

Liek s ukončenou platnosťou registrácie

PRÍLOHA I

SÚHRN CHARAKTERISTICKÝCH VLASTNOSTÍ LIEKU

Vgpvq"nkgm"lg"rtgfovgvq o " cn-kgjq" o qpkvqtqxcpc0"Vq"w o qflp"t ejng" | f"umcpkg"pqx ej "kphqt o ^ek" o dg | rg pqvuk0"Qf" | ftcxqvp"em{ej"rtceqxp"mqx"uc"x {flcfwlg."cd{ "jn^uknk"cm^mq xgm"rqfq | tgpkc"pc" pglkcfweg"tgcmeq0"Kphqt o ^ek"q vq o ."cmq"jn^uk "pglkcfweg"tgcmeq."p^lfvg"x cuv"60:0

1. NÁZOV LIEKU

P [ZVJ TCEKU 100 o i l o n"mqpepvt^v pc"kpHÀ | p{ "tq | vqm

2. KVALITATIVNE A MXCPVKVCV^XPG" \ NQfiGPKG

Mcfif " o n"mqpepvt^vw"qducjwlg"100 o i "qdknvqzczk o cdw0
Lgfpc"8 o n"kp l gm p^a"nkgmqxmc"qducjwlg"822 o i "qdknvqzczk o cdw0

Qdknvqzczk o cd"je rtqfwmqxc p x dwpm^ej" o {-kgjq" o {gn» o w" IU-PU2"rq o qeqw"vejpqn»ikg"
tgmq o dkpcpvgl" FPC}

Rq o qep^a"n^vmc"uq" | p^a o { o "À kpmq o :

Mcfif " o n"mqpepvt^vw"qducjwlg"58 o i "uqtdkvqmw0

—rnp " | q | pc o "rq o qep ej "n^vqm."rq | tk" cu "8030

3. LIEKOVÁ FORMA

Kqpepvt^v"pc kpHÀ | p{ "tq | vqm" *uvgtknp "mqpepvt^v"0
P [ZVJ TCEKU lg" | t{ "cfl"qrcnk | wL^ek."dg | hctgdp "cfl"uxgvnqflnv "cfl"uxgvnqj p g f q -flnv "tq | vqm."mvqt " o 1/2flg"
qducjxqc "pkgmq mq"rtkj cfp ej cfl"dkgn{ej"dkgnmqxkpqx ej" cuv"e" *mvqt^2"uc"qfuvt^a"pkc"kp-line
hknv^a"ekqw+"u"r J 7.7" c"qu o qncnkqvq"499 – 52: o Qu o lmi0

4. KLINICKÉ ÚDAJE

4.1 Terapeutická indikácie

P [ZVJ TCEKU lg"kp f kmqxc p "x"mq o dkp^ekk"u"xjqfp ok cpykdcmvgtk^a"np{ ok"nkgm ok"x-gvm m xgmqx m
umwrkp^a"m pc"nkg dw"kpjcnc p^2jq"cpvtczw"ur/zuqdp^2jq"dcmv^2tkw" *Bacillus anthracis* *rq | tk" cu "703+0

P [ZVJ TCEKU lg"kp f kmqxc p "x-gvm m xgmqx m umwrkp^a"m pc"rquv-gzrq | k pÀ"rtqh{nczkw"kpjcnc p^2jq"
cpvtczw."cm"envgtpe"xp"nkg dc"pkg"lg"xjqfp^a"cnqdq"pkg"lg"m"fkurq | f"ek" *rq | tk" cu "703+0

4.2 Dŕkovanie a spôsob podávania

P [ZVJ TCEKU uc" o ^a"rqfc "ijpg ."cmq"lg"mnkpkem{"kp f kmqxc p 0

X"rt"rcfg"cpch{ncmvkemgl"wfncquvk"rq"rqfcp"nkgmw" P [ZVJ TCEKU o ^a"d{ "xflf{ " cjm"q"fqvwrp^a"
rtko"gtcp^a"nkg dc"cnm^a"tum{"fqj cf0

F^xmqxcpkg

QfrqtÀ cp^a f^axmc nkgmw" P [ZVJ TCEKU w"fqurn ej"rcekpvcx"u vngupqw"j o qvpqu qw"pcl o gpgl
62 kg je jednqtc | qx^a kpvtxgp» | pc"kpHÀ | kc"38 o i lmi "vngupgl"j o qvpquv0"QfrqtÀ cp^a f^axmc nkgmw"
P [ZVJ TCEKU w"fqurn ej"rcekpvcx"u vngupqw"j o qvpqu qw" o gpgl"cmq"62 kg je jednqtc | qx^a
kpvtxgp» | pc"kpHÀ | kc"46 o i lmi "vngupgl"j o qvpquv0

Rtgf"rqfcp"o"nkgmw"P [ZVJ TCEKU uc"qfrqtÀ c"rtgogfkm^aekc"cpvkjkuvc o kpkmq o"*rq|tk" cuv"606"
c 60: +0

—rtcx{"f^axm{ x"rt|rctfg"tgcme"uÀxkukcekej"u"rqfcp"o"kphÀ|kg"uÀ"wxgfgp²"x"vcdw mg"30

Vedw mc 1: Pravy dŕky obiltoxaximabu v prípade reakcií v sŕiacich s podanŕm infŕie

\ ^a xclpqu " reakciŕ sŕiacich s podanŕm infŕie	Prava dŕky
30 – 50"uvwrg tgcme" uÀxkukcekej"u"rqfcp"o"kphÀ kg	<p>KphÀ kc"qdknvqzczk o cdw"uc" o ^artgtw-k "c" o ^auc"rqfc "rqfrqtp"^ankg dc0</p> <p>Pri rtxqo "rt rctfg"ukrqvw."dtqpejqurc o w"engdq"i gpgtenk qxcpgl"wtvkm^atkg" 50 uvwr c"uc" o ^aqdknvqzczk o cd"pcvtxcnq"x {ucfk 0</p> <p>Rtk"qremqxcpq o "ukrqvg"engdq"wtvkm^atkk"40 uvwr c"engdq"rtk"qremqxcpq o"x um{vg" cm ejmq xgm"rt pcmqx"50 uvwr c"uc" o ^aqdknvqzczk o cd"pcvtxcnq"x {ucfk 0</p> <p>Kpcm"uc"rq"Àrnpq o "qf pgp"rt pcmqx" o ½flg"kphÀ kc"qdpqkx "rtk"72 ' "t ejnquvk" fquckjpwvgl"rtgf"rtgtw-gp"o"X"pgrt vq o pquvk"rt pcmqx"urqlgp ej"u"kphÀ kqw" lg"t ejnqu "kphÀ kg"qr"ucp^a"x"vcdw mg"50</p> <p>O^auc"rqfc "rtgogfkm^aekc0</p>
60"uvwrg tgcme" uÀxkukcekej"u"rqfcp"o"kphÀ kg	<p>KphÀ kc"qdknvqzczk o cdw"uc" o ^akj pg cuvcxk 0</p> <p>O^auc"rqfc "rqfrqtp"^ankg dc0</p> <p>Qdknvqzczk o cd"uc" o ^apcvtxcnq"x {ucfk 0</p>

Quqdkvp²"umwrkp{"rcekpvpqx

Staršŕiacienti

U rcekpvpqx"xq"xgmw"× 87 tqmqx"pkg"lg"rqvtgdp^a"Artexc" f^axmqxcpkc"*rq|tk" cu "704+0

Pediatrickŕpopulŕia

QfrqtÀ cp^a"f^axmc"rtg"rgfkcvtkem ej"rcekpvpqx"lg" |cnqflgp^a"pc"vngupgl"j o qvpquvk."cmq"lg"wxgfgp²" x vcdw mg"4 pkfl-kg0

Vedw mc"4"QfrqtÀ cp^a"f^axmc"qdknvqzczk o cdw"v pediatrickej populŕii (dŕkovanie na zŕade telesnej hmotnosti)

Vngup ^a "j o qvpqu "mi+	F ^a xmc"] o ilmi "telesnej hmotnosti]
62	38
> 37"cf"62	46
37"engdq" o gpgl	54

Ur½uqd"rqf^axcpkc

Qdknvqzczk o cd"uc" o wu"rqf^axc "kpvtxgp» |pqw"kphÀ|kqw"rq cu"; 2 o kphÀv0

Opatrenia pred zaobchŕzanŕm alebo podanŕm lieku

kplgm p^a"nkgmqxmc"uc pg o ^artgtvr^axc 0"Rtgf"rqfcp"o"htq o qw"kpvtcxgp» |pgl"kphÀ|kg"uc"qdknvqzczk o cd" o wu" |tkgfk "x"klgm pq o "tq |vqmw"ejnqtkfw"uqfp²jq"u mqpegpvt^aekqw"; o ilon"*2.; ' +"*rq|tk" cu "808+0

\tkfggp^akpvtcxgp>|pc"kpH|kc"qdknvqzczk o cdw"uc" o wu"rqf^axc "rq cu";2 o kpAv"t ejnqu qw"kpH|kg" wxgfgpqw x"vcdw mg"5. u"rqwflkv|o kpH|pgj q"xcmw"cnqdq"kpH|pgl"uvtkgmc m{"c"2.44- o kmt>>pqx²jq"kp-nkpg"hnvtc0

Rcekgpvk" o wuke"d{ "rq cu"egngl"fqd{"rqf^axcpkc"kpH|kg" c"pcl o gpgl"lfgpw"jqfkw"rq"rqfcp"rq|qtpg" ungfqxcpl"pc"rtglcx{"c"rtf|pcm{"rtgekvnkxgppquv⁰"*rq|tk" cu "606+0" Tgcmekg"urqlgp²"u"kpH|kg"uc" o cIA" o cpcflqxc "vcm."cmq"lg"wxgfgp²"x"vcdw mg"30

Pc"mqpek"kpvtcxgp>|pgl"kpH|kg"uc" o "ajcfk mc"rtgrn^aejpw "kplgm p o"tq|vqm q o"ejnqtktfw"uqfp²jq" u mqpegpvt^aekqw"; o ilon^a*2.; ' +0

Vcdw mc"5<"F^axcmc"qdknvqzczk o cdw."egnmqx "qdlg o"kpH|kg" c"t ejnqu "kpH|kg"rqf^a c"vngupgl" hmotnosti

Vngup ^a j o qvpqu "mi+ (dkovanie na zhlade telesnej hmotnosti)	Egnmqx "qdlg o"kpH kg" [ml] [infuzny vak alebo kpH pc"uvtkgmc mc ,	T ejnqu "kpH kg"] onlj_
> 40 mi"cnqdq"fqurgn "38 o ilmi"vngupgl" j o qvpquv⁺		
> 62	472	389
> 15 mi"cff"62 mi"46 o ilmi"vngupgl" j o qvpquv⁺		
53"cff"62	472	389
38"cff"52	100	89
15 mi"cnqdq" o gpgl"54 o ilmi"vngupgl" j o qvpquv⁺		
33"cff"37	100	89
7"cff"32	50	55.5
5.3"cff"6. ;	47	39
4.3"cff"5	42	35.5
3.3"cff"4	15	10
3"cnqdq" o gpgl	9	6.9

, Rqm{p{"pc"tkfgpgk"nkgmw" c"rqwflkvk"kpH|pgj q"xcmw"cnqdq"kpH|pgl"uvtkgmc m{"rtgf"rqfcp"o." rq|tk cu "8080

4.3 Kontraindikcie

Rtgekvnkxgpqu "pc"nkg kxq"cnqdq"pc"mvqtAmq xgm"|rq o qep ej"n^avqm"wxgfgp ej"x cuvk"8030

4.4 Osobitné upozornenia a qrcvtgpkc"r tk"rqwfl{xcp|

Ungfqcxcvg pqu

Cd{"uc"|ngr-knc"*fq-ungfqcxcvg pqu "dkqnqikem²jq"nkgmw." o "uc"|tq|wokvg pg"|c|pc o gpc "p^a|qx" c "unq" -ctflg"rqfcp²jq"nkgmw0

