

A gyógyszerkészítmény forgalomba hozatali engedély megszerzését

I. MELLÉKLET

CNMCNOC\FÜGGVÉNYT.FU

G|c"i {>>i {u|gt"hqmq|qv"hgñi {gngv"cnv"am." o gn{"ngjgv x2"vgu|k"c|"Ál"i {>>i {u|gtdk|vqpu^aik" kphqt o^aek>>m"i {qtu"q|ppqu"v^au^{v0}"C|"gi²u|u²iñi {k"u|cmg o dgtgmgy"cttc"m²tlÁm."jq i {"lgngpvugpgm" d^at o kn {gp"hgñ²vngg|gv" o gñ²mjcv^auv⁰"C" o gñ²mjcv^auqm"lgngpv²u²pgm" o >>flckt>n" c"60: rqpvdcp"mcr jcvpcm" vqx^addk^vl²m|vcv^auv⁰

1. C" I [~ I [U\GT"PGXG

P [ZVJTCEKU 100 o i l o n"mqpepvt^avw o "qnfvcqu"kphÀ|k>jq|

2. OKP U! IK" :U" OGPP [KU! IK" ..UU\GV! VGN

100 o i "qdknvqzck o cdqv vctvcn o c|" o knknkvtgpgm²pv a mqpepvt^avw o 0"

600 o i "qdknvqzck o cdqv vctvcn o c|" 8 ml-gu"klgmek>>u"Áxgi gpm²pv⁰

C|"qdknvqzck o cdqv"gi²t" IU-PU²" o {gnq o c-uglvmdgp"am"vl^am"gn "tgmq o dkp^apu" FPU-vgejppn> ik^axcn⁰

Ku o gtv"jcv^au^Á"ugi²fcp{ci

36 o i "u|qtdkvqv"vctvcn o c|" o knknkvtgpgm²pv" a mqpepvt^avw o 0

C"ugi²fcp{ciqm"vgnlgu"nkuv^al^av"n^auf" c"803 rqpvdcp⁰

3. I [~ I [U\GTHQTOC

Mqpepvt^avw o "qnfvcqu"kphÀ|k>jq| "uvgtkn"mqpepvt^avw o +0

C|"P [ZVJTCEKU^avn^avu|>>xc i {"qrcngu|m^an>>."u|p"vngp xci { jcnx^ap{u^atia, xci {"jcnx^ap{"dctp^auu^atia u|p "qnfcv."cogn {"p²j^ap {"^avvgvu| "xc i {"hgj²t"u)p ."hgj²tlgu|gt "t²u|geum²v"vctvcn o c|jcv"*g|gmgy" c" dg²r"v"v"u| t "gnv^axq"v"lc+0"C|"qnfcv"m² o jcv^aue"7.7."q| o qncnk^auc"499-52: o Quo lmi⁰

4. MNKPKMCK"LGNGO \ M

4.1 Terhajtavallatok

C|"P [ZVJTCEKU *Bacillus anthracis* okozta kpjcn^aek>>u"*vÁf -+"cpvjtcz"mg|gn²u²tg"lxcnmqv" o gi hgñn " cpvkdcmvgtk^anku"u|gtgmmgn"mq o dkp^aek>>dep."xcnc o gpp {"k"mqtqu|v^an {"dcp"*n^auf"703 rqpvt+0

C|"P [ZVJTCEKU az kpjcn^aek>>u"*vÁf -+"cpvjtcz"posztgzrq|flek>s rtqrj {"nczku^atc"lxcnmotv" o kpfgp" mqtqu|v^an {"dcp."c o gpp {"kdgp" o^au"mg|gn²ugm"pg o" o gi hgñn gm xci {"pg o "annpcm"tgpfgnm|²utg"*n^auf" 703 rqpvt+0

4.2 Adagolási alkalmazás

C|"P [ZVJTCEKU-t c"ngjgv "ngi j c o ctdddg"mgm"cfpk."c o kpv"cnmnc o c|^auc"mnkpkmknci"lxcnmqv⁰

Mgi hgñn "qtxquk"gu|m³/₄mpgm²u"hgñi {gngvpgm mkipki"tgpfgnm|²utg"mgm"annpk"arra az esetre, ha az P [ZVJTCEKU dgc f^auc"vv^ap"cpcrj {"nczku^atgcmek>>m³/₄xgvm|pg"dg⁰

Cfcinq^au

C|"P [ZVJTCEKU cl^apnqv"cfclc ngicn^add"62 kg-qu"hgñp w"dgvgigmp²n"38 o ilvguv³/₄ o gimknogramm *vmi+"gi {u|gtk"kpvtcx²p^au"kphÀ|k>dep⁰"C|"P [ZVJTCEKU cl^apnqv"cfclc qn^auc"62 mi"cnvkv"hgñp w" dgvgigmp²n"46 o ilvmi"gi {u|gtk"kpvtcx²p^au"kphÀ|k>dep⁰

C | "P [ZVJTCEKU dgc f^auc"gn v"cpvkjku |vc o kppcn"x² i | gw" r t g o g f k m^aek>"lcxcuqv"n^auf"606"2u"
60: rqp v+0"

C | "kphÀ | k>>xcn^{3/4}uu | ghÀ i i t g c m e k >>"*kphwukqp-tgncv g f"tgcev k q p."KTT+"gugv²p"cnm c n o c | c p f >>"
f>> | ku o >> fqu^va u q m c v" c | "30 v^a d n^a | c v"ku o g t v g v k l o

1. táblázat: Az obiltoxaximab javasolt dózisfőosztályai infúziós reakciók esetében

