluturi Cvenebis SemTxvevaSi da roca potenciuri sargebeli aWarbebs SesaZlo riskebs nayofisTvis.

laqtacia

adeqvaturi monacemebi adamianebsi laqtaciis dros gamoyenebis Sesaxeb da cxovelebsi adeqvaturi reproduciuli kvlevebi ar aris xelmisawvdomi.
raime ukuCveneba ar aris dadgenili.

avtomobilisa da sxva meqanizmebis marTvaze gavlena

ar aris mosalodneli, rom vaqcinam raime gavlena iqonios avtomobilisa da sxva meqanizmebis marTvis unarze.

gverdiTi reaqciebi

qvemoT mocemuli usafrTxoebis profili dafuznebulia monacemebs, romlebic miRebulia 5,300-ze meti piridan.

sixSire aRwerilia Semdegairad:

Zalian xSiri: ($\geq 1/10$)

xSiri: ($\geq 1/100 - < 1/10$)

araxSiri: ($\geq 1/1,000 - < 1/100$)

iSviaTi: ($\geq 1/10,000 - < 1/1,000$)

Zalian iSviaTi: ($< 1/10,000$)

<u>sixSire</u>	<u>gverdiTi reaqciebi</u>
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<u>klinikuri kvlevebi</u>	
Zalian xSiri	gaRizianebadoba, ineqciis adgilis tkibili da siwiTle, daRliloba
xSiri	madis dakargva, Tavis tkibili (Zalian xSiri 10 mkg formulis gamoyenebisas), Zilianoba, kuW-nawlavis simptomebi (rogoricaa: gulisreva, Rebineba, faRaraTi, muclis tkibili), ineqciis adgilis SeSupeba, sisuste, ineqciis adgilis reaqcia (rogoricaa gamkvriveba), cxeleba ($\geq 37.5^{\circ}\text{C}$)
araxSiri	Tavbrusxveva, mialgia, gripis msgavsi daavadeba
iSviaTi	limfadenopaTia, paresTezia, gamonayari, qavili, WinWris cieba. arTralgia
<u>postmarketinguli monacemebi</u>	
meningiti, Trombocitopenia, anafilaqsia, alergiuli reaqciebi, maT Soris, anafilaqtoiduri reaqciebi da Sratismieri daavadebis imitacia, dambla, krunCxvebi, hipotesTezia, encefaliti, encefalopaTia, neiropaTia, nevriti, hipotenzia, vaskuliti, angionevrozuli SeSupeba, brtyeli lijeni, multiformuli eriTema, arTriti, kunTebis sisuste	

SedarebiT kvlevaSi, romelic Catarda 11 wlidan 15 wlis asakis CaTvliT pirebSi, adgilobrivi da zogadi arasasurveli simptomebis sixSire, romlebic aRiniSna enjeriqsi–B-s 20 mkg-iT ordoziani sqemiT acris Semdeg, zogadad analogiuri iyo enjeriqsi–B-s 10 mkg-iT standartuli samdoziani sqemiT acris Semdeg aRwerilis.

dozis gadaWareba

dozis gadaWarbebis SemTxvevebi aRiniSna postmarketinguli dakvirvebis periodSi. gverdiTi movlenebi, romlebic aRiniSna dozis gadaWarbebis dros, msgavsi iyo normalurad Catarebuli vaqcinaciis dros aRniSnuli movlenebis.

farmakologiuri Tvisebebi

farmakodinamika

farmakoTerapiuli jgufi: B hepatitis vaqcina, aTq kodi: **J07BC01**

enjeriqsi–B ainducirebs specifikur humorul antisxeulebs HBsAg-s (anti-HBs antisxeulebis) winaaRmdeg. anti-HBs antisxeulebis koncentracia $\geq 10 \text{ msem/l}$ Seesabameba HBV-s infeqciisgan dacvas.

- damcvelobiTi efeqtianoba da xangrZlivi imunuri pasuxi

yvela riskjgufi:

eqsperimental kvlevebSi damcvelobiTi efeqtianoba aRiniSna 95%-sa da 100%-s Soris axalSobilebSi, bavSvebsa da riskis qveS myof mozdilebSi.

95%-iani damcvelobiTi efeqtianoba naCvenebi iqna axalSobilebSi, romelTa dedebi iyvnen HBeAG dadebiTi, romelTa imunizacia moxda 0, 1, 2 da 12 an 0, 1 da 6 Tviani sqemebiT da dabadebisas ar momxdara HBIG-s erTdrouli miReba. HBIG-s da vaqcinis erTdrouli gakeTeba dabadebisas zrdis damcvelobiT efeqtianobas 98%-mde.

bavSvobis dros pirveladi vaqcinaciidan 20 wlis Semdeg pirebs, romelTa dedebi iyvnen HBV matarebbebi, gaukeTdaT enjeriqsi–B-s sakontrolo doza. erTi Tvis Semdeg, araucires 93% pirebs (N=75), aRenisnaT anamnezuri pasuxi, romelmac aCvena imunuri mexsiereba.