Tgcmekg"uAxkukceg"u"rqfcp"o"kpH|kg."rtgekvnkxgpqu "c"cpch{nczkc

Rq cu"mnkpkem ej"umÀ-cp"u"qdknvqzczk o cdq o "w"|ftcx ej"À cuvp"mqx"uc" cuvq"rq|qtqxcnk"tgcmekg" urqlgp²"u"rqfcp"o"kpH|kg"l|"rtgekvnkxgppquv⁰" \ "f½xqfw"tk|kmc"|^axcflp ej"tgcmek"cnqdq"cpch{nczkg" o "a" qdknvqzczk o cd"rqf^axc "x{-mqngp "rgtuqp^an"x" o qpkvqtqxcpq o "rtquvtgf"x{dxcgpp o "pc"nkg dw" cpch{nczkg0"Rq cu"rqf^axcpkc"kpH|kg" c"pcl o gpgl"lfgpw"jqfkw"rq"lgl"rqfcp"lg"rqvtgdp²"rcekgpvqx" rq|qtpg"ungfqcxc 0

Mg flg"uc"mnkpkem²"umÀ-cpkc"x{mqp^axcnk" w"|ftcx ej"fqdtqxp p"mqx."kpH|kg"qdknvqzczk o cdw"uc"|cuvcxknk" rtk"p^auwrg"cmglmq xgm"tgcmekg0" Pc" |^ammc fg"umÀugppquv"u"kp o k" o qpqmnqp^anp{ o k"rtqvkn^avmc o k" rqwfl{xcp o k"pc nkg dw |^axcflp ej"|ftcxqvp ej"uvcxqx"lg"qdx{mng" o qlfp²"kpH|kg"fqmqp k ."cm"uc" mqpvqtqwlÀ"xjfqfp o "ur½qudq o 0" Tgcmekg"uAxkukceg"u"rqfcp"o"kpH|kg"uc" o cIA"nkg k "vcm."cmq"lg" wxgfgp²"x"vcdw mg"30

Rtgf"rqfcp"o"qdknvqzck o cdw"uc"qfrqtÀ c"rtg of g fkm^aekc"cpvkjkuvc o kpkmq o."pcrt0"fkhgj { ftc o"pq o"
*rq|tk" cu "604+0"X"mnkpkem ej"umÀ-cpkcej"u"qdknvqzck o cdq o"uc"fkhgj { ftc o"p"rqf^axcn"52 o kPv"rtgf"
nkg dqw"qdknvqzck o cdq o"Rtg of g fkm^aekc"cpvkjkuvc o kpkmq o"pg|cdt^apk"cpch{nczkk"o"½flg"o cumqxc "
cngdq"qf fkcnc "p^auvwr"rtf||pcmqx"rtgekvnkxgpquvk0

Cpvtczqx^a o gpkpikv^ffc

Qdknvqzck o cd"pgrtgej^af|c"jg o cvqgpeghcnkemqw"dctk²tw"o"pg|cdt^apk"cpvtczqxgl"o gpkpikv^ffg."cpk"lw"
pgnkg k0

Rgfkvtkem^a rqrwn^aekc

V rgfkvtkemgl"rqrwn^aeki uc"pgwumwvq pkn"flkcfpg"-vÀfkg"dg|rg pquvk"cpk"het o cmqmkpgvkm{"
qdknvqzck o cdw"rq|tk" cu "704+0

Kpvgtcmeq"u"ncdqtcv»tpf o k"vguvc o k

X{uvcxgpkg"nkgmw"P [ZV J TCEKU o ½flg"kpvgthgtqxc "uq"u²tqnq i kem o k"vguvc o k"pc"cpvtcz0

Uqtdkvqn

Mcfll "o n"nkgmw"P [ZV J TCEKU qducjwlg"58 o i"uqtdkvqnw"rq|tk" cuvk"4"o"803+0
Nkgm{"qducjwlg"uqtdkvqn"o ½flw"d{ "flkxqv"qj tq|wlg"cm"uc"rqf^axclÀ"kpvtcxgp»|pg"rcekpvpq o
u jgtgfkv^atpqw"kpvnqgtcpekq"htwmv»|{"* JHK+0"Qdknvqzck o cd"uc"pg o^a"rquwfl"xc "w rcekpvpqx"u"JHK"
qmtg o"rtf"rcfqx"lgfpg|pc pgl"mnkpkemgl"kp fkm^aekg."cm"p"uA"fqvwrp²"kp²"cngtpev{x{0"Owu"uc"x{mqpc "
fgvcknp^a"cpc o p²|c"mcfll²j q"rcekpvc"u"qj cfq o"pc"u{ o r v» o {" JHK"rtgf"rqfcp"o"vqjvq"nkgmw0

Fql cv^a"c"o cn²"fgvk"*xq"xgmw"o gpgl"cmq"4"tqm{+uA"o k o qtkcfpg"tk|kmqx^a"rqrwn^aekc."rtgvqflg"o"v-g"
pg o wuk"o c "fki pquvkmqxcPÀ"jgtgfkv^atpw"kpvnqgtcpekq"htwmv»|{"* JHK+0

Uqf^fm

Vgvpq"nkgm"qducjwlg"o gpgl"cmq"3 o o qn"uqf^fmc"*45 o i+"x"mcfllgl"8 o n"klpgm pgl"nkgmqxmg."v0 l0"
x rqfuvcvg"|cpgfdcvg p²"o pqfluvxq"uqf^fmc0

4.5 Liekovia infinterakcie

Ekrqhnqzce^fp

X"kpvgtem pgl"-vÀfkk"uc"62 À cuvp^fmq o"rqfenc"lgfpgtc|qx^a"f^axmc"qdknvqzck o cdw"uc o quvcvpg"cnqdq"
uÀdglpg"u"ekrqnqzce^fpq o 0"Rq cu";"fp^f"fqv^axcnq"42"À cuvp^fmqx"uc o qvp "qdknvqzck o cd"
c 42 À cuvp^fmqx"fqv^axcnq"qdknvqzck o cd"uÀdglpg"u"ekrqnqzce^fpom0"Rqfcpkg"kpvtcxgp»|pgl"kphÀ|kg"
qdknvqzck o cdw"x f^axmg"38 o i l m i"rtgf"kpvtcxgp»|pqw"kphÀ|kq"ekrqnqzce^fpw"cnqdq"rgtqt^anp{ o "
rqfcp"o"vodnigv"ekrqnqzce^fpw"fxcm^av"fgppg"pg| o gpknq"het o cmqmkpgvkmw"qdknvqzck o cdw0"
Qdknvqzck o ed"vemkuvq"pg| o gpkn"het o cmqmkpgvkmw"ekrqnqzce^fpw"rqf^axcp²j q"rgtqt^anp"cnqdq"
kpvtcxgp»|pg0

Pgwumwvq pkn"uc"flkcfpg" cn-kg"kpvgtem p²"-vÀfkg0"Mg flg"qdknvqzck o cd"lg"o qpqmmqp^anpc"rtqvkn^avme."
tk|kmq"kpvgtcmeq"lg"p^f|mg0

608 Hgtvknkc."i texkfkvc"o laktia

I texkfkvc

Pkg"uÀ"m"fkurq|fekk"Àfclg"q"rqwflk^f"qdknvqzck o cdw"i texkfp ej"flkqp."lg"x-cm"|p^a o g."flg" wfum "Ki I"
rtgej^af|c"rncegp^atpqw"dctk²tw0

TMvÀfkg"pc"|xkgctv^aej"pgrtgwm^a|cnk"rtk o g"cnqdq"pgrtk o g"-mqfnkx²"À kpm{"|"}j cfkumc"tgtrqfwm pgl"
vqzkek{ "rqt|tk" cu "705+0
Ako rtgxgpv^axpg"qrcvtgpkg"lg"xjqfpgl-kg"x{j pÀ "uc"wfll^axcpkw"nkgmw" P [ZVJTCEKU rq cu"itcxkfkv{0

Fql gpkg

Pkg"lg"|p^a o g." k"uc"qdknvqzck o cd"x{nw wlg"fq" wfum²jq" o nkgmc⁰"Lg"|p^a o g."flg"uc" wfum "Ki I"x{nw wlg"
fq" o cvgtum²jq" o nkgmc"rq cu"rtx ej"fp^a"rq"r^{1/2}tfqg" c |cmt^avmq potom kngupg"pc"p^a|mg"mqpegpvt^aelgl"
Rtgqv^apkg"lg" o qflp²"rq cu"vqjvq"mt^avmgjq"qdfqdkc"x{nÀ k "tk|kmq"rtg"fq gp²"fgvk⁰"Rqwfllkvg"
qdknvqzck o cdw"uc" o 1/2flg |x^aflk "rq cu"fqg pkc."kdc"cm"lg"vq"mnkpkem{"rqtgdp²0

Hgtvknkv

U"qdknvqzck o cdq o "uc"pgwumwvq pknk"-vÀfkg"htgvknkv{0

4.7 Qxrñ{xpgpkg"uejqrpqvk"xkgu "xq|kfn^a"c qdumwjxc "uvtqlg

Qdknvqzck o cd" o 1/2flg" o c " o cn "xrn{x"pc"uejqrpq "xkgu "xq|kfn^a"c qdumwjxc "uvtqlg."rtgvqflg"rq"
rqfcp^a"nkgmw" P [ZVJTCEKU uc" o 1/2flw"x{um{vpÀ "dqnguvk"jnxc{"|"}^axtcv{"Apcc" c"xtcecpkq"rq|tk" cu "
60: +0

4.8 Pgfllcfweg"À kpm{

UÀjtp"dg|rg pquvp²jq"rtqhkñw

Dg|rg pqu "qdknvqzck o cdw"uc"umÀ o cnc"kdc" w"|ftcx ej"fqrgn ej"lgfkpeqx0

Dg|rg pqu "qdknvqzck o cdw"uc"jqfppqknc"x"vtqej"mnkpkem ej"-vÀfkaej" w"542 |ftcx ej"À cuvp^amqx"xq"
xgmw"qf"3:"fq"9; tqmqx+nkg gp ej"lgfpqw"cnqdq"fxq o c"kpvtcxgp»|p{ o k"fa xmc o k"38 o ilmi0

Egnmqxq"472"| "542 À cuvp^amqx"fqvcnq"lgfpqtc|qxÀ f^axmw"38 o ilmi"qdknvqzck o cdw⁰"Pgfllcfweg"
tgcmeqg"urqlgp²"u"rtgkvnkxgpqu qw*x^atpcp^ax{t^aflm{+}uc"x{um{vnc" w"; ' '*441472+v ejvq"À cuvp^amqx."
u lgfp o"rt^arcf^ao"cpch{nczkq."mvqt^auc"x{um{vnc"rq cu"rqf^axcpkc"kpHÀ|kg⁰"kpHÀ|kc"dqnc"rtgtw-gp^a"
w 5 ' '*:1472+À cuvp^amqx"|f^{1/2}xqfw"rtgkvnkxgpquk"cnqdq"cpch{nczkq0

Pcl cuvgl-kg"jn^augp o k"pgfllcfweg" o k"tgcmeq o k"dqnc"dqnguvk"jnxc{"*6 ' .";1472+."rtwtkvwu"*6 ' .";1472+
c wtkm^atkc"*4 ' .".81472+0

Pcl cuvgl-kg"rq|qtqxc²"pgfllcfweg"tgcmeqg"rq cu"rtx ej"vtqej"jqf^ap"rq"|c cv^a r^aqf^axcpkc"kpHÀ|kg"dqnc"
rtwtkvwu"*p"?9="4.: ' .".wtkm^atkc"*p"?8="4.6 ' +."dqngu "jnxc{"*p"?6="3.8 ' +."x{t^aflmc"*p"?5="3.4 ' +."
mc-g "*p"?5="3.4 ' +."|^axtcv{"*p"?5="3.4 ' +}*|c j " c"|^axtcv{"c"rquvwt^anpq"|^axtcv{+0
Vkgvq"|^axclp²"pgfllcfweg"tgcmeqg"uc"x{um{vnc"rq cu"rtx ej"vtqej"jqf^ap"rq"rqfcp^a|kpHÀ|ke<"wtkm^atkc"*p"?
3."2.6 ' +."rtwtkvwu"*p"?3."2.6 ' +c"dqngu "ejtdvc"*p"?3."2.6 ' +0

Pcl cuvgl-kg"rq|qtqxc²"pgfllcfweg"tgcmeqg"fq"5 cfl"46 jqf^ap"rq"|c cv^a r^aqf^axcpkc"kpHÀ|kg"dqnc"
dqngu "jnxc{"*p"?5="3.4 ' +0

Vcdw mqx "rtgj cf pgfllcfweej"tgcmeq

X"vcdw mg"6"uÀ"wxgfgp²"pgfllcfweg"tgcmeqg. tq|fgngp²"rqf c"vtkgf{"qti^apqx ej"u{uv² o qx" c"htgmngxgpek"
x um{vw."rq|qtqxc²"rtk"rqwflkv^a"qdknvqzck o cdw" w"472 |ftcx ej"qu^{1/2}d."mvqt^a"fqvcnk"lgfpqtc|qxÀ
kpvtcxgp»|pw" f^axmw"38 o ilmi"qdknvqzck o cdw0