C "KTT" súlyossága	Dózisfőosztály
1–50 fokq cvÀ" KTT	O g i "m g m"u c m ^v v c p k" c "q d k n v q z c z k o c d" k p h À k >> v" 2 u" v ^a o q i c v >> "m g g n ² u v" m g n" c n m c n o c p k 0 3-cu"uÀn { quu ^a i k" h q m À" k j ^a n ^a u." d t q p e j q u r c u o w u" x c i { " i g p g t c n k ^a p v" w t v k e c t k c" g n u " g n h q t f w n ^a u c m q t" x ² i n g i n g" m g n n" a n n ^v c p k c "q d k n v q z c z k o c d- m g g n ² u v 0 X k u u c v ² t "4-gu"uÀn { quu ^a i k" h q m À" k j ^a n ^a u x c i { " w t v k e c t k c." k a n g v x g" d ^a t o g n { "3-as uÀn { quu ^a i k" h q m À" v Æ p g v" m k À l w n ^a u c" g u g v ² p" x ² i n g i n g" m g n n" a n n ^v c p k c "q d k n v q z c z k o c d- m g g n ² u v 0 G i { ² d" g u g v d g p" – j c" c" v Æ p g v g m" v g n l g u g p" g n o À n v c m" c "k p h À k >> h q n { v c v j c v >> "c" o g i u c m ^v v ^a u" g n v k" u g d g u u ² i "72 ' - ^a x c n 0" C o g p p { k d g p" p g o " c n c m w n" m k" k p h À k >> u" t g c m e k >>." c" 50 v ^a d n ^a c v d e p" d g o w v c v q v" u g d g u u ² i i g n" m g n n" d g c f p k" c "k p h À k >> v 0" R t g o g f k m ^a e k >> "c n m c n o c ^a u c" u Æ m u ² i g u 0
60 fokq cvÀ"KTT	C q p p c n" n g" m g n n" a n n ^v c p k" c "q d k n v q z c z k o c d" k p h À k >> v 0 V ^a o q i c v >> "m g g n ² u v" m g n n" c n m c n o c p k 0 X ² i n g i n g" m g n n" a n n ^v c p k c "q d k n v q z c z k o c d- m g g n ² u v 0

MÀn^{3/4} p n g i g u" d g v g i e u q r q t v q m

K f u g m

P k p e u" u | Æ m u² i " f >> | ku o >> fqu^va u t c" 87² x g u" 2 u k f u g d d" d g v g i g m p² n" n^a u f" 704 r q p v+0

I { g t o g m g m" 2 u" u g t f Æ n m

I { g t o g m g m p² n" 2 u" u g t f Æ n m p² n" c" v g u v^{3/4} o g i g p" c n c r w n" c | "c n m c n o c | c p f >> " f >> | ku." amelyet a 40 v^a d n^a | c v"
ku o g t v g v 0

2. táblázat: Az obiltoxaximab javasolt dózisa i { g t o g m g m p² n" 2 u" u g t f Æ n m p² n" * v g u v^{3/4} o g i g p" c n c r w n" >> adagolása

V g u v ^{3/4} o g i * m i +	F >> k u" o i l v m i +
@62	16
@37 – 62	46
37 x c i { " m g x g u g d d	54

C | "c n m c n o c |^a u" o >> f l c"

C | "q d k n v q z c z k o c d q v" k p v t c x² p^a u" k p h À | k >> d c p" m g n n" d g c f p k"; 2 r g t e" c n c v w 0

7 x k p v² / m g f² u g m" c" i { >> i { u / g t" g n m² u / v² u g x c i { " c n m c n o c /^a u c" g n v v

C | "k p l g m e k >> u" Æ x g i g v" p g o" u | c d c f" h g n t^a | p k 0" C | "q d k n v q z c z k o c d q v" k p v t c x² p^a u" k p h À | k >> d c p" v^{3/4} t v² p " d g c f^a u"
g n v w"; o i l o n" * 2.; ' -q u+ p^a v t k w o - m n n q t k f" q n f c v v c n" m g n n" j^v i^v c p k" n^a u f" 808 r q p v+0"

Híjíváuvm³/xgv gp az qdknvqzczk o cd"kpvtcx²p^au"kpHá|k>>" ; 2 rgte"cnvwmgnm"dgcfpk" c"50 v^adn^a |cvdcp" dg o wvcvqv"ugdgu² i i gn."kpHá|k>>" |u^amqv"xc i {"kpHá|k>>"hgeumgpf v²u"2.44 o kmtqpqu"dg²r"v²gv"u| t v" cmcn o c |xc⁰"

C |"kpHá|k>>"uqt^ap"u|qtqu" o gi hki {gn²u"cnvwmgnm"vctvcpk" c"dgvg i mgv."pg o "cnvwmgnm-g"mk"p^anwm" v^adn²t |²mgp{u² i tg"vvcn>>"lgnm"2u"v^aApvgm⁰"C" o gi hki {gn²uv" c"dgcf^au"vv^ap"ku"hn {vcvpk"mgm" o² i "ng i cn^add" gi {">t^ap"mgtgu |v^adn^auf"606 rqp+⁰"C |"kpHá|k>>"tgcmek>>mcv" c |"30 v^adn^a |cvdcp"ng"tvcn"u |gtkp v mgm"mg |gnpk⁰"

C |"kpvtcx²p^au"kpHá|k>>"x²i²p" c"u |gtgn²mgv^av"mgm"³dn"v²gpk"; o i l o n"2.; ' -qu+"p^avtkw o -m^antkf"qn f^avyon⁰"

3. táblázat: Az obiltoxaximab dózis, az infúzió teljes térfogata és az infúzió sebessége a v²gvv³/o gi f²gv² nyben

V ² gvv ³ /o gi f ² gv ² nyben *v ² gvv ³ /o gi g ² pcnrcrn>>"c fci qn ^a u+	Teljes infúzió térfogat *o n+ *kpHá k>>" u ^a m"xc i {" hgeumgpf +,	Infúzió sebesség *o n ² (s)
> 40 mi"xc i {"hgnp v²"*38 o ilvvi+		
@62	472	389
> 15 kg – 40 mi"*46 o ilvvi+		
31 – 62	472	389
16 – 30	100	89
15 mi"xc i {"cpp^an"mgxgudd"*54 o ilvvi+		
11 – 37	100	89
7 – 10	72	33,3
3,1 – 6.;	47	39
4,3 – 3	42	13,3
1,1 – 4	37	10
3"xc i {"cpp ^a n"mkugdd	9	6.9