janmrTeli pirebi:

cxrilSi Sejamebulia seroproteqciis koeficientebi (e.i.. pirebis procenti, romlebsac aqvT anti-HBs antisxeulebis koncentracia ≥ 10 mse/ml), romelic miRweul iqna ssvadasxva sqemebiT Catarebul klinikur kvlevetSi, romelic mocemulia “dozirebis” paragrafSi.

populacia	sqema	seroproteqciis koeficienti
janmrTeli pirebi	0, 1, 6 Tve 0, 1, 2 - 12 Tve	me-7 Tves: $\geq 96\%$ 1-l Tves: 15% me-3 Tves: 89% me-13 Tves: 95.8%
20 wlis da meti asakis janmrTeli pirebi	0, 7, 21 dRe – 12 Tve	28-e dRes: 65.2% me-2 Tves: 76% me-13 Tves: 98.6%

xangrZlivi imunuri pasuxi Sefasda klinikur kvlevetSi, romelic Catarda pirveladi vaqcinaciis momentSi 11 wlidan 15 wlis CaTvliT asakis pirebSi. seroproteqciis koeficientebi, romlebic miRebul iqna ori gansxvavebuli dozirebisa da sqemis gamoyenebis Semdeg, Sefasda pirveladi vaqcinaciis pirveli dozidan 66 Tvemde periodSi da mocemulia qvemoT moyvanil cxrilSi:

vaqcinis jgufeti	seroproteqciis koeficienti:						
	Tve 2	Tve 6	Tve 7	Tve 30	Tve 42	Tve 54	Tve 66
enjeriqsi-B 10 mkg (0, 1, 6 Tviani sqema)	55.8%	87.6%	98.2%	96.9%	92.5%	94.7%	91.4%
enjeriqsi-B 20 mkg (0, 6 Tviani sqema)	11.3%	26.4%	96.7%	87.1%	83.7%	84.4%	79.5%

es monacemebi miuTiTebs, rom pirveladi vaqcinacia enjeriqsi-B vaqciinT iwvevs anti-HBs antisxeulebis cirkulirebas, romelic narCundeba araumcires 66 Tvis ganmavlobaSi. pirveladi kursis damTavrebis Semdeg, 2 vaqcinis jgufis Sedarebisas drois TiToeul momentSi ar aRiniSneba klinikurad mniSvnelovani gansxvaveba seroproteqciis koeficientebs Soris. orive vaqcinis jgufSi Semaval yvela pirs (maT Soris, pirebs anti-HBs antisxeulebis koncentraciiT <10 mse/ml) gaukeTdaT sakontrolo doza pirveladi vaqcinaciidan 72-78-e Tves. sakontrolo dozidan erTi Tvis Semdeg, yvela pirs aRenisna anamnezuri pasuxi sakontrolo dozis mimarT da iyvnen serologjurad daculebi (e.i. anti-HBs antisxeulebis koncentracia ≥ 10 mse/ml). es monacemebi miuTiTebs, rom B hepatitis winaaRmdeg dacva SeiZleba gadaeces imunuri mexsierebiT yvela pirs, romlebsac pasuxi hqondaT pirvelad vaqcinaciaze, magram dakarges anti-HBs antisxeulebis seroproteqciis done.

xangrZlivi persistentoba Sefasda klinikur kvlevaSi, 15-16 wlis asakis pirebSi (N=292), romlebic acrilebi iyvnen dabadebidan pirvel 2 welSi enjeriqsi-B-s 3 doziT. anti-HBs seroproteqcia iyo 65.4% pirveladi vaqcinaciidan me-14 wels [intervali 13.5-15.5 wlebi]. drois am momentSi yvela pirs (maT Soris, pirebs anti-HBs antisxeulebis koncentraciiT <10 mse/ml) gaukeTda sakontrolo doza. sakontrolo dozidan erTi Tvis Semdeg naCvenebi iqna, rom 97.9% piri iyo serologiurad daculi. anamnezuri pasuxi aRiniSna 92.9% pirSi, romlebic seronegatiurebi iyvnen sakontrolo dozamde (N=84) da 98.6% pirSi, romlebic seropozitiurebi iyvnen sakontrolo dozamde (N=207).

Tirkmlis ukmarisobis mqone pacientebi, maT Soris, romlebic itareben hemodializs:

asaki (wlebi)	sqema	seroproteqciis koeficienti
16 weli da zemot	0, 1, 2, 6 Tve (2 x 20 mkg)	me-3 Tves: 55.4% me-7 Tves: 87.1%

II tipis diabetis mqone pacientebi:

asaki (wlebi)	sqema	seroproteqciis koeficienti me-7 Tves
20-39	0, 1, 6 Tve (20 mkg)	88.5 %
40-49		81.2 %
50-59		83.2 %
≥ 60		58.2 %

- hepatocellularuli karcinomis SemTxvevebis Semcireba bavSvebSi:

hepatocellularul karcinomis SemTxvevebis mniSvnlovani Semcireba aRiniSna 6-14 wlis asakis bavSvebSi B hepatitis sawinaaRmdego sayovelTao vaqcinaciis Semdeg taivanSi. aRiniSna B hepatitis antigenis gavrcelebis mniSvnlovani daqveiTeba, romelic warmoadgens hepatocellularuli karcinomis ganviTarebis ZiriTad faqtors.

araklinikuri informacia

Catarda saTanado usafrTxoebis testebi.

farmacevtuli informacia

damxmare nivTierebebis CamonaTvali

natriumis qloridi, natriumis fosfatis dihidrati, natriumis dihidrofosfati, saineqcio wyali. polisorbati 20 warmodenilia warmoebis procesis Sedegad narCeni formis saxiT.