Htgmngxgpek"pgfllcfweej"tgcmeq"lg"fgkppxcp^a"pcungf^axpg<"xg ok" cuv²"*x 3132+." cuv²"*x 31322" cfl"
< 3132+ c o gpgl" cuv²"*x 1/1 222" cfl"> 31322+0"X t^a o ek"lgfpqvnkx ej"umwr^a"p"htgmngxgpek"uÀ"pgfllcfweg"
tgcmeqg"wxgfgp²"x rqtcf^a"mguclÀeg1"|^axclpqukv0

Vcdw mc"6<"Pgfllcfweg"tgcmeqg"jn^augp²"w"|ftcx ej"fqrgn ej"os²

Vtkgfc"qti ^a pqx ej"u{uv ² o qx" rqf c"fcvcd ^a {"OgfFTC	cuv ²	Ogpgl" cuv ²
Rqtwej {"k o wpkvp ² jq"u{uv ² o w		cpch{ncmvkem ^a "tgcmeck rtgekvnkxgpqu
Rqtwej {"pgtxqx ² jq"u{uv ² o w	dqngu "jncx{	^a xtecv{ rqvwt ^a npq" ^a xtecv{ j{rqguv ² kc
Rqtwej {"qmc		hqvqh»dkc
Rqtwej {"wejc" c ncd{tkpw		fkumq o hqtv"x"wejw
Rqtwej {"ekgx		hngdkv fc
Rqtwej {"f ejcegl"uÀuvex{"j twfp mc" c o gfkcu pc	mc-g	rqft ^a flfgpkq"jtfnc f{uh»pkc mqpi guek"u pwuqx f{urpqg
Rqtwej {"i cuvtqkpvguv ^a npqj q"vtcmvw		dqngu "rkg
Rqtwej {"mqflg" c rqf mqflp ² jq" vmcpxc	rtwtkvwu."wtvkm ^a tkc x{t ^a flmc	cngtikem ^a "fgt o cwk fc i gpgtcn qxep ^a "x{t ^a flmc gzhqk ^a ekc"mqflg
Rqtwej {"mqvtxqgl" c uxcnqxgl" uÀuvex{ c urqlkxqx ² jq"vmcpxc		dqngu "x"mqp cvkpg uxcnqx ² "m g" uxcnqx ² " ^a -mnd{ dqngu " g wuvg"
Egnmqx ² "rqtwej {"c tgcmeqg"x" o kguvq"rqfcpkc	dqngu "x" o kguvq" rqfcpkc"kpHÀ kg	dqngu fkumq o hqtv"x"j twfp mw k o pkc Àpcxc qrwej"x" o kguvq"rqfcpkc"kpHÀ kg dqngu "x"j twfp mw"pgmctfk ^a npqj q" r½xqfw ekvnkxqu dqngu "x" o kguvq"rtgrkejpwkc"ekgx{

Orku"x{dtecp ej"pgflkfwekej"tgcmeq|

Rtgekvnkxgpqu "c"cpch{nczkc

Pgflkfweg" tgcmeqg" jn^augp²" w": qu½d." w" mvqt ej" dqnc" kphÀ|kc" qdknvqzczo cdw" rtgtw-gp^a" rtg" o qflpÀ"
rtgekvnkxgpqu ." |cj cnk" wtvkm^atkw." x{t^aflmw." mc-g ." rtwtkvwu." |^axtecv{." rqft^aflfgpkq" jtfnc." f{uh»pkw."
f{urpqg" c"fkumq o hqtv"x"j twfp|mw0"Quvevp²"quqd{"u"rtgekvnkxgpqu qw" o cnk"rtgxcflpg"mqflp²"rt|pcm{."cmq"
uÀ" rtwtkvwu" c" x{t^aflmc." c" 8 qu½d" jn^auknq" mc-g 0" Wfcnqu " cpch{nczkg" dqnc" ejctcmvgtk|qxcp^a fkhÀ|pqw"
uxtdkceqw" wtvkmctk^anpq" w" x{t^aflmqw" pc" x0 -kpg" vgn" xt^avcpq" mtmw." j twfp|mc." ejtdvc." dtwejc." tÀm" c" p½j."
f ejcxk pqw qw" e"mc- qo0

PggzkuvwIÀ" f½mcl{|}q"vq o." flg" tgcmeqg" |" rtgekvnkxgpquv" c" x{t^aflm{" dqnk" x{qxncp²" wxq ppp|o" e{vqm|pqx="
pgdqk"rq|qtqxcp²"mnkpkem{"x |pc o p²"| o gp{"x"e{vqm|pqej0

Imunogenita

X|pkm"rtqvkn^avqm"rtqv"qdknvqzczo cdw"uc"jqfppqvk"x"vtqej"mnkpkem ej"-vÀfk^aej" w"x-gvm ej"À cuvp|mqx."
mvqt|"fquvcnk"lgfpqtc|qxÀ" c" fxlkvÀ" f^axmw" qdknvqzczo cdw0" Qug o" À cuvp|mqx"]4.7 ' ' * :1542+_" mvqt|"
fquvcnk" pel o gpgl" lgfpw" kpvtxegp»|pw" f^axmw" qdknvqzczo cdw." ocnq" rq|kv|xpw" qfrqyg " pc"
cpkvgtcrgvwkem²"rtqvkn^avm{"*CVC. cpvk-vjgtergwke"cpvkddf{"+rq cu"nkg d{0"Mxcpvkcv|xpg"vkvtg"dqk"p|mg"
x" tq|ogf|q" qf" 3:42" fq" 3:5420" W" À cuvp|mqx" u" qfrqyg qw" pc" CVC" uc" pg|kuvknk" f½mcl{|} | o gpgpgl"
hct o cmqmkpvgkm{"cngdq"rtqhknw"vqzkekv{0

Jn^augpkg"rqfq|tgp"pc"pgflkfweg"tgcmeqg

Jn^augpkg"rqfq|tgp"pc"pgflkfweg"tgcmeqg"rq"tgi kvu^aekk"nkgmw"lg"fl/2ngflkv²0"wo qfl wlg"rtkdgflp²"
o qpkvqtqxcpgk"rq o gtw"rt"pquw"ctk|kmc"nkgmw⁰"Qf"|ftcxqvp"em{ej"rtceqxp"mqx"uc"x{flcfwlg."cd{"jn^auknk"
cm²mq xgm"rqfq|tgp"pc"pgflkfweg"tgcmeqg"pc"p^atqfp²"egpvtw o "jn^augpkc"wxgfgp²"x [Rt"nqjg"X0](#)

4.9 Predkovanie

X"rt"rcfg"rtgf^axmqxcpkc"lg"rqvtgdp²"rcekgpvqx"ungfqxc ."k"uc"w"pkej"pgx{um{vwl^acm²mq xgm"rtgicx{"
cngdq"rt"|pcm{"pgflkfweg"tgcmeqg"pc"p^atqfp²"egpvtw o "jn^augpkc"wxgfgp²"x

5. FARMAKOLOGICKÉ VLASTNOSTI

5.1 Farmakodynamické vlastnosti

Hcto cmqvtcrgwvkm^a"umwrkpc"K o wpou²tc"ck o wpqi nqdw"p{".-rgekhem²"k o wpqi nqdw"p{"."CVE"m»f<"
L28DD44

Ogejcpk|owu^akpmw

Qdknvqzczo cd"lg"o qpqmnp^anpc"rtqvkn^avmc."mvqt^axkcf"qejtcpp"cpvki²p"dcmv²tkg"*B. anthracis*⁰"
Qdknvqzczo cd"kpjkdwl"pcxkc|cpkg"qejtcpp²j"cpvki²pw"pc"lg"j"q"dwpmqx²"tgegrvqt{"c v o"dt^apk"
kpvtegnw^atpgo w"xuvrwr"u o tvg p²j"q"hcqvte"cpvtczw"c"hcqvte"gf²o w." q u^a"|nqflm{"gp|{o cvkem²j"q"
vqz"pw"|qfrqxfp²"|c"rcvqi²ppg^akpm{"vqz"pw"cpvtczw

Hcto cmqf{pc o kem²"^akpm{

Qdknvqzczo cd"xkcf"qx p "qejtcpp"cpvki²p"u"tqxpx^aflp"q"fkuekcc pqw"mqp-vcpvq"chkpkv{"*Mf+
2.55 pO⁰

In vitro uc"qdknvqzczo cd"xkcf"pc"qejtcpp"cpvki²p|"m o g qx"C o gu."Xqnmw o "c"Uvgtpg"dcmv²tkg"*B. anthracis*⁰"
Grkvq"pc"qejtcpp"cpvki²pw"pc"mvqt "uc"xkcf"qdknvqzczo cd."lg"j"n^augp ej"m o g qx"*B. anthracis* |cejqxc p⁰

TMv^afk"*in vitro* x"dwpmqxl"cpcn |g"u"rqwflk"o "o {-ce"ej"o cmtq^ai qx"pc|pc w^al."flg"qdknvqzczo cd"
pgwvtcnk|wlg"vqzkm²"^akpm{"u o tvg p²j"q"vqz"pw." q"lg"mq o dkp^aekc qejtcpp²j"q"cpvki²pw"u o tvg p²j"q"
hcqvte⁰

TMv^afk"^akppquk"*in vivo* pc"pqxq|²npcfum ej"dkgn{ej"mt^ankmqej"co cmcmqej"fnjqejxquv ej"
x{uvcxgp ej"ur»tc o "*B. anthracis* m o g c"C o gu"kpjcnc pqw"eguvq"rtgwm^a|cnk"rtgf flgpk"rtgflkvc"rq"
nkg dg"qdknvqzczo cdq o "a xkm²"qf"fa xm{"Gzrq|"ekc"ur»tc o "*B. anthracis* xkgfnc"m"|x -gpkw"
mqpegvt^aek"qejtcpp²j"q"cpvki²pw"x"u²tg"pqxq|²npcfum ej"dkgn{ej"mt^ankmqej"co cmcmqej"fnjqejxquv ej⁰"
Po lig dg"qdknvqzczo cdq o "fq-nq"m"rqmnguw"mqpegvt^aek"qejtcpp²j"q"cpvki²pw"wx⁰ -kp{"|xkgtcv." q"
rtgflknk⁰"Mqpegvt^aek"qejtcpp²j"q"cpvki²pw"|"xkgtcv."mvqt o "dqng"rqf^axcp²"rncegdq."uc"|x{-qxcnk"cf"
fq"u o tvk⁰

— kppqu

Rtgvlq"pk"lg"wumwvq pkv p²"cngdq"gvkem²"x{mqp^axc mqpvtnqxcp²"mnkpkem²um^a-cpkc"w" wf"
u kpjcnc p o"cpvtczq o."^akppqu "qdknvqzczo cdw"rqf^axcp²j"q"x"o qpqvtcrrk"x"rtqtxpcp"u"rncegdq o"
rtknkg dg"kpjcnc p²j"q"cpvtczw"lg"|cnqflgp^apc"-v^afk^aej"^akppquk"pc"pqxq|²npcfum ej"dkgn{ej"mt^ankmqej"
c o cmcmqej dnjqejxquv ej⁰