, "C" i {">i {u |gt"cmcn o c |^au"gn vk"j"i"v^au^atc."xcnc o kp v" c |"kpHá|k>>" |u^am"xc i {"hgeumgpf "jcu |p^ancv^atc" xqpcvmq |>>"wcvu"v^auqmcv"n^auf" c"808 rqpvdcp⁰"

4.3 Ellenjavallatok

C"m²u |v²o²p {"jcv>cp {ci^axcn"xc i {"c"803 rqpvdcp"hgnuqtqnv" d^at o gn {"ugi² fcp {ci^axcn"u |g o dgpk" v^adn²t |²mgp{u² i⁰"

4.4 M^an³pnig i g²hki {gn o g |v²gv²ugm"2u" c |"cmcn o c |^auucn"mcreuqncvqu">> xkp² |mg f²ugm

N {q o qpm³/xgv j gv u² i

C"dkqn> ikck"m²u |v²o²p {gm"p {q o qpm³/xgv j gv u² i²pgm"lex"v^auc"2tfgm²dgp" c |"cmcn o c |qv v"m²u |v²o²p {"pgx²v²u" i {"^atv^auk"v²gnu |^a o^av"gi {"²tvgn o gp"mgm"hgnav^apvgvpk⁰"

KpHá|k>>"tgcmek>> m."v^adn²t |²mgp{u² i "2u" cper j {nczkc

C |"qdknvqzczk o cd"gi²u |u² i gu"t²u |vxgx mmgn"x² i |gvv"mnkpkmck" xk |u^ancvckdcp" i {cmtcp" hki {gnvgn" o gi" kpHá|k>>"v^adn²t |²mgp{u² i k"tgcmek>>mcv⁰"C"u^adn {qu"tgcmek>> m"xc i {"c |"cper j {nczkc"mqem^a |cvc" o kcvv" c |" qdknvqzczk o cdqv" o gi hki {gn²u" o gmgv"mgm"dgcfpk"qn {cp"u |cmu |g o²n { |gvpgm."c o gn {"v^auf^auucn²u" gu |m³/4mmgn"tgpfngm |km c |"cper j {nczkc"gn^av^au^ahoz⁰"C"dgvg i mgv"u |qtqu" o gi hki {gn²u"cnvwmgnm"vctvcpk" c |"kpHá|k>>"dgcf^auc"m³/4 |dgp."xcnc o kp v" c"dgcf^au"vv^ap" o² i "ng i cn^add" gi {">t^ap"mgtgu |v^adn⁰"

C"mnkpkmck" xk |u^ancvqmcv"gi²u |u² i gu"³pm²pvgugmmgn"x² i g |v²m."g |²tv" c |"qdknvqzczk o cd"kpHá|k>>"v^adn²t o kn {gp"tgcmek>> m"kcncmwn^auc" gugv²p"ng^ann"vqv^am⁰"C |"qtxquk"mg |gn²uv"ki²p {n "u^adn {qu"anncr qvqm" mg |gn²u²dgp"cmcn o c |qv v"gi {"²d" o qpqmnq^anku"cpkvgugmmgn"u |gt |gvv"vcrcu |vcncvqm"cncl^ap" c |"kpHá|k>>mcv" tgp fu |gtkp v"vgnlgugp"dg"ng jgv"cfpk."j c" o gi hggn "gn^av^au"p {Alvcpcm⁰"C |"kpHá|k>>"tgcmek>>mcv" c |"30 v^adn^a |cvdcp"dg o wvcvqv"gn^at^auqmpcm" o gi hggn gp"mgm"mg |gnpk⁰"

Cpvkjku|vcokppcn."rn0"fkhgpkjftcokppcn"x²i|gvv"rtgogfkm^aek>>"lxcuqnv"a|"qdknvqzckocd"dgcf^auc"gn vv"
*n^auf"604 rqp+v0"C|"qdknvqzckocddcn"x²i|gvv"mnkpkmkck"xk|ui^ancvqmdcp"c"fkhgpkjftcokpv"52 rgteegn"cl"
qdknvqzckocd-mg|gn²u"gn vv"cfv^am"dg0"C|"cpvkjku|vcokppcn"x²i|gvv"rtgogfkm^aek>>xcn"pg o"gn |jgv "og i"
c|"cperj|nczkc."vqx^add^a"gnhgfvjgk"xci{"m²ungnvgvjgk"c"vAn²t|²mgp{u²i"vÄpgvgkpgm"mkncmwn^au^av0

Cpvjtez"qmq|vc"ogpkikvku

C|"qdknvqzckocd"pg o"lww^av"cx²t-ci{"i^avqp."¶i{"pg o"cnmno cu"cl"cpvjtez"qmq|vc"ogpkikvku"
ogign |²u²tg"xci{"mg|gn²u²tg0"

I{gtogmgm²u"ugtfÄn m

C|"qdknvqzckocddcn"pg o"x²ig|vgm"dk|vqpu^aiquu^aik xci{"hct o cmqmkpgvkmck"xk|ui^ancvqmcv"
i{gtogmgm²n²u"ugtfÄn mp²n*n^auf"704 rqp+v0

Kpvgtcmek>m"ncdqtcv>tkw ok"xk|ui^ancvqmmcn

C|"P[ZVJTCEKU gzrq|¶ek>lc"ogi|cxctjvcl"cl"cpvjtez"mk o wvcv^au^atc"kt^ap{wn>"u|gtqn>ikck"
xk|ui^ancvqmcv0