Senaxvis vada

vaqcinis Senaxvis vada miTiTebulia SefuTvaze.

Senaxva

inaxeba macivarSi (2°C - 8°C).

dauSvebelia gayinva. inaxeba originaluri SefuTviT sinaTlisagan dasacavad.

stabilurobis monacemebi miuTiTebs, rom enjeriqsi-B stabiluria 37°C-mde temperaturebze 3 dRis ganmavlobaSi da 25°C-mde - 7 dRis ganmavlobaSi. es monacemebi gankuTvnilia samedicino personalis saxelmZRvanelod mxolod Senaxvis temperaturis droebiTi gadaxris SemTxvevebSi. Senaxvis pirobebi detalurad mocemulia SefuTvaze.

konteineris forma da Semcveloba

vaqcinis 10 mkg doza

0.5 ml suspenzia winaswarSevsebul mza SpricSi (I tipis mina) dguSis sacobiT (butilrezini) da rezinis wveros mqone TavsaxuriT an 0.5 ml suspenzia flakonSi (I tipis mina) sacobiT (butilrezini).

vaqcinis 20 mkg doza

1 ml suspenzia winaswarSevsebul mza SpricSi (I tipis mina) dguSis sacobiT (butilrezini) da rezinis wveros mqone TavsaxuriT an 0.5 ml suspenzia flakonSi (I tipis mina) sacobiT (butilrezini).

Tavsaxuris wvero da winaswarSevsebuli mza Spricis dguSis sacobi da flakonis sacobi damzadebulia bunberivi rezinis lateqsisagan.

yvela SefuTvis forma ar aris xelmisawvdomi yvela qveyanaSi.

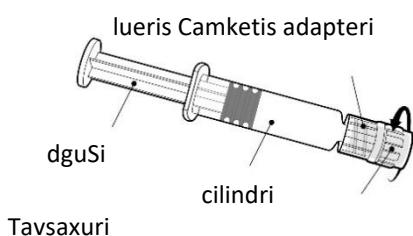
SeuTavsebloba

enjeriqsi-B ar unda Seerios sxva vaqcinebs.

gamoyeneba da moxmareba

Senaxvisas SeiZleba aRiniSnos wvrili, TeTri naleqi gamWvirvale, ufero supernatantiT. gamoyenebis win vaqcina kargad unda SeinjRres, raTa miRebul iqna odnav gaumWvirvale, TeTri suspenzia. gamoyenebis win vaqcina unda daTvalierdes vizualurad masSi ucxo nawilakebis arsebobaze da/an fizikur garegnobis cvlilebaze. raime cvlilebis aRmoCenis SemTxvevaSi, vaqcina ar unda gakeTdes. flakonis gamoyenebisas gamoyenebul unda iqnes ssvadasxva nemsebi rezinis sacobis gasavretad da vaqcinis ineqcisaTvis.

instruqciebi winaswarSevsebuli mza SpricisaTvis

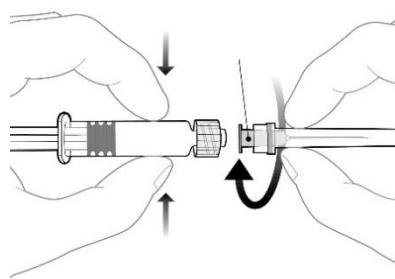


Sprici daWeril unda iqnes cilindriT da ara dguSiT.

unda amoixraxnos Spricis Tavsaxuri misi datrialebiT saaTis isris sawinaaRmdego mimarTulebiT.

produqtis Sesaxeb saerTaSoriso informacia

nemesis
damakavSirebeli



konfidentialuri

nemesis dasamagreblad damakavSirebeli
unda miuerTdes lueris Camketis adaptors
da mobrundes saaTis isris momarTulebiT
meoTxedi brunviT, sanam ar SeigrZnoba,
rom Caketilia.

ar unda gamoiqaCos Spricis dguSi
cilindridan. aseT SemTxvevaSi ar unda
gakeTdes vaqrina.

ganadgureba

nebismieri gamouyenebeli produkti an narCeni masala gadagdebul unda iqnes adgilobrivi
moTxovnebis Sesabamisad.

versiis nomeri: GDSD17/IPI13

gamocemis TariRi: 2022 wlis 12 agvisto

გაცემის წესი:

ფარმაცევტული პროდუქტის ჯგუფი II, გაიცემა ფორმა №3 რეცეპტით