X^v ejvq"-v^afk^aej"dqnk"|xkgtcv^a"x{uvcxgp²"cgtqu»nw"ur»t"*B. anthracis* *m o g "C o gu+"x"rtkdnkflp"422"z"
NF₅₀ c^aungfpg dqnk"x"t^{1/2}|p{ej"cuqx ej"dqf"qej"nkg gp²"qdknvqzczo cdq o⁰"X"-v^afk^aej"nkg d{"
kpjcnc p²j"q"cpvtczw"uc"|xkgtcv^a o"rqf^axenc"nkg dc"rqvq o."cmq"uc"w"pkej"rtglcxknk"mnkpkem²"rtglcx{"cngdq"
rt"|pcm{"u{uv²o qx²j"q"cpvtczw⁰"X"quv-gzrq|k p ej"rtqh{ncmvkem ej"-v^afk^aej"dqnk"|xkgtcv^a"nkg gp²"rq"

gZRQ|fkk"dcmv²tkk"B. anthracis."cng"rtgf"tq| xkpww"o u{ o rv» o qx0"Ocmcm{ "fnjqejxqv²"dqnk"nkg gp²"
 x cug"rq|kv|xpgjq"vguvw"ngmvtqejgo knw o kpkuegpekq"GEN+x"u²tg"pc"qejtcpp "cpvki²p"dcmv²tkg"B.
 anthracis u rtkgogtp o" cuqo" rtkdnkflpg"62 jqf"p"rq"x{uvcxgp"dcmv²tkk"B. anthracis0"X"-vÀfk^aej"nkg d{
 pqxq|²ncpfum ej"dkgn{ej"mt^ankmgx"dqnk"|xkgtcv^a"nkg gp²"rq"rq|kv|xpgjq"vguvw"GEN"pc"qejtcpp "cpvki²p"
 cngdq"rq"rtgvtx^axclAeqo"|x -gp"o"vnggupgl"vgrnqv{"pcf"x ejqfkumqxÀ"jqfppqv."u"rtkgogtp o" cuqo"
 rtkdnkflpg"52 jqf"p"rq"x{uvcxgp"0"X"pkfl-kg"qr"ucp ej"-vÀfk^aej"uc"rtgflkvkq"jqfppqvknq"4: fp"rq"qphkmqxcp"
 dcmv²tkqw"B. anthracis0

— kppqu "lgfpqtc|qxgl"kpvtcxgp»|pgl"fa^axm{"qdknvqzczk o cdw"x"o qpqvgtcrkk"pc"nkg dw"kpjcnc p²jq"
 cpvtczw"uc"jqfppqvknq"x"lgfpgl"-vÀfk"lq -vÀfk"pc"pqxq|²ncpfum ej"dkgn{ej"mt^ankmgqej"cx"vtqej"-vÀfk^aej"
 pc"o cmcmqej"fnjqejxqv ej"*CR424."CR426"CR523+="x-gvm{"-vÀfkq"dqnk"rncegdq o"mqpvtqhxcp²."
 tcpfqok|qxcp²"c"ur cnk"rqflkfcxcm{"urt^axpgl"ncdqtcv»tpgl"rtczgl"vÀfkq"CT255."CR424"CR523"dqnk"
 |cungrgp²="-vÀfkq"CR426"dqnc"|cungrgp^a"x|j cfqo"pc"umwrkpw0

Vedw mc 7<"Okgtc"rtgfl"viania x"-vÀfk^aej"À kppquvk"qdknvqzczk o cdu v monoterapii *38 o ilmi+

		Rqfkg"rtgfl"viania na konci štĕie * "]rtgflkx- ejlp ₊	Hodnota p ²	95 % IS ³
		Placebo	Qdknvqzczk o cd"38 o ilmi	
Nkg dc"- Novozĕandskĕie krĕky				
TM _{vÀfk} "CT255 ¹	2"*2135+	83.7 ' "":135+	2.2235,	*2.4;2."2.:83+
Nkg dc"- Makaky dlhochovstĕĕ				
TM _{vÀfk} "CR426 ¹	8 ' "":3138+	68.9 ' "":9137+	2.228: ,	*2.2: ;".2.8:3+
TM _{vÀfk} "CR424 ¹	2"*2139+	53.5 ' "":7138+	2.22:7,	*2.29;".2.7:9+"
Post-gzrq k p^a"rroflaxia – Makaky dlhochovstĕĕ				
TM _{vÀfk} " CR523 ⁶	3:"j po gzrq fkk	2"*218+	100 ' "":818+	2.2234, *2.693."3.222+
	46"j po gzrq fkk	--	:5 ' "":718+	2.2264, *2.452."2.:;8+
	58"j po gzrq fkk	--	50 ' "":518+	2.2567 (-2.259."2.: :4+

KU<"kpvtxcn"urq c jnkxquvk

¹ Rtgfl"xcpkq jqfppqv²4: fp"rq"x{uvcxgp"ur»tc o."x-gvm{"tcpfqok|qxcp²"|xkgtcv^a"rq|kv|xpg"pc"
 dcmvgtk²okw"rtgf"nkg dqw."nkg dc"x{xqncp^a"x |pcop o"|x -gp"o"vnggupgl"vgrnqv{"-vÀfkq"CT255+
 cngdq"rq|kv|xpgjq"vguvw"ngmvtqejgo knw o kpkuegpekq"qejtcpp²jq"cpvki²pw"-vÀfkq"CR426"
 c CR424+0

⁴ p-jqfppqv"lg"|lgfpgl"cpvtcxgp²jq"Dquejnqxxjq"vguvw"*u"Dgtigt-Dquqxq"o qfkhk^aekw"ic o c"? "2.223+
 x rqtqxcpp"u"rncegdq o

⁵ Rtgup " ;7 ' "kpvtxcn"urq c jnkxquvk"tq|fkgw"x"okgtg"rtgflkvk

⁶ Rtgflkvkq"uc"jqfppqvknq"4: fp"rq"x{uvcxgp"ur»tc o

* Q|pc wlg"-vcvkemÀ"x |pcopqu "pc"Àtqxp"2.247

Rgfkvtkem^a"rqrwn^aekc

Gwt»rumc"ci gpvÀtc"rtg"nkgm{"wfgnkq"qfmncf"| rqxkppquvk"rtgfnqflk "x ungfim{"-vÀfk"u liekom
 P [ZVJ TCEKU x lgfpgl"cnqdq"xqxcegt ej"rqfumwrkpa ej"rgfkvtkemgl"rqrwn^aekg rtg"nkg dw"
 dcmvgtk^anpgl"qphgmekq"qkphqt o^aekg"q rqwflkv"x rgfkvtkemgl"rqrwn^aekk."rq|tk" cu "604+0

Vgpvq"nkgm"dnq"tgikvtxcp "|c"v|x0"okoqtkcfp{ej"qmqqquv"0"Vq"|pcogp^a."flg"rtg"|tkgfmcxqu "x um{vw"
 vqjvq"qejtgpkc"|"gkem ej" f¹/2xqfqx"pgdq"o qflp²"|umc "x-gvm{"kphqt o^aekg"q vq o vq"nkgmw0
 Gwt»rumc"ci gpvÀtc"rtg"nkgm{"mclfl "tqm"rquÀfk"pqx²"fquvwrp²"kphqt o^aekg"q vq o vq"nkgmw" c vgpvq"uÀjtp"
 ejctcmvgtkukem ej"xncuvpquv"nkgmw"dwfg"rqf c"rqvtgd{"cmvvcnk|qxc 0

5.2 Farmakokinetické vlastnosti

Cduqtrekc

Hct o cmqmkpgvkmc"qdknvqzck o cdw"lg"nkpq^atpc"x"tq | ogf | f^axqm"qf"6 o ilmi "2.47-p^auqdm"pclpkf-gl" qfrqtÀ cpgl" f^axm{+ "fq"38 o ilmi "rq"lgfpqtc|qxq o "kpvtxgp»|pq o "rqfcp" | ftex o "quqd^a o "Rq" lgfpqtc|qxq o "kpvtxgp»|pq o "rqfcp" qdknvqzck o cdw"38 o ilmi" | ftex o "quqd^a o mwflum²jq c flgpum²jq"rqjncxkc dqnk"rtkg o gtp²"jqfppv{ "E_{ocz} 622"Ö"; 3.4 Üil on" c" CWE_{kph} 5 392"Ö"3 582 Üi fg lon" Rqn cu"qdknvqzck o cdw"dqn"rtkdnkflpg"42 fp"rtkg o gt+0

FkuvtkdÄekc

Rtkg o gtp "fkuvtkdw p "qdlg o "qdknvqzck o cdw"x"tqpxq^aflpq o "uvcxg"dqn"9;.9"Ö"3;.4 ml lmi "c"x@ -"cmq" rnc | o cvkem "qdlg o." q"pc|pc wlg"wt kvÀ"fkuvtkdÄekw"x"vmcpkx^aej0

Dkqvtepuhqt o ^aekc

U"qdknvqzck o cdq o "uc"pgwumwvq pknk"flkcfpg"htq o "npg"-vÄfkg" o gvcdqnk | o w0 Fkurq | f^aekc" o qpqmnp^anp {ej "rtqkn^avqm"x-cm" | x{ clpg" | c j c"fkuvtkdÄekw" o k o q"xcumwn^atpgj q" rtkguvqtw" u"rqvqpek^anp { o "xuvwrq o "fq"vmcp" | x" c"mcvcdqnk | o wu"rtqvg^a | c o k"pc o c²" rgrvkf { "c" o c kpm { ugnkp { ."mvqt²" uc"p^aungfpg" | c ngpkc"fq"gpfi²ppgj q" | ftqlc"engdq"uc"x{nÄ kc0

Gnk o kp^aekc

Rtkg o gtp²"jqfppv{ "mn"tgpw"qdknvqzck o cdw"dqn"5.57"Ö"2;.54 o n l lmi "c"qxg c"pkf-k g cmq"t ej nqu " inq o gtw^atpgl"hnvt^aekg." q"pc|pc wlg."flg"tgp^anp { "mn"tgpw"qdknvqzck o cdw"pkg"lg" rtmvkem { "flkcfp {0

Quqdkvp²"umwrkp { "rcekp^aqx

Xrn{x"rqjncxkc."xgmw" c"tcu{

Hct o cmqmkpgvkmc"qdknvqzck o cdw"uc"jqfppqknc"pc" | ^amncfg"rqrwnc pgl"ht o cmqmkpgvkemgl"cpnc | { " u rqwflv" | o "x | qtkgm"u²c"qf"592 | ftex ej "Ä cuvp"mqx."mvqt" fquvcnk"lgfpqtc | qxÄ kpvtxgp» | pw" f^axmw" x 6 mnkpkem ej "umÄ-cpkcej"0" P c" | ^amncfg"vglvq"cpnc | { "pg o cno rqjncxkg"*flgpum²"oproti o wflum² o w+. "tcuc" *pgmcwmc | um^aoproti mcwmc | umej+ "epk xgm" *uvct- "oproti oncf o + "x | pc o p "xrn{x"pc"ht o cmqmkpgvkem²" rctc o gvtg"qdknvqzck o cdw"0" Mnkpem²" -vÄfkg"u"qdknvqzck o cdq o "x-cm"pg | c j cnk" fquvcvq p "rq gv" Ä cuvp"mqx"xq"xgmw"87 tqmqx" c uct- "ej"pc"wt gpkg." k"uc"kej"ht o cmqmkpgvkmc"n"-k"qf" o ncf- "ej" Ä cuvp"mqx"0" \ "542 Ä cuvp"mqx"x"mnkpkem ej "-vÄfk^aej"u"qdknvqzck o cdq o "o cnq"; .6 " "521542+" Ä cuvp"mqx"87 tqmqx" c" xkce. | cvkc " q"4 " "81542+" Ä cuvp"mqx" o cnq"97 tqmqx" c" xkce0

— kpm{ "uÄxkukceg"u"vngupqw"j o qvpqu gw

Mn"tgpw"rtk{x"uqmg"vngupgl"j o qvpquv"32; mi+"dq"rtkdnkflpg"q"5: "x{-"cmq"x"tghgtgp pgl"rqrw^aekk0" Rq"rqfcp" f^axm{ "pc" | ^amncfg"vngupgl"j o qvpquv"38 o ilmi+"vq"xgfk"m" | x -gpkw" CWE_{kph} q"34 " . " q"pkg" lg"mnkpkem { "x | pc o p²0

Pediatrické zopulžka

U fg"uc"ht o cmqmkpgvkmc"qdknvqzck o cdw"pgjqfppqknc"0" Qf rqtÄ cpkc"rtg" f^axmqxcpkg"wxgfgp²" x vcdw mg"4"* cu "604+"uÄ"qfxqfgp²" | q"uk o wn^aek" | x" wfl"xclÄekj"rqrwnc p "ht o cmqmkpgvkem "rt"uvwr" p cxtj p wv "vcn."cd { | qfrxgfcn"rq | qtqxcpgl"gzrq | f^aek" fquvgn ej"qdknvqzck o cdw"rtk" f^axmg"38 o ilmi0

5.3 Predklinické údaje o dg | rg pqukv

Rtgf mnkpkem² Ä fclg" | f^aumcp²"pc" | ^amncfg"qdx { mn ej"ht o cmqnikem ej"-vÄfk"dg | rg pqukv."vzkekv { "rq" qrcmqxcpq o "rq" f^axcp" | c tgrtqfwm pgl"vzkekv { "c x xkpw"pgqf j cnknk"flkcfpg"quqdkvp²"tk | kmq"rtg w f"0