U|qtdkv

C|"P[ZVJTCEKU 36 o i"u|qtdkvqv"vctvcn o c|" o knknkvgtgpm²pv³n^auf"40²u"803 rqp+v0"
C"u|qtdkwctvcn o Ä"i {>>i {u|gtgm"kpvtcx²p^au"cnmno c|^auc"¾t¾mngvgu"htwmv>|kpvqngtcpeka dcp"*jgtgfvct {"
htwevqg"kpvnqgtcpeg."JHK+u|gpxgf "g o dgtgm"u|^ao^atc"x²i|gvv"mk o gpgvgn "ngjgv0"C|"qdknvqzckocd"
mk|^at>nci"cnmqt"cnmno c|jcv>>¾t¾mngvgu"htwmv>|kpvqngtcpekc"hgpp^ann^auc"guv²p."jc"cnmno c|^auc"
mnkpkmkckci"hgvn²vngpÄn"u|Ämu²igu²u"pg o"am"tgpfngmg|²utg"o^au"i {>>i {u|gt0"C"i {>>i {u|gt"cnmno c|^auc"
gn vv"okpfgp"gi|gu"dgvgi"guv²dgp"ogi"mgm"ku o gtpk"cl²t²u|ngvgu"m>tv¾tv²pgvgv."mÄn¾p¾u"vgmkpvvgvgn"cl"
¾t¾mngvgu"htwmv>|kpvqngtcpekc"vÄpgvgkpgm"lgngpvng|²u²tg0

C"eugeugo m²u"4²xgup²n"hcvcncdd"mku i {gtogmgm"mÄn¾p¾ugp"xgu|²n {g|vgvgvwm."p^anwm"wi {cpku"o²i"
fkcipqu|vk|^ancvcp¾t¾mngvgu"htwmv>|kpvqngtcpekc"amjcv"hgpp0"

P^avtkw o

C"m²u|¶v o²p {"mgxgugdd"okpv"3 o o qn"*45 o i+"p^avtkw o qv"vctvcn o c|"8 ml-gu"kplgmek>>u"Äxgi gpm²pv."c|c|"
i {cmqtacvknci"šp^avtkw o o gpvgu60

4.5 I {>>i {u|gtm¾neuv"pjcv^auqm²u"gi {²d"kpvgtcmek>m

Ekrqhnqzcekp

Gi {"kpvgtcmek>u"xk|ui^ancvdep"cl"qdknvqzckocd"gi {u|gtk"fv>|ku^av"cnmno c|v^am"¾poci^adcp"xci {"
ekrtqhnqzcekppcr"gi {Äv"62²t²u|vxgx p²n0"JÄu|"t²u|vxgx "eucm qdknvqzckocdqv."42²t²u|vxgx "rgfki"
qdknvqzckocdqv²u"ekrtqhnqzcekpv"mcrqvv"; perki0"C"ekrtqhnqzcekp"kpvtcx²p^au"kpHÀ|k>>"dgcf^auc"xci {"c"
perk"m²v|gtk"ekrtqhnqzcekp"vcdngvvc"dgx²vngngn vv"cnmno c|qv"38 o ilvvi"qdknvqzckocd"kpvtcx²p^au"
kpHÀ|k>>"guv²p"pg o"x^anvq|qv"ogi"cl"qdknvqzckocd"hct o cmqmkpgvkm^alc0"J cuqpn>m²r rrgp"cl"qt^ankucp"
xci {"kpvtcx²p^aucp"dgcfqv"ekrtqhnqzcekp"hct o cmqmkpgvkm^al^av"ug o"dgqpn {^auqnv"cl"qdknvqzckocd0

Vqx^addk"kpvgtcmek>u"xk|ui^ancvqmcv"pg o"x²ig|vgm0"C|"qdknvqzckocd"o qpqmnp^anku"cpvkvguv."g|²tv"cl"
kpvgtcmek>m"mqem^a|cvc"eugm²n {0

608 Vgt o²mgp{u²i."vgtjguu²i²u"u|qrvcv^au

Vgtjguu²i

C|"qdknvqzczk o cd"vgtjgu"p mp²ⁿv^{3/4}tv²p "cnmcn o c|^auc"vgmkpv²dgp"pg o "a^mtgpfngmg|²utg"kpht o^aek>." o kpf c|qp^anvca"ku o gtv."jq i {"c"j w o^ap"Ki I^av^lw"v" c" rncegp^ap0 f^mncvm^u2 tngv^mpg o "k i c|qnvcm" fktgm^vxc i {"k p fktgm^vm^atqu" jcv^auqmcv" c" tgr tq fwmv^lx"vqzkekv^au"vgmkpv²dgp" *n^auf"705 rqp^v+0 C|"P [ZVJTCEKU cnmcn o c|^auc"gn xki {^a|cvqu^aid>n"mgtAngpf "c"vgtjgu²i"cnvcv0

U|qrvcv^au

Pg o "ku o gtv."jq i {"c|"qdknvqzczk o cd"mkx^ancu|v>fkm-g" c"j w o^ap"cp{cvgl dg0"ku o gtv."jq i {"c"j w o^ap"Ki I^a"c" u|Angv²u"vv^apk"gnu "p²j^ap{"pcrdcp"mkx^ancu|v>fkm" c|cp{cvgl dg." o clf"mgx²uugn"vv^apc"ngeu³ammgb" c" mqqepvt^aek>lc0"m³4xgvmg|²um²r rgp"pg o|"^atjcv>"mk" c"u|qrvcvqv"eugeug o mgv²tkpv "mqem^alc"gd dgp" c" t³4xkf"kf u|cmdep0" C|"qdknvqzczk o cd"cnmcn o c|^au^av" g|"w^ap" c" rgtk>fwu"vv^ap"ku"eucm akkor lehet o gi hqpvpqpk" c"u|optat³2 kf u|cm^adcp, ha az mnkpkmcnc i "hgnv²vngpAn"u|Amu²igu0

Vgt o²mgp{u²i

C|"qdknvqzczk o cddcn"pg o "x²i g|vgm"vgt o²mgp{u²ik" xk|ui^ancvqmcv0

4.7 C^m2u|v o²p{"jcv^auck" c"i²rl^at o xg|gv²ujg|"²u" c"i²rgm"mg|gn²u²jg|"u|Amu²igu"m²rguu²igmtg

C|"qdknvqzczk o cd"mku" o²tv²mdgp" dghqn{^auqj cvlc" c"i²rl^at o xg|gv²ujg|"²u" c"i²rgm"mg|gn²u²jg|" u|Amu²igu"m²rguu²igmgv."wi {cpku" c|"P [ZVJTCEKU cnmcn o c|^auc"vv^ap"gn hqt fwnjcv" hglh^a1^au."u|²fAn²u." h^atcfv^ai²u"j^ap{^au" *n^auf"60: rqp^v+0

4.8 P g o m{x^apcvqu"j cv^auqm." o gmn²mj cv³ok

C"dk|vqpu^ai quu^aik"rtqhkⁿ3/4uu|ghqi ncn^auc

C|"qdknvqzczk o cd"dk|vqpu^ai quu^ai^av"mk|^at>nc i "gi²u|u²igu" hgnp vgm²n" xk|ui^anv^am0

C|"qdknvqzczk o cd"dk|vqpu^ai quu^ai^av"542"gi²u|u²igu" xk|ui^ancv^k"t²u|vxgx p²n"vc^pwn o^ap{q|v^am" *2ngvmtwm<" 3: - 9; ²x+."cmkmgv"gi {"xc i {"mgv "38 mg/kg- qu"kpvtcx²p^au" f>|kuucn"mg|gnv^m"j^atq o "mnkpkmcck" xk|ui^ancvdep0

"uu|guu²i²dgp" c"542"t²u|vxgx "m³4|An"472-gp"mc^rvcm"38 o i lmi"qdknvqzczk o cdqv"gi {u|gtk" f>|kudcp0" VAn²t|²mgp{u²i i gn³4uu|ghAi i "o gmn²mj cv^auqm" *dng²tvxg" c" d tmkAv²uv+ "g|gp"t²u|vxgx m"; ' -^ap^an" *44|472+ "hqt fwnvcm" gn 0"Gi {"cpcrj|nczk^au" gugv"m³4xgvmg|gv^v"dg" c|"kphA|k>" dgc f^auc"m³4|dgp0" C|"kphA|k>" dgc f^au^av" c"t²u|vxgx m"5 ' -^ap^an" *1472+ "mgngv" o gi u|cm^lvcpk"vAn²t|²mgp{u²i "xc i {"cpcrj|nczk" o kcv0

C"ngi i {cmteddep"lgngpv^v o gmn²mj cv^auqm" c" hglh^a1^au" *6 ' ."; 1472+."c"rtwkvwu" *6 ' ."; 1472+²u" c|"wtvkectk" *4 ' ."/6/472+ "xqnvcm0

C"ngi i {cmteddep" o g^rhki {gnv"pg o m{x^apcvqu" tgcme<>m" c|"kphA|k>" o gi mg|f²ug"vv^apk"gnu "j^atq o">t^adcp" c" m³4xgvmg| m"xqnvcm<"rtwkvwu" *p = 9="4. : ' +."wtvkectk" *p = 8="4.6 ' +."hglh^a1^au" *p = 6="3.8 ' +."d tmkAv²u" *p = 5="3.4 ' +."m³4j³4i²u" *p = 5="3.4 ' +."u|²fAn²u" *p = 5="3.4 ' +." *dng²tvxg" c"u|²fAn²uv" *u" c" rquvwtenku" u|²fAn²uv+0

C"uAn|qu"pg o m{x^apcvqu" tgcme<>m" c|"kphA|k>" dgc f^auc"vv^apk"gnu "j^atq o">t^adcp" c"m³4xgvmg| m"xqnvcm<" wtvkectk" *p = 3."2.6 ' +."rtwkvwu" *p = 3."2.6 ' +"²u"j^avh^a1^au" *p = 3."2.6 ' +0

C"leggyakqt kdd"pg o m{x^apcvqu" tgcme<>" c|"kphA|k>" o gi mg|f²ug"vv^apk 3 - 46 ~~12~~ dcp" c" hglh^a1^au" xqnv" *p = 5=" 3.4 ~~10~~

C"o gmn²mj cv^auqm"v^adn^a|cvqu" hgnuqtqn^auc

C"60 v^adn^a|cv" c|"qdknvqzczk o cd" c|qp" o gmn²mj cv^auckv"ku o gtv^{gk}"u|gtxtgp fu|gtk"mcv^gi>>tk^am"2u"i {cmqtka^ai" u|gtkpv."c o gn{gmgv"472"gi²u|u²igu"u|g o²n{p²n" hki {gnv^m" o gi"38 o i lmi"qdknvqzczk o cd"gi {u|gtk." kpv^tcx²p^au" cfcil^apcm" dgc f^au^av"m³4xgv gp0

C" o gnm²mjcv^auqm"i {cmqtk^aik"mcvgi»tk^ak"cm³/xgvmg| m<"pci {qp"i {cmqtk^{*}× 3132+."i {cmqtk^{*}× 1/100 – < 3132+²u"pg o"i {cmqtk^{*}× 1/1000 – < 31322+0"C|"gi {gu"i {cmqtk^aik"mcvgi»tk^amqp"dgn^Ån"o gnm²mjcv^auqm"eu³/mmgp "u^Ån{qu^ai"u|gtkpv"mgt^Ånpgm"o gicf^autcl