N² | kg"egpvt^anpj q"pgtxqx² j q"u { uv² o w"*dcmv²tkg. | a rcn { ."mtx^aecpkg" c"rt"ngflkvquvpg"pgmt> | c+"uc" rq | qtqxcnk" w"pqxq | ²ncpfum ej"dkgn { ej"mt^ankmaq" c" w" o cmcmqx"fnj qej xquv ej" kphkmqxc p ej"cpvtczq o."

mvqt² pgrtgflknk" c" mvqt o "dqnx" cug" rqvxtfgpkc" qejqtgpkc" kpvtxcgp» | pg" rqfcp " qdknvqzczk o cd"
*× 6 o ilmi+ "cngdq" mqvptqna^a "n^a vmc" * rncegdq+0" Okmtqumqrkem²" | o gp{ "w" | xkgtecv. "mvqt² pgrtgflknk" c" mvqt²
fqv^a xcnk" qdknvqzczk o cd. "dqnk" ur^{1/2} uqdg² rt^{1/2} vq o pqu qw" gzvtxcumwn^a tp{ ej " dcmv² tk". "c" pkg" A kpmq o "
qdknvqzczk o cdw⁰ Rtk" jkuvqrcvqn» ikk" o q | i w" uc" pg | kuvkn" x | c j" qf r q x g f g" c" f^a x m { 0" U cpvtczq o "
kphkmqxc p ej " p q x q | 2 ncpfum ej " dkg n { ej " m t^a n k m q x. " m v q t² r t g f l k n k " * p c " 4 : 0 f g +. " c p k " w " o c m c m q x "
f n j q e j x q u v e j " * f q " 7 8 0 f c + u c " r q " l g f p q t c | q x q o " r q f c p " q d k n v q z c z k o c d w " x " f^a x m g " c f " f q " 3 8 m g / k g "
* m t^a n k m { + " c c f l " f q " 5 4 m g / k g * o c m c m { + p g | k u v k n k " n² | k g " x " o q | i w " u A x k u k c e g " u " n k g d q w⁰ " W " o c m c m q x "
f n j q e j x q u v e j " k p h k m q x c p e j " c p v t c z q o . " m v q t² r t g f l k n k . " u c " r q " n k g d g " q d k n v q z c z k o c d q o " p g r q | q t q x c n k "
f l c f p g " p g w t q d g j c x k q t^a n p g " A k p m { " u A x k u k c e g " u " q d k n v q z c z k o c d q o 0

Lg f p c " - v A f k c " g o d t { q p^a n p g j q l h g v^a n p g j q " x x q l c " u c " x { m q p c n c " w " i t c x k f p e j . " | f t c x e j " p q x q | 2 n c p f u m e j "
d k g n { e j " m t^a n k m q x . " m v q t o " u c " r q f^a x c n k " 6 k p v t c x g p » | p g " f^a x m { " q d k n v q z c z k o c d w " c f l " f q " 5 4 m g / k g "
* f x q l p^a u q d q m " f^a x m { " w " w f . " x { l c f t g p² " x " o i l m i + " p c " 8 0 . " 3 2 0 . " 3 5 0 " c " 3 9 0 i g u v c p " f g 0 " P g r q | q t q x c n k " u c "
f l c f p g " f^{1/2} m c | { " r q - m q f g p k c " u r^{1/2} u q d g p² " q d k n v q z c z k o c d q o " w " i t c x k f p g l " o c v m { " c p k " w " n q f w⁰ " M w o w n c v " x p g "
g z r q | e k g " w " p q x q | 2 n c p f u m e j " d k g n { e j " m t^a n k m q x * 3 2 0 0 0 i E f g l o n + " r t k " P Q C G N " 5 4 o i l m i l f^a x m c " * p " ? "
6 f^a x m { + " p c " |^a m n c f g " C W E₀₋₁₅ f p " d q n k " r t k d n k f l p g " f x q l p^a u q d p² " x " r q t q x p c p " u " m g o d k p q x c p q w " r t k g o g t p q w "
C W E " w " o w f l q " c " f l k g p " r t k " m n k p k e m g l " k p v t c x g p » | p g l " f^a x m g " 3 8 o i l m i 0 " J q f p q v " E o z r q " r q f c p " "
5 4 o i l m i l f^a x m c " d q n k " 3 3 : 2 i E f g l o n 0

U" qdknvqzczk o cdq o "uc" pgwumwvq pknk" -vÀfkg" mctekpqi gpkv{ . " igpqvzkekv{ "c" hgtvknkv{ 0

80 FARMACEUTICKÉ INFORMACE

803 \q|pc o"rq o qep ej"n^avqm

j kuvk f^{1/2} p
u q t d k v q n * G 6 4 2 +
r q n { u q t d^a v : 2 * G 6 5 5 +
m { u g n k p c " e j n q t q x q f " m q x^a * G 7 2 9 . " p c " À r t c x w " r J +
j { f t q z k f " u q f p " * G 7 4 6 . " p c " À r t c x w " r J +
x q f c " p c " k p l g m e k g

804 Inkompatibility

V g p v q " n k g m " u c " p g u o k g " o k g - c " u k p o k " n k g m o k " q m t g o " v e j . " m v q t² u À " w x g f g p² " x c u v k " 8 0 8 0

805 cu"rqwflkg pquvk

P g q v x q t g p^a " k p l g m p^a " n k m q x m c

9 t q m q x

\ t k g f g p " t q | v q m " x " k p h À | p q o " x c m w

P q | t k g f g p " x " k p h À | p q o " x c m w " d q n c e j g o k e m^a . " h { | k m^a n p c " c " o k m t q d k^a n p c " u v c d k n k v c " r t k " r q w f l " x c p l " "
r t g w m^a | c p^a " r q " f q d w " : j q f^{1/2} p " r t k " k | d q x g l " v g r n q v g " * 4 2 ° C - 4 7 Å E + " c n g d q " x " e j n c f p k m g " * 4 ° C - : Å E + 0

\ " o k m t q d k n q i k e m² j q " j c f k u m c " u c " o^a " n k g m " r q w f l k g " q m c o f l k v g . " c m " o g v » f c " q v x^a t c p k c l t g m q p - v k v À e k g l t k g f g p k c " "
p g x { n w w l g " t k | k m q " o k m t q d k^a n p g l " m q p v c o k p^a e k g 0

C m " u c " n k g m " p g r q w f l k g " q m c o f l k v g . " | c " c u " c " r q f o k g p m { " w e j q x^a x c p k c " r q c u " r q w f l " x c p k c " | q f r q x g f^a "
r q w f l " x c v g 0

\tkgfgp "tq|vqm"x"kpHÀ|pgl"uvtkgmc mg

\tkgfgp "tq|vqm"nkgmw"P [ZVJTCEKU uc"o^a"rq"rt"rtcxg"qmc o flkv"rqfc "c"pgwejqx^axc 0"Cm mq xgm" pgrqwfkv "nkgm"uc"o^a"|nkmxkfqxc 0

806 Špeciálne upozornenia na uchovávanie

Wejqx^axclvg"x"ejncfpk mg^{*4} °C – : ÅE+0
Pgwejqx^axclvg"x otc|pk mg0
Wejqx^axclvg"x r½xqfppq o "qdcng"pc"qejtcpw"rtgf"uxgvnq o 0

Rqf okgpm{"wejqx^axcpkc rq"tkgfgp"nkgmw."rq|tk" cu "8050

807 Druh obalu a obsah balenia

822 o il8 on"mqpegpvt^avw"x"kpIgm pgl"nkgmqxmg"*umnq"v{rw"K+u"iwoqxqw"|^avmqwc"rq|rtqr{n²pqx o" xkg mq o"u"jnkpmqx o" w|^axgtq o 0
Dcngpkg"qducjwlg"3 kplgm pÀ"nkgmqxmw0

808 Špeciálne opatrenia na likvidáciu a inžinierstvo s liekom

F½ngflkv²"rqm{p{"pc"rt"rtcxw

- € Rtgf"rqfcp"o"lg"rqvtgdp²"kpHÀ|p{"mqpegpvt^av"xk|w^anpq"umqpvtnqxc "pc"rt"vq o pqu " cuv"e" c |ogpw"htcd{0"P [ZVJTCEKU lg" t{"cfl"qrenk|wLek"dg|htgdp "cfl"uxgvnqflnv cfl uxgvnqjppgfq-flnv "tq|vqm."mvqt "o½flg"qducjxqc "pkgmq mq"priej cfp ej cfl"dkgn{ej"dkgnmqxkpx ej" cuv"e" *mvqt²"uc"qfuvt^apk"kp-nkpg"hnvt^aekw+0
- € Kplgm pÀ"nkgmqxmw"|nkmxkfwlvq."cm"o^a"tq|vqm"|ogp pÀ"htcdw"cnqdq"qducjwlg"ewf|qtqf² cuvkeg" *rq|tk" cu "5+0
- € Kplgm pÀ"nkgmqxmw"pgrtgtgr^axclvg0

Rt"rtcxw"o"tkgfgpk"x"kpHÀ|pq o "xcmw

- 30 X{rq "vclvg"rqvtgdp²"o pqlvuxq"qdknvqzczk o cdw"x"o knki tco qej"x{p^auqdgp"o"qf rqtÀ cpgl" f^axm{"x"o ilmi"x"vcdw mg⁴*rq|tk" cu "604+"vngupqw"j o qvpqu qw"kp f k x k f w^anpqj"q rcekpvc" x mknqitco qej0
- 40 X{rq "vclvg"rqfclqxc"qdlg o"mqpegpvt^avw"qdknvqzczk o cdw"pc"kpHÀ|p{"tq|vqm"x"o knknvtqej" c rq gv"kpIgm p ej "nkgmqxkmg"rqvtgdp ej"pc" f^axmw"x{fgngp"o"x{rq "vcpgl" f^axm{"x"o knki tco qej" *30"mtqm+"mqpegpvt^aekw"322 o ilon0"Mcfl f^a"kplgm p^a"nkgmqxmc"wo qfl wlg"pqfcpkg"8 ml mqpegpvt^avw"qdknvqzczk o cdw pc"kpHÀ|p{ tq|vqm0
- 50 \xq vg kpHÀ|p{"xcm"xjqfpgl"xg mquvk"u"kpIgm p o"tq|vqm"o"ejnqtqfw"uqfp²jqu mqpegpvt^aekw" ; o ilon"2. ; "+0"Qfdgtvg"|kpHÀ|pgjq"xcmw"vcm "qdlg o"tq|vqm."mvqt "uc"tqxp^a"x{rq "vcp² o w" qdlg o w"qdknvqzczk o cdw"x"o knknvtqej"x"40"mtqmw"wxgfgpq o"x{—kg0" \nkmxkfwlvq"tq|vqm."mvqt "dq" qfdqtcv " |kpHÀ|pgjq"xcmw0
- 60 \ "kplgm pgl"nkgmqxm{"*nkgmqxkmg+"nkgmw"P [ZVJTCEKU qfdgtvg"rqfclqxc"qdlg o"mqpegpvt^avw" pc"kpHÀ|p{"tq|vqm"x{rq "vcp "x"40"mtqmw+0" \nkmxkfwlvq"x-gmw pgrqwfkvÀ" cu ".mvqt^a"|quvcnc"x" kplgm pgl"nkgmqxmg"*nkgmqxm^aej+"nkgmw"P [ZVJTCEKU0
- 70 Rqfclqxc"qdlg o"mqpegpvt^avw"qdknvqzczk o cdw"pc"kpHÀ|p{"tq|vqm rtpguv"fq"x{dtp²jqu" kpHÀ|pgjq"xcmw0
- 80 kpHÀ|p{"xcm"lg o pg"rtgxt^a vg."cd{"uc"tq|vqm"rtg o kg-cn0" Pgrtgtgr^axclvg0
- 90 kpHÀ|kc"uc"o wu"rqf^axc "rq"fqdw";2 okpÀ"u"t ejnqu qw"kpHÀ|kg"wxgfgpqw"x"vcdw mg⁵*rq|tk" cu "604+. "u"rqwfkv"o "2.44-o kmt»pqx²jqu"kp-nkpg"hnvtc0
- :0 Rtkrtcxgp "tq|vqm"lg"uvcdknp "rq cu": jqf"p."cm"uc"wejqx^axc"rtk" |dqxgl"vgrnqvq"42 °C – 47 °C cngdq": jqf"p."cm"uc"wejqx^axc"x"ejncfpk mg"rtk"vgrnqvq"4 °C – : ÅE0