4. v^adn^a |cv<"Gi²u|u²igu"hgpp vvgmp²n"lgnppvgv" o gnm²mjcv^auqm

OgfFTC"u gtxtgpfu gtk" kateória	Gyakori	Pgo"i {cmqtk
Ko o wptgpfu gtk"dvgv i u ² i gm ² u" v ^Å ppvgm		Cpcrj {nczk ^a u"tgcmek»" V ^Å n ² t ² mgp{u ² i
Kf g i t g p f u g t k " d v g v i u ² i g m ² u"v ^Å ppvgm	Hglh ^a l ^a u	U ² f ^Å n ² u Rquvwtknku"u ² f ^Å n ² u J { r q c g u v j g u k c
U g o d v g v i u ² i g m ² u"u g o ² u g v k" v ^Å ppvgm		Rj q v q r j q d k c
C" h ^Å n ² u" c " g i { g p u ^Å n { - ² t ² mgn " " u g t x " d v g v i u ² i g k ² u"v ^Å ppvgk		Mgnng o gvngp" ² t ² u c" h ^Å ndgp
l t d v g v i u ² i g m ² u"v ^Å ppvgm		Rj n g d k v k u
N ² i t g p f u g t k " o g n m m c u k ² u o g f k c u v k p c n k u " d v g v i u ² i g m ² u"v ^Å ppvgm	M ³ /j ³ i ² u	Vq t q m k t t k ^a ek»" F { u r j q p k c " Uk p w u " e q p i g u v k q " F { u r p q g c
G o ² u v t g p f u g t k " d v g v i u ² i g m ² u" v ^Å ppvgm		C l c m h ^a l f c n q o
C" d t ² u" c" d t" c n c w k u ³ /xg v" d v g v i u ² i g k ² u"v ^Å ppvgk	Rtwtkwu."wtvkectk. d t m k ^Å v ² u	C n n g t i k ^a u " f g t o c v k v k u " I g p g t c n k ^a n v " m k ^Å v ² u " D t j ^a o n ^a u
C" e u q p v - k q o t g p f u g t ² u a m ³ /v u ³ /xg v" d v g v i u ² i g k ² u"v ^Å ppvgk		X ² i v c i h ^a l f c n q o " K q o u r c o w u " K q o t ^a p i ^a u " f n m m c r q e u h ^a l f c n q o "
f n v c n ^a p q u " v ^Å ppvgm. az alkalmaz ³ / ₂ j g n { ² p" h g m ² r " t g c m e k » m	C k p h ^Å k » " d g c f ^a u ^a p c m " j g n { ² p" h g m ² r " " h ^a l f c n q o	H ^a l f c n q o " O g n m m c u k " f k u m q o h q t v ² t ² u J k f g i t ^a ^a u " H ^a t c f v u ^a i " F w c p c v " a " k p h ^Å k » " d g c f ^a u ^a p c m " j g n { ² p " P g o " e c t f k c n k u " g t g f g v " o g n m m c u k " h ^a l f c n q o " l t ² mgp{u ² i " H ^a l f c n q o " c " v u ^Å t ^a u " j g n { ² p

Gi {gu"mkx^ancu|vqw" o gnm²mjcv^auqm"ng¹t^auc

V^Ån²t|²mgp{u²i"u"anaphylaxia

C|qm" c"pg o m³ x^a pcvqu"tgcmek»m."c o gn {gmgv"cpp^an" c": t²u|vxgx p²n hki {gnvgn" o gi."cmkmp²n"ngjgvu²igu" v^Ån²t|²mgp{u²i" o kcv" hgnh^Åi igu|vgv²m c|qdknvqzcczko cd" kph^Å|k»"cnmnc o c|^au^av."c"m³/xgvmg| m"xqnvcm<" wtvkectk."d t m k^Åv²u."m³/j³i²u."rtwtkwu."u|²f^Ån²u."vqtqmkttk^aek»."f {urjqpkc."f {urpqg²u" o gnm²mjcv^auqm" fku|m q o h q t v² t |² u " C " v^Ån²t |² m g p { u² i " a v³/d d k² t k p v g v p² n " g n u u q t d c p " d t t g n " m c r e u q n c v q u " v^Å p p v g m d g p " p { m x^a p w n v " o g i . " r² n f^a w n " x k u | m g v² u u g n² u " d t m k^Å v² u u g n " l^a t v , 6 t² u | v x g x " r g f k i " m³/j³i² u t n " u |^a o q n v " d g⁰ " C | " c p c r j { n c z k^a u " g u g o² p { " u q t^a p " m k v g t l g f v . " r t w t k w u u | c n " l^a t > . " w t v k e c t k^a u " l g n n g i " m k^Å v² u " l g n p p v g m | g v " c " v g u v " n g i v³/d d " t² u |² p . " d g n g² t v x g " c " p { c m c v . " c " o g n m m c u v . " c " j^a v c v . " c " j c u c v . " c " m c t v² u " c " h^a d c v . " g | g p " m³/x^Ån² i u | q o l² u " k³/i² u " h q t f w n v " g n 0

Pgo" o wvcvmq|qv" ctte" wvcn»" dk|qp{v²m."jq{i" c" v^Ån²t|²mgp{u²ik" tgcmek»mcv" ²u" d t m k^Åv²u g m g v " e k v q m k p h g n u | c d c f w n^a u " x^a n v q v c " x q n p c " m k = " p g o " ²u | n g n v² m " c " e k v q m k p g m " m n k p k m c k n c i " l g n g p v u " x^a n v q |^a u c k v 0

K o o w p q i g p k v^a u

C|"qdknvqzck o cd"gmngpk"cpvkvguvgm"mkncmwn^au^av"o kpfgp"t²u|vxgx p²n"xk|ui^anv^am."cmkm"gi {u|gtk"xc i {" m²vu|gtgu" f>>|ku^À"qdknvqzck o cdq"mcrcm"j^atq o "mnkpkmc" xk|ui^ancvdcpl"C"ngicn^Àdd"gi {"cfc i "kpvtx²p^au" qdknvqzck o cdq"mcrc>>"t²u|vxgx m^m3/4|Àn": h "4.7 ' '*:1542++"cfqvrq|kv"x"gtgf o²p{v c"mg|gn²u"jcv^au^atc" mkncmwnv"vgt^arkcgnngpgu"cpvkvguvgm"*cpvk-vjgtrgwke"cpvkdf{"CVC+"xk|ui^ancvcmtl"C"mxcpvkcv"x"vkvgt" cncuqp{"xqnv."3<42"2u"3<542"m³/4|3/4v"x^anvq|qv0"CVC-x^ancu|v"cf>>"t²u|vxgx mp²n"pg o" o wvcvmq|qv" c" hct o cmqmkpvgkmc"xc i {"c"vqzkekv^aurtqhn" o gix^anvq|^au^atc" wvcn>>"dk|qp{v²m0

Hgnv²vng|gvv" o gnn²mjcv^auqm"dglngpv²ug

C"i {> i {u|gt"gpigf²n{g|²u²v"m³/4xgv gp"n²p{gi gu" c"hgngv²vng|gvv" o gnn²mjcv^auqm"dglngpv²ug." o gtv" g|" hqpva"gu|m³/4|g"eppcm."jqi {"c"i {"> i {u|gt"gn p{lmqem^a|cv"rtqhn^Àv"hn{c o cvqucp"hk i {gng o o gn"hgjuugp" m[u²tpk]"C|"gi²u|u²i^Ài {"k"u|cmg o dgtgm^vm²tlÀm."jqi {"lgngpv²m"dg" c"hgngv²vng|gvv" o gnn²mjcv^auqmcv" c" jcv>>u^a i "t²u|t²g" c|"X0" h^À i i gn²mdgp vcn^anjcv>>"gn²tjgv u²i gm"xcnc o gn{km²p"mgtgu|v^Àn0

4.9 T~~h~~adagol~~h~~

V^Àncfc i qn^au" gugv²p" o qpkvqtq|pk"mgnn" c"dgvgi gv."pg o "lgngpv²m|pgm-g"p^anc" o gnn²mjcv^auqmtc" wvcn>>"lgngm"2u" v^Àpgv²m0

5. HCTOCMQN ~ IKCK"VWNCFLQPU f IQM

5.1 Hct o cmqfka o k^au"vwncl f qpu^a i qm

Hct o cmqvt^ark^au"euqrqtv<"K o o wpu|²tw o qm"2u" k o o wpi nqdwk²pqm."urgekkmwu" k o o wpi nqdwk²pqm."CVE" m>>f<"L28DD44

Jcv^au o gejc²pk| o wu

C|"qdknvqzck o cd" c"B. anthracis rtqvgm"x"cpvki²pl²jg|"*RC+"mcreuq>>f>>" o qpqmnp^anku"cpvkvguv0"C|" qdknvqzck o cd" o gi^avqnlc."jqi {"c"RC"j q| |^amcreuq>>flqp" c"egmwn^atku"tgegrvqtckj q|."fi {" o gi cmcf^an{q| |c" c|"cpvjtcz"ngv^anku"hcmtv^apcm²u"3/4f² o chcmvt^apcm"*c|"cpvjtcz"vqzka"rcvq i²p"jcv^auck²tv" hgngn u"gp|k o cvkmwu"vqzka"m o rppgugm+"dglw^au^av" c"uglv" dngugl²dg0

Hct o cmqfka o k^au"jcv^auqm

C|"qdknvqzck o cd"u|cdcf"RC"kt^apvk"chhkpv^au^apcm"gi {gpa^Àn{k"fk u|qek^aek>>u^amncpf>>lc"*Mf+"2.55 pO0" kp"xkvtq c|"qdknvqzck o cd" c"B. anthracis C o gu."Xqnnw o "2u"Uvgtpg"v³4t|ugkv n"u|^at o c|>>"rtqvgm"x" cpvki²pgmjg|"mcreuq>>fkm0"C.B. anthracis ku o gtv"v³4t|ugkdgp"x^anvq|cvncp" c"RC" c|qp"grkv>>rlc."c o gn{ jg|" j q| |^amcreuq>>fkm" c|"qdknvqzck o cd0

Gi {"uglvncr^Àvgu|vpp."gi²t"gtgfgv " o cmtqh^a i qmmcn"x²i |gvv"kp"xkvtq xk|ui^ancvqm"cncl^ap" c|" qdknvqzck o cd" ugo ngi gu"vk" c"ngv^anku"vqzka" - c"RC" - "ngv^anku"hcmtv"mq o dka"ek>> - vqzkmwu"jcv^auckv0"

kp"xkxj jcv^auqu^a i k"xk|ui^ancvqmdcp" c"B. anthracis C o gu"v³4t|u²pgm"ur>>t^akxcn"kpjcn^aek>>u^aAvqp"x²i |gvv" rtqxqm^aek>>v^m3/4xgv gp"P \ Y"*Pgy" \ gncp f" Y jkv+ "p{wncm^an²u" o cm^am>> o cl o qmp^an" f>>|kuh^À i i gp"p w" c"v^Àn²n²u"qdknvqzck o cd-mg|gn²uv"m³/4xgv gp0"C.B. anthracis ur>>t^akxcn"u|g o dgpk"gzrq|f"ek>>" gtgf o p{gm²p" o gip w" c"RC"mqpegpvt^aek>>lc" P \ Y"p{wncm²u" o cm^am>> o cl o qm"u|²tw o^adcp0"C|" qdknvqzck o cd-mg|gn²u" wv^ap" c"v^Àn²n²u" ^ancvqm"v³4ddu²i²p²n"eu³ammgp" c"RC"mqpegpvt^aek>>lc0"C" rncgd>>" mcrq" ^ancvqmp^an" c|"gnjwn^auwmki"p w" c"RC"mqpegpvt^aek>>lc0