Rt{rtxc" c" | tkgfgpk" x" kphÀ | pgl" uvtkgmc mg

30 X{rq {vclvg" rqtgdp" o pqfluvxq" qdknvqzczk o cdw" x" o knki tco qej" x{p^auqdgpl" o qfrqtÀ cpgl" f^axm{ "x" o ilmi" x" vcdw mg" 4" *rq|tk" cu "604+ "vngnupqw" j o qvpqu qw" kpfkxfw^a npgj q" rcekgpvc" x mknqitc o qej 0

40 X{rq {vclvg" rqlcfqxc p "qdlg o" mqpegpvt^a vw" qdknvqzczk o cdw" pc" kphÀ | p{ "tq | vqm" x" o knknvtqej" c rq gv" kplgm p ej" nkgmqxkgm" rqtgdp ej" pc" f^axmw" x{ fgngp" o "x{ rq {vcpgl" f^axm{ "x" o knki tco qej" *30" mtqm+ "mqpegpvt^a ekqw" 322 o ilon0" Mcff^a "kplgm p^a "nkgmqxmc" w o qfl wlg" pqfcpkg" 8 ml mqpegpvt^a vw P [ZVJTCEKU pc" kphÀ | p{ "tq | vqm 0

50 \xq vg uvtkgmc mw" xjqfpgl" xg mquvk" rtg" egmqsx "qdlg o" kphÀ | kg. "mvqt^a uc" o^a "rqfc 0

60 U" rqwflkv" o "x{ dtcpgl" uvtkgmc m{ "c" 2.44- o kmt> pqx² jq" kp-nkpg" hknvtc" odoberte rqlcfqxc p" qdlg o" mqpegpvt^a vw" qdknvqzczk o cdw" pc" kphÀ | p{ "tq | vqm *x{ rq {vcp "x" 40" mtqm w+ 0" \nkmxkf wlvq" x-gvmw pgrqwflkvÀ" cu . "mvqt^a | quvcnc" x" kplgm pgl" nkgmqxmg" *nkgmqxm^a ej+ "nkgmw" P [ZVJTCEKU 0

70 Qf qdgtvg rt{unw-p²" o pqfluvxq" kplgm p² jq" tq | vqm w" ej nqtkfw" uqfp² jq" u mqpegpvt^a ekqw"; mg/ml *2.; ' + "pc" rt{rtcxw" egmqsx² jq" qdlg o w" kphÀ | kg" wxgfgp² jq" x" vcdw mg" 40

80 Tq | vqm lgo pg" rtg o kg-clvg 0" Pgrtvtgr^a xclvg 0

90 \tkgfgp "tq | vqm" qdknvqzczk o cdw" rqlcfvg" kjpg "rq" lgj q" rt{rtcxg 0" Tq | vqm pgwejqx^a xclvg" x uvtkgmc mg 0" Pgrqwflkv "nkgm" | nkmxkfwlvq 0

Nkmxkf^a ekc

X-gvqm" pgrqwflkv "nkgm" cngdq" qfrcf" x | pkmpwv " | nkgmw uc" o^a " | nkmxkf qxc "x uAncfg" u p^a tqfp o k" rqlkfcxmc o k 0

7. FT{KVG "TQ \ JQFPWVK" Q REGISTRU

UHN" Rjct o cegwkecnu" Fgwwuejnepf" I o d J
Octkg-Ewtkg-Uvtcuug":
9;75; N%ttcej
Pgo gemq

8. TG I KUVTC P | " ~UNQ* UNQ+

GW13142136: 7/001

9. D{UM PRVEJ TG I KUVT f EKG I RTGF fiGPK" TG I KUVT f EKG

F^avw o" rtxgl" tgi kvt^a ekq<3:0" ppxg o dtc" 4242

10. D{UM REVZIE TEXTU

Rqftqdp²" kphqt o^a ekq" q" vq o vq" nkgmw" uÀ" fquvwrp²" pc" kpvgtpgvqxgl" uvt^a pmg" Gwt> rumgl" ci gpvÀt{ "rtg" nkgm{ "[jvvr<ly y y 0g o c 0gwtqrc 0gw](#)>c" pc" kpvgtpgvqxgl" uvt^a pmg" TM^a vpgj q" Àuvcxw" rtg" mqpvtqmw" nkg kx" jvvr<ly y y 0uwmn0um@0

PRÍLOHA II

- A. X TQDEC"DKQNQIKEM; JQ"NKG KXC"C"X TQDEC"
\QFRQXGFP "\C"WXQ PGPKG"™CTfG
- B. PODMIENKY ALEBO OBMEDZENIA TKAJZE SA
VPAJA A RQWfKVKC
- C. CN™KG"RQFOKGPM["C RQfKCF CXM["TG I KUVT fEKG
- D. PODMIENKY ALEBO OBMEDZENIA TKAJZE SA
DG\RG P; JQ"C — KPP; JQ"RQWfXCPKC"NKGMW
- E. QUQDKVP; "RQfKCF CXM["PC"URNPGPKG"
RQUVTG I KUVTC P E J"QRCVTGP"RTK"TG I KUVT fEKK"
ZA MIMORIADNYCH OKOLNOSTI

**A. X TQDEC*X TQDEQXKC+DKQNQIKEM!JQ"NGK KXC"*DKQNQIKEM EJ"
NGK KX+C VROBCA (VROBCOVIA) ZODPOVEDN#ZODPOVEDN#
ZA WXQ PGPKG"TMCTfiG**

P^a|qx" c cftguc" x tqdew" *x tqdeqx+" dkqnqikem² jq" nkg kxc" *dkqnqikem ej" nkg kx+

Nqp|c"Dkqnqikeu."kpe0
323"Kpvgtpcvkqpcn" Ftkxg
Rqtvu o qwj."PJ"25:23
WUC

P^a|qx" c cftguc" x tqdew" *x tqdeqx+" |qfrqxgfp² jq" *|qfrqxgfp ej+" |c wxq ppgkg"-ctfg

Cegtvrjct o c"D0X0
Dquejuvtccv"73
6:33" IE."Dtgfc
Jqncpfumq

B. PODMIENKY ALEBO OBMEDZENIA TKAJE SA VPAJA A RQWfiKVKC

X fcl"nkgmw"lg"xkc|cp "pc"ngm^atum{"rtgfrku

C. CNTMKG"RQFOKGPM ["C RQfiKFCXM ["TG IKUVT f EKG

€ **Periodicky aktualizovaný správy o dg|rg pquvk"Rgtkqfke"uchgv{"wrfcvg"tgrqtvu."RUWT+**

Rqfkcfcxm{"pc"rtgnqflgpk"RUWT"vqjvq"nkgmw"uA"uvcpqxp²"x |q|pc o g"tghgtgp p ej" f^avw o qx"
—pkg*"|q|pc o "GWT F+"x uAncfg"u n^apmq o "329e"qfu0"9"u o gtpkeg"42231:51GU" c x-gvm ej"
p^aungfp ej"cmvwcnk|^aek|"wxgtglpgp ej"pc"gwtrunq o "kpvgtpgvqxq o "rqtva"nk"rtg"nkgm{"0

**D. RQFOKGPM ["CNGDQ"QDOGF \ GPKC"V MCL—EG"UC"DG \ RG P : JQ" C — KPP : JQ"
RQWfi"XCPKC"NKGMW**

€ **Přizriadenia rizik (RMP)**

Ftflkvq "tq|jqfppwkc"q tgi kvt^aekk"x{mqp^a"rqfclfxcp²" kppquvk" c |^aucj {"x t^a o ek"fqj cfw"pcf"
nkgm ok."mvqt²"uA"rqftdpg"qr"ucp²"x qfuÀjncugppq o "TOR"rtgnqflgppq o "x o qfwng"30:04"
tgi kvtc pgl"fqmw o gpv^aek" c xq x-gvm ej" cn-"ej"qfuÀjncugp ej"cmvwcnk|^aek^aej"TOR0

Cmvwcnk|qxcp "TOR"lg"rqvtgdp²"rtgnqflk <

€ pc"flkcfqu "Gwt>rumgl"ci gpvAt{"rtg"nkgm{.

€ xflf{"x rt|rcfg" | o gp{"u{uv² o w"tkc fgpkc"tk|qm."rtgfqx-gvm o "x f¹zungfmw" |f"umcpkc"pqx ej"
kphqt o^aek|. "mvqt²" o 1/2flw"xkgu "m x tc|pgl" | o gpg"rq o gtw"rt|pquw" c tk|kmc."cngdq" x f¹zungfmw"
fqkjcjpwkc" f¹zungflkv²jq" o gf|p|mc"x t^a o ek"fqj cfw"pcf"nkgm ok" cngdq" o kpk o cnk|^aek"tk|kmc+0

**E. QUQDKVP : "RQfiKFCXM ["PC"URNPGPKG"RQUVTG IKUVT C P EJ"QRCVTGP"RTK"
REGISTR#II ZA MIMORIADNYCH OKOLNOST#**

V^avq"tgi kvt^aekc"dqnc"uejx^angp^a"|c" o k o qtkc f p {ej"qmnpquv|. "c"rtgvq" o^a"rqf c" n^apmw"36"qfu0": "
pctkcfgpkc" *GU+" 0 94814226"ftflkvq "tq|jqfppwkc"q tgi kvt^aekk"fq wt gp²jq"vgt o |pw"x{mqpc "
pcungfwlAeg"qrcvtgpkc

Popis	Termíny a zvykonania
<p>Pc"À gn{"xcnkf^aekg"het o cmqmkpgvkemgl" o gv>>f{"qdknvqzczk o cdw" * I EN-382+"x" wfumq o "u²tg" o ^a"ftflkvg "tq jqf^apwwk"q"tgikuvt^aekk" rtgf"rqwflk\ o "vguvw"pc"cpn w"x qtkgm"rtg"mnkpkemÀ"-vÀfkw"C J 723 rtgfnqflk x ungf^m{"xcnkf^aekg"vguvw"rtg"pcungfwlÀeg"curgm^v{"<" kpvgtgtht^gpek"qejtcpp o "cpvki²pq o "^a*85" c":5+."GH."NH" c"rtqvkn^avm{" rtqvkn^angmw."c"À kppqu "vguvw"x"jg o qn{vkemq o "c"nkr g o kemq o "u²tg0" Rctengnp²"vguv{"uc"x{mqpclÀ"u"x ungf^p o k"x qtmc o k "rn^apqxcpgl" qvxtgpgl"vgt²ppgl"-vÀfkg"C J 7230</p> <p>U"ekg q o "x{jqf^apqwk "mnkpkemÀ"qfrq^xg ."dg rg pqu "c" p^a-cpnkxqu " xt^avcpg"rtkgdgjw"qejqtgpkc"rtgflkvc"w"À cuvp^mmqx"u"rqf^q tgp^o"pc" k^pj^cnc p "cpvtcz."u rtxfgrqf^qdpqu qw"kpj^cnc p²jq"cpvtczw cngdq" u rqvxtf^gp o k^pj^cnc p o cpvtczom nkg gp ej qdknvqzczk o cdq o " o ^a ftflkvg "tq jqf^apwwk"q"tgikuvt^aekk"wumwvq pk r^qf c"uejx^angp²jq" rtqvqm^qnw"qvxtgpgl"vgt²ppw"-vÀfkw"C J 723" h^a {"6"r^q"x{r^wmpwv" cpvtczw"x"mtclp^aej."x"mvqt ej"lg"qdknvqzczk o cd"r^qxqngp "c" fquvwrp ."c"rtgfnqflk x ungf^m{"^axgtg pgl"urt^ax{"q"-vÀfkk0</p>	<p>OclÀ"d{ "ptgfnqflgp²"urqnw" uq"^axgtg pqw"mnkpkemq" urt^axqw" q"-vÀfkg"C J 723</p> <p>Mcl^fqt^g pg"rtgfmncfcp² urt^ax{ \^axgtg p^a"urt^axc"dwfg" rtgfnqflgp^a"pclpgum¹/t" 34 o gukceqx"r^q"r^qungf^pq o " r^qfcp^o"qdknvqzczk o cdw" cngdq"r^qungf^pq o " dgtg" Àfclqx"x"rt^o"r^cfg" tgv^tqur^gmv^o"xpgj^q" dgtw" Àfclqx</p>

Liek s ukonfenou platnos. Ouberegistr. cie

Liek s ukončenou platnosťou registrácie

PRÍLOHA III

Q\PC GPKG"QDCNW"C P\OMNENFORMEIA PRE RQWf"XCVG C

Liek s ukončenou platnosťou registrácie

A. Q\PC GPKG"QDCNW

—FCLG."MVQT | "OCL—"D ["WXGFGP | "PC"XQPMCL™QO"QDCNG

™MCVW MC

1. NÁZOV LIEKU

P [ZVJTCEKU 100 o i l o n " u v g t k n p " m q p e g p v t ^a v
q d k n v q z c z k o c d

2. NKG KXQ* NKG KX f +

1 ml: 100 o i " q d k n v q z c z k o c d w l

3. ZOZNAM POMOCNÝCH LÁČOK

R q o q e p ² " n ^a v m { < " j k u v k f | p . " u q t d k v q n . " G 655 . " m { u g n k p c " e j n q t q x q f | m q x ^a . " | f t q z k f " u q f p . " x q f c " p c " k p l g m e k g l

4. LIEKOVÁ FORMA A OBSAH

K q p e g p v t ^a v p c " k p h A | p { " t q | v q m
822 o i l 8 ml
1 k p l g m p ^a n k g m q x m c

5. SPÔSOB A CESTA (CESTY) PODÁVANIA

R t g f " r q w f l k v | o " u k " r t g " | v c l v g " r | u o p A " k p h t o " e k w " r t g " r q w f | x c v g c l
k p v t c x g p » | p g r q " | t k g f g p | 0
N g p " p c " l g f p q t c | q x ² r q w f l k v k g l
P g r t g v t g r ^a x c l v g l

S T " m » f . " m v q t " d w f g w x g f g p / + y y y 0 q d k n v q z c z k o c d - u h n l g w

80 ™RGEK f NPG"WRQ \ QTPGPKG."fiG"NKGM"UC"OWU~"WEJQXfXC "OKOQ"FOJ CFW"
A DOSAHU DETI

7. KP | ™RGEK f NPG"WRQ \ QTPGPKG*"WRQ \ QTPGPKC+."CM"LG"VQ"RQVTGDP |

8. DĽUŽIE EXPIRÁCIE

GZR

9. ŠPECIÁLNE PODMIENKY NA UCHOVÁVANIE

Wej q x ^a x c l v g " x e j n c f p k m g l

Pgwejqx^axclvg"x otc|pk mg0
Wej qx^axclvg"x r½xqf pq o "qdcng"pc"qejtcpw"rtgf"uxgvnq o 0

10. TMRGEK fNPG"WRQ \ QTPGPKC"PC"NKMXKF fEKW"PGRQWfKV EJ"NKGMQX"CNGDQ"
ODPADOV Z PKEJ"X \ PKMPWV EJ."CM"LG"VQ"XJQFP :

11. NZOV A CFTGUC"FTfKVG C"TO ZHODNUTIA O REGISTRACII

UHN"Rjcto cegwkecnu" Fgwwuejncpf" I od J
Oetkg-Ewtkg-Uvtcuug":
9;75; N¾ttcej
Pg o gemq

12. TGIKUVTC P ! " ~UNQ"* ~UNC+

GW13142136:7/001

13. ~UNQ"X TQDPGL"TMCTfG

0"-ctflg

14. \CVTKGFPGK"NKGMW"RQF C"UR ~UODW"X FCLC

15. RQM[P ["PC"RQWfKVKG

380 INFORMACIE V BRAILLOVOM PISME

\ f½xqfpgpgk"pgwx^af |c "kphqto^aekw"x Dtcknnqxq o "r½u o g"uc"cmegrvwlg0

17. ŠPECIFICKÝ IDENTIFIKAČNÝ KOD – FXQLTQ \ OGTP " KCTQX "M ~ F

Fxqltq | o gtp " kctqx "m»f"uq"-rgekhhem o "kfgpvkhkm^avqtq o 0

18. ŠPECIFICKÝ IDENTIFIKAČNÝ KOD – ČAJE KVCVG P ! " WFUM O"QMQO

PC
UP
NN

OKPKO fNPG"—FCLG."MVQT ! "OCL—"D["WXGFGP ! "PC MALOM VNORNOM OBALE
™V~VQM"PC"KPLGM PGL"NKGMQXMG

1. NÁZOV LIEKU A CESTA (CESTY) PODĽANIA

P [ZVJTCEKU 100 o ilon"uvgtkmp "mqpegvt^av
qdknvqzckocd
k0x0 rq" | tkgfgp⁰

2. SPÔSOB PODĽANIA

Ngp"pc"lgfpqtc | qx² rqwflkvkg0

3. DEJUM EXSPIRĀIE

GZR

4. ~UNQ"X TQDPGL"™CTfiG

0"-ctflg

5. OBSAH V JOQVPQUVP EJ."QDLGOQX EJ"CNGDQ"MWUQX EJ"LGFPQVMfEJ

822 o i18 ml

80 INĚ

Liek s ukončenou platnosťou registr., cie

Liek s ukončenou platnosťou registrácie

B. R^UQOP f["]KPHQTO f^EKC["]RTG["]RQWfi[~]XCVG C

Rfuo p^a"kphqt o^aekc"rtg"rqwflxcvg c

**NYXTHRACIS 100 o il o n^mqpepvt^av na inf^{ny} roztok
qdknvqzczk o cd**

Vgppvq"nkgm"lg"rtgfg o gvq o " cn-kgj q" o qpqvqtqxcpc k0"Vq"wo qflp"t ejng" | f^{um}cpkg"pqx ej "kphqt o^aek"
o dg | rg pqvuk" O^{1/2}flgvg"rtkurkg "v o."flg"pcjn^aukvg"cm²mq xgm"xgf cl-kg"À kpm{."cm"uc"wx^au"x {um {vpÀ"
kphqt o^aekg"q vq o."cmq"jn^auk "xgf cl-kg"À kpm{."p^a1fgvg"pc"mqpek" cuv^k"60

**Rq|qtpg"uk"rtg f^{vcl}vg"egnÀ"rfuo p^a"kphqt o^aekw"rtgfv o."cmq" | c p^{gv}g"rqwflxc "vgppvq"nkgm."rtgvqflg"
qducjwlg"rtg"x^au" f^{1/2}ngflk^v"kphqt o^aekg.**

- V^Àvq"rfuo p^a"kphqt o^aekw"uk"wuej qxcclvg0" Oqflpq"dwfg"rqvtgdp²."cd { "uvg"uk"lw" | p^{qxw}rtg f^vcnk0
- Cm"o^avg"cm²mq xgm" cn-kg"qv^a | m{."qdt^a vg"uc"pc"uxqlj q"ngm^atc."ngm^atpkmc"cn^{gd}q" | ftcxqvpÀ"uguvtw0
- Cm"uc"wx^au"x {um {vpg"cm mq xgm"xgf cl-¹"À kpmq."qdt^a vg"uc"pc"uxqlj q"ngm^atc."ngm^atpkmc"cn^{gd}q" | ftcxqvpÀ"uguvtw0 To uc"v mc"cl"cm ejmq xgm"xgf cl-¹"ej"À kpmqx."mvqt²"pk^g"u^a wxgfgp²"x tejto r^fuo p^gl"kphqt o^aek0"Rq|tk" cu "60

V tejto p^řomnej inform^či sa dozviete:

- 30 q"lg"p [ZV J TCEKU c pc" q"uc"rqwflxc
- 40 q"rqvtgdwlgvg"xgflg "rtgfv o."cmq"x^ao"dwfg"rqfcp P [ZV J TCEKU
- 50 Ako x^ao"dwfg"rqfcp "P [ZV J TCEKU
- 60 Oqflp²"xgf cl-kg"À kpm{"
- 70 Cm^q"wej qx^axc "P [ZV J TCEKU
- 80 Qducj"dcngpkc" c cn-kg"kphqt o^aekg

1. q"lg"NYXTHRACIS a pc" q"uc"rqwflxc

P [ZV J TCEKU qducjwlg"nkg kxq"qdknvqzczk o cd" Qdknvqzczk o cd"lg" o qpqmnp^anc"rtqvkn^avmc."v { r" dkgm^qxkp{."mvqt^a uc"xkcf^gpc"vqz"p { "rtqfwmqxcp²"dcmv²tkc ok."mvqt²"ur^{1/2}zudw^lÀ"cpvtcz."c"kp^{cm}vxwlg"ke j0

P [ZV J TCEKU uc"rqwflxc"urqnv"u"cpv^kckqvkmc ok"pc"nkg dw"fqurgn ej" c"fgv"u"cpvtczq o"ur^{1/2}zudgp o" xf ejpww"o" dcmv²tk" *kpjcnc p "cpvtcz+0

P [ZV J TCEKU uc" o^{1/2}flg"rqwflk "cl"x rt"rcfg."cm"uvg" o qjnk"rt"u "fq"mqpvcmw"u" dcmv²tkc ok"cn^{gd}q" ur>tc ok"cpvtczw."cn^gpg o^ag"flk fpg"rt" | pcm { "oejqtgpkc."c"cm"pk^g"lg"m"fkurq | f^{ekk}"cn^{gd}q"pk^g"lg"xjqfp^a" flk fpc"kp^a"nkg dc0

2. q"rqvtgdwlgvg"xgflg "rtgfv o."cmq"x^ao"dwfg"rqfcp NYXTHRACIS

NYXTHRACIS x^ao"pg o^ad { "rqfcp

- cm"uvg"cn^{gt}i kem "pc"qdknvqzczk o cd"cn^{gd}q"pc"mvqtÀmq xgm" | cn-¹"ej" | nqflkgm"vqjvq"nkgm"
*wxgfgp ej"x cuv^k"8+0

Upozornenia a opatrenia

Rtgfv o."cmq"x^ao"dwfg"rqfcp "P [ZV J TCEKU."qdt^a vg"uc"pc"uxqlj q"ngm^atc."ngm^atpkmc"cn^{gd}q" | ftcxqvpÀ"uguvtw<

- cm"x { "cn^{gd}q"xc-g" fkg c" o^avg"fgfk p^apg | p^a-cpⁿxqu "htwmv> | { "umtcv^mc" JHK." | "cpⁱnkem²jq" jgtgfkvet { "htwevqug"kp^vqngtepeg+cn^{gd}q"xc-g" fkg c"wl"xkce"pg o^{1/2}flg"rtkl"o c "uncfm²"lgfn^a"cn^{gd}q" p^arqlg."rtgvqflg"rqek wlg"pgxq pqu ."xtcekc."cn^{gd}q" o^a"pgrt"lg o p²"rqekv { "cmq"p^{er}t^fmmc f" pchwmqxcpkg."flcnÀfq p²"m g."cn^{gd}q"jpc mw0

Cngtikem²tgcmekg."mvqt²uc" o 1/2flw"x{um{vpÀ "rq"nkg dg"P [ZV J TCEKU." o 1/2flw"d{ "pkmgf{" | "xcflp²"
Ptgf"rqfcp" o "nkgmw P [ZV J TCEKU x^a o " o 1/2flg"d{ "rqfcp²"cpvkjkuvco kpkmw o."cd{"uc" | p{flkq"tk | kmq"
cngtikem ej"tgcmek{0

Inžieky a NYXTHRACIS

Cm"vgtc|"rqwfl{xcvg"engdq"uvg"x rqungfpq o " cug"rqwfl{xcnk." k"rt^axg"dwfgvg"rqwfl{x " cn-kg"nkgm{"
rpxgf |vg"vq"uxql o w"ngm^atqxx"engdq"ngm^atpkmqxx0
Cmq"rqoqe"rtk"nkg dg"kpjcnc p²j q"cpvtczw"x^a o " o 1/2flw"d{ "rqfcp²"cpvkdkvkm^a"pcrt0"ekrtqhnqzce"p+0

Tehotenstvo a fql gpgk

Cm"uvg"vgjqvp^a"engdq" fql "vg."cm"uk" o {un{vg."flg"uvg"vgjqvp^a"engdq"cm"rn^apwlvgv"qvgjqvpkg "rqtca"vg"uc"uq"
uxql" o "ngm^atqo"rtgfv o."cmq"x^a o "dwfg"rqfcp "vgpvq"nkgm0

Pkg"lg" |p^aog." k"P [ZV J TCEKU o 1/2flg"rq-mqfk xc-g ppgctqfgp²" fkg c0

Pkg"lg" |p^aog." k"P [ZV J TCEKU rtgej^a f |c"fq" o cvgtum²j q" o nkgmc0"X{"c"x^a "ngm^a"tq | j qfpgvg." k" o^avg"
fql k "rq"rqfcp" P [ZV J TCEKU0

Vedienie vozidiel a obsluha strojov

P [ZV J TCEKU o 1/2flg"ur¹/2uqdqxc "xgf cl-kg"À kpm{"cmq"uÀ"dqnguvk"jucx{" | "xtecv{"."Àpcxc" c xteccpkg0"
O 1/2flg"vq"qxrn{xpk "xc-w"uejqrpqu "xkgu "xq |kfn^a"engdq"qdunwj qxc "utqlg0

NYXTHRACIS obsahuje sorbitol (E 420)

Uqtdkvq"lg" | ftqlom htwm>> | {"*v{r"ewmtw+0" Cm"x {"*engdq"xc-g" fkg c+" o^avg"fgfk pÀ"kpvnqtcpekw"htwm>> | {"
* JHK+." |tkgfmcx² igpgvkm² qejqtgpkg."x^a-ngm^at" o 1/2flg"tq | j qfpa ".flg"x {"*engdq"xc-g" fkg c+"pgu o kgvg"
fquvc "vgpvq"nkgm0"Rcekgpvk"u" JHK"pgxgfk"tq |nqflk "urteeqxc "+"htwm>> |w." q o 1/2flg"ur¹/2uqdk " | "xcflp²"
xgf cl-kg"À kpm{0

Cm"x {"*engdq"xc-g" fkg c+" o^avg" JHK."engdq"xc-g" flg c" wfl"xkce"pg o 1/2flg" rtkl" o c "uncfm²"lgfn^a"engdq"
p^a rqlg."rtgvqflg"r qek wlg"pgxq pqu ".xtcekc."engdq" o "pgrt"lg o p² r qekv {"cmq"pcrt"mncf"pchwmxcpkg."
flcÀfq p²"m g"engdq"jpc mw." o wu"vg"vq" |p^aok "uxql o w"ngm^atqxx"rtgfv o."cmq" fquvcpgvg"vgpvq"nkgm0

NYXTHRACIS obsahuje sodík

Vgpvq"nkgm"qducjwlg" o gpgl"cmq"3 o o qn"uqf"mc"45 o i+"x"mcflfgl"8 o n"klgm pgl"nkgmqxmg"
P [ZV J TCEKU."v0 10 x rqfuvvg" |cpgfdcg p² o pqfluvxq"uqf"mc0

3. Ako vŕn bude rqfcp " NYXTHRACIS

P [ZV J TCEKU x^a o "rqf^a"ngm^at"engdq" | ftcxqvp^a"uguvtc0"X^a-ngm^at"engdq" | ftcxqvp^a"uguvtc"x {rq "vclÀ"
f^axmw"pc" | "mncfg"xc-g"l"vngupgl"j o qvpquvq"*engdq"vngupgl"j o qvpquvq"x^a-j q" fkg c c+0

X^a-ngm^at." | ftcxqvp^a"uguvtc"engdq"ngm^atpkm" rtkrtcxkc kphÀ | p {"tq | vqm0

Tq |vqm" P [ZV J TCEKUuc"dwfg"rqf^axc "cmq"kphÀ |kc"*mxrcmcp" o "+"rq"fqdw";2 o kpÀv"fq"flkn{" | x { clpg"
fq"twm{0"Rq cu"rqf^axcpkc" P [ZV J TCEKU c"pcl o gpgl"lgfpw"j qfkpw"rq"kphÀ |kk"dwfgvg"ungfqxcp"0
Rtgfv o."cmq" fquvcpgvg" P [ZV J TCEKU."x^a o | x { clpg"dwfÀ"rqfcp²"nkgm {"pc"rtgxppek"engdq"
| okgtppkg" cngtikem ej"tgcmek{0

Cm" o^avg"cm²mq xgm" cn-kg"qv^a | m {"v mclÀeg"uc"rqwflkvc"vqjvq"nkgmw."qr vclvg"uc"uxqlj q"ngm^atc."ngm^atpkmc"
engdq" | ftcxqvpgl"uguvt{0

4. Oqflp²"xgf cl-kg"À kpm{

Vcm"cmq"x-gvm {"nkgm {"cl"vgpvq"nkgm" o 1/2flg"ur¹/2uqdqxc "xgf cl-kg"À kpm {"j qek"uc"pgrtglcxc" w mclf²j q0

Kj jgg q |p^a o vg"uxql o w"ngm^atqxx"engdq"quqdg."mvqt^a"x^a o "rqf^axc"kphÀ |kw."cm"urq |qtwlgvg"
mvqt mq xgm" | "pcungfqxp ej xgf cl-ŕej"À kpmqx<

Uxtdgpkg."x{t^aflmc."f ejcxk pqu "cngdq"ukrqv"rtk" f ejcpf"— o½flg"u "q"rtglcx{ cngtikemgl"tgcmekg"
*rtgekvnkxgpquvk+0

Ogf |k" cñ-kg" xgf cl-kg"À kpm{"NYXTHRACIS patria:

- cuv² * o½flw" rquvkj qxc cfl"3"quqdw" | 32+<
- dqngu "jncx{.
- mc-g .
- dqngu "x" o kguvg" r q f c p k c" k p h À | k g.
- uxtdgpkg."mqflp^a"x{t^aflmc"xt^avcpqg"uxtdkcegl"x{uvÀrgpgl"x{t^aflm{"*flkj cxmc+0

Ogpgl" cuv² * o½flw" rquvkj qxc cfl"3"quqdw" | q"322+<

- cngtikem²"tgcmekg.
- |^axtecv{.
- pgekvnkxqu .
- |tcmqx^a ekvnkxqu "pc"uxgvnq*"hqvqh»dkc+.
- pgrtflgop "rqekv x"wejw.
- rqft^aflfgpkg"jtfnc.
- |cejtrpww "jncu.
- wrejcvkg"rtkpquqx ej"fwf|p.
- f ejcxk pqu .
- dqngu "rkgt.
- gm|²o."qnwrqxcpg"mqflg.
- uxcnqx²"|^a-mmd{"c"m g.
- Àpexc.
- |k o p k e c" * r q e k v" e j n c f w +.
- pgrtflgop "rqekv x"jtwfpmw.
- dqngu "x-ggdgepg" c" dqngu "rquvkjw"Àec"mqp cvkp{"jtwfpm." g wu ."uxcn{"x@|{"- cej{"cngdq"
mqvkv.
- qrwej."dqngu "cngdq" hngdkv|fc"* |^arcn"fl"n" x" o kguvg" r q f c p k c" k p h À | k g 0

Jn^augpk" xgf cl-|ej"À kpmqx

Cm"uc" w x^au" x {um{vpg"cm mq xgm" xgf cl-|ej"À kpmq." qdt^a vg"uc"pc"uxqlj q"ngm^atc."ngm^atpkmc" cngdq"
|ftexqvpÀ"ugvwtw0 To uc"v mc"cl"cm"ejmq xgm" xgf cl-|ej"À kpmqx."mvqt²"pkg"uÀ"wxgfgp²"x vglvq"r"uq o pgl"
kphqt o^aekkl"Xgf cl-kg"À kpm{" o½flgvg"jn^auk "cl"rtkc o q"pc"p^atqfp²"egpvtw o"jn^augpkc"wxgfgp²"
x [Rt|nqjg V0](#)" Jn^augp"o" xgf cl-|ej"À kpmqx" o½flgvg"rtkurk" m |flumcpkw" cñ-|ej" kphqt o^aek"q dg|rg pquvk"
vqjvq"nkgmw0

5. Cm"wej qx^axc "NYXTHRACIS

Vgpvq"nkgm"wej qx^axclvg" o k o q" f q j c f w" c f q u c j w" f g v 0

Pgrqwf|xcldg"vgpvq"nkgm"rq" f^avw o g"gzurkt^aekg."mvqt "lg"wxgfgp "pc"-mcvw mg" c"pc"-v|vmw"rq"GZR0" F^avw o "
gzurkt^aekg"uc"X| c j w l g"pc"rqungfp "fg "x f c p q o" o g u k c e k 0

Wejqx^axclvg"x"ejncfpk mg"*4 °C — : ÅE+0

Pgwej qx^axclvg"x o t c | p k m g 0

Wejqx^axclvg"x r½xqfpq o "qdcng"pc"qejtcpw"rtgf"uxgvnq o 0

Pq | t k g f g p | " x" k p h À | p q o " x c m w" d q n c e j g o k e m^a."h{ | k m^an p c" c" o k m t q d k^an p c" u v c d k n k v c" r t k" r q w f l | x c p f |
r t g w m^a | c p^a" r q" f q d w" : j q f | p" r t k" k | d q x g l" v g r n q v g" * 4 2 ° C — 4 7 Å E + " c n g d q" x" e j n c f p k m g" * 4 ° C — : Å E + 0

P [Z V J T C E K U u c" o^a" r q" | t k g f g p | " x" k p h À | p g l" u v t k g m c m g" q m c o f l k v g" r q f c " c" p g w e j q x^a x c 0" C m m q x g m"
p g r q w f l k v " n k g m" u c" o^a" | n k m x k f q x c 0

80 Obsah balenia a cn-kg" kphqt o ^ekg

q"NYXTHRACIS obsahuje

- Nkg kxq"lg"qdknvqzck o cd0"Mcflf " o n"mqpepvt^vw"qducjwlg"322 o i"qdknvqzck o cdw0"Lg fpc"8 ml kplgm p^a"nkgmqxmc"qducjwlg"822 o i"qdknvqzck o cdw0
- cn-kg" | nqflm{ "uA" j kuvkf"p."uqtdkvqn"*G 642+."rqn{uqtd^a v": 2"*G 655+."m{ ugnkpc"ej nqtqxqf"mgx^a" *G 729+"c" j { ftqzkf"uqfp " *G 746+0"Rq| tk"vkgfl" cu "4"š P [ZV J TCEKU qducjwlg"uqtdkvqn0

Ako vyzere NYXTHRACIS a obsah balenia

P [ZV J TCEKU Ig" ¶t{"cfl"qrcnk | wLÀek."dg | hctgdp "cfl"uxgvnqflnv "cfl"uxgvnqj p g f q - flnv mqpepvt^a v"pc kphÀ| p{ tq | vqm0
P [ZV J TCEKU Ig" fquvwrp "x"dcngpkcej"qducjwLÀekej"3" kplgm pÀ nkgmqxmw0

Ftflkvg "tq|jqfpwkc"q"tgikvut^akk

UHN"Rjct o cegwkecnu" Fgwwuejncpf" I o d J
Oetkg-Ewtkg-Uvtcuug":
9;75; N¾ttcej
Pg o gemq

X tqdec

Cegtvrjct o c"D0X0
Dquejuvtccv"73
6:33" I E."Dt gfc
Jqncpfumq

Tto pñomnñ informñia bola naposledy aktualizovaná

Vgpvq"nkgm"dqn"tgikvutqxcp " | c"v|x0" oko qtkcfp{ej"qmnpquv"0"Vq" | pc o gp^a."flg"rtg" | tkgfmcxqu "x um{vw" vqjvq"qejqtgpkc" c" | "gvkem ej" f½xqf qx"pgdqg" o qflp2" | ¶umc "x-gvm{"kphqt o ^ekg"q"vq o vq"nkgmw0
Gwt>rumc"ci gpvÀtc"rtg"nkgm{"mcflf "tqm"rqvÀfk"pqx2" kphqt o ^ekg"q vq o vq"nkgmw" c vÀvq"r¶uq o pÀ" kphqt o ^ekw"dwfg"rqf c"rqvtgd{"cmvwcnk | qxc. 0

cn-kg" | ftqlg" kphqt o ^ek

Rqftqdp2" kphqt o ^ekg"q vq o vq"nkgmw" uÀ" fquvwrp2"pc"kpvgtpgvqxgl" uvt^a pmg" Gwt>rumgl"ci gpvÀt{"rtg"nkgm{< [jvr<ll y y 0g o c0gwtqrc0gw](#)"P^a"lfg"vc o"cl"qfmc | {"pc" cn-kg"ygdqx2" uvt^a pm{"q" | tkgfmcx ej" qejqtgpkcej" c kej"nkg dg0

V^a vq"r¶uq o p^a" kphqt o ^ekc"lg" fquvwrp^a" xq" x-gvm ej"lc | {mqej" G—lG J R"pc ygdqxgl" uvt^a pmg" Gwt>rumgl" ci gpvÀt{"rtg"nkgm{0

cn-kg" kphqt o ^ekg< [y y 0g o c0gwtqrc0gw](#) dwfg"xnqflgp " S T"m>f"