Hat~~h~~össz

O kxgn"pg o "ngjgv²i gu"²u"pg o "ku"ngppg"gvkmwu+"mqpv²qnnqu"mnkpkmc" xk|ui^ancvqmcv"x²i g|pk"kpjcn^aek>>u^a *v^Àf -+"cpvjtcz|cn" hgtv |3/4v" g o dgtgm²n."c" o qpqvt^ark^adcp"cnmnc o c|qv"qdknvqzck o cd"v^Àf cpvjtcz" mg|gn²u²dgp"xcn>> jcv^auqu^a i c" rncgd>>xcn³/4uu|g jcuqpn"vxc" P \ Y"p{wncm²u" o cm^am>> o cl o qmmcn" x²i |gvv"jcv^auqu^a i k"xk|ui^ancvqmq"cncl^ap" c|km0"

G|gmdgp" c"xk|ui^ancvqmdcp" c|"^ancvqmcv" B. anthracis *C o gu^v4t|u^aur>t^akd>n^m2 r|gv^vcgtqu|qmcnⁿ r tqxqm^anv^am^c|"NF₇₂-cv^m3/4t^Åndgn^Ån⁴²²-u|qtqucp" o gi j cncf>" o gpp{ku² i dgp." o cl f^mÅn^{3/4}pd^{3/4}| " kf r qpvqmdcp" qdknvqzck o cd-mg|gn²uv^ccnmcn o c|vcml⁰C|"kpjcn^aek>u^vÅf -+^acpvjtcz" mg|gn²u²v^v vcpwn o^ap{q|>>xk|ui^ancvqmdcp" c|u|v² o^au^acpvjtcz" mnkpkmck" lgnkv" xc i {"v^Åpgvgk^v o wvcv>>"^ancvqmcv" mg|gnv²m⁰C|"gzrq|flek>>"wv^apk" r tqhkcckute" kt^ap{wn>>"xk|ui^ancvqmdcp" c|"^ancvqmcv" c" B. anthracis gzrq|flek>>"lc" wv^ap. c|qpdep" c"v^Åpgvgm" lgnpvmg|²ug" gn v^vmg|gnv²m⁰C" o cm^am>> o cl o qmcv" cmmqt" mg|gnv²m⁰ c o kmqt" c" B. anthracis r tqvgm^vx" cpvk i²pl²tg" kt^ap{wn>>"u²tw o" gngmvtqmg o knw o kpgu|gpek^au^a*GEN+^a" xk|ui^ancv^rq|kv^vx"gtgf o²p{v^cf qv.^avnc i qucp" m^{3/4}t^Åndgn^Ån⁶² >t^axcn" c" B. anthracis-rtqxqm^aek>v^m4xgv gp⁰" P \ Y" p{wncmmcn" x² i |gv^vmg|gn²ugu" xk|ui^ancvqmdcp" c|"^ancvqmcv" cmmqt" mg|gnv²m⁰ c o kmqt" c" RC-^{tc}kt^ap{wn>>" GEN" xk|ui^ancv^rq|kv^vx"gtgf o²p{v^cf qv.^axc i {"c"vguv j o²tu²mngv" jw|c o qucdd" kfgk i" c" mkkp^fw^adk²tv²m⁰ h^{3/4}n²" g o gnmgf gv.^avnc i qucp" m^{3/4}t^Åndgn^Ån⁵² >t^axcn" c" rtqxqm^aek>v^m4xgv gp⁰" C|"c^add" ku o gtv²gv^v" xk|ui^ancvqmdcp" c"v^Ån²uv" c" B. anthracis-rtqxqm^aek>"wv^ap" 4: p crrcn²tv²mgnv²m⁰

C|"kpjcn^aek>u^vÅf -+^acpvjtcz" mg|gn²u²tg" o qpqvgt^ark^adep" cmmcn o c|qv^vqdknvqzck o ed" gi {u|gtk" kpv^{tc}x²p^au^cfci^al^apcm" jcv^auquu^a i^av" gi {"P \ Y" p{wncmmcn" x² i |gv^vxk|ui^ancvdep" xcn o kpv" j^atq o" o cm^am>> o cl o qmmcn" x² i |gv^vxk|ui^ancvdep" *CR424. "CR426" ²u" CR523+²tv²mgnv²m⁰ o k p f g i {k m" rncegdqmqpv^tqm^{qu}. "tcp^fq o k |^anv²u" c" I NR" u|gtkp^vx² i |gv^vxk|ui^ancv^xqnv⁰" C|"CT255. "CR424" ²u" CR523" xk|ui^ancv^xcm" gntgp^fg |²u . "o^fi" c|"CR426" euqrqt^vu|gtkp^vxcm" gntgp^fg |²u "xqnv⁰"

5. v^adn^a |cv<V^Ån²uk"ct^ap{qm" c|"qdknvqzck o cd" o qpqvgt^ark^axcn" *38 o ilmi+^x2 i |gv^vjcv^auquu^a ik" vizsg²atokban

		T ² ar ² ny a vizsg ² at v ² it ²		p- ² it ² ;7' -os CI ³	
		Placebo	Qdknvqzck o cd" 38 o ilmi"		
Kezel² – P \ Y" p{wlak					
CT255" xk ui ^a ncv ¹	2" *2135+	83.7	' *351: +	0,0013*	*2.4; 2. "2. : 83+
Kezel² – Mak²hajmok					
CR426" xk ui ^a ncv ¹	8 ' *3813+	68.9	' *3719+	2.228; ,	*2.2; ; "2.8: 3+
CR424" xk ui ^a ncv ¹	2" *2139+	53.5	' *3817+	2.22: 7,	*2.29; "2.7: 9+"
Gzrq flek>>"wv^apk" r tqr j {nczku" – Mak²hajmok					
CR523" xk ui ^a ncv ⁶	3: ² á az gzrq flek>>" wv ^a p	2" *218+	322 ' *818+	2.2234,	*2.693. "3.222+
	46 ² á az gzrq flek>>" wv ^a p		: 5 ' *817+	2.2264,	*2.452. "2. ; ; 8+
	36 ² á az gzrq flek>>" wv ^a p	--	72 ' *815+	2.2567	*-2.259. "2. : : 4+

EK" o gid² |jcv>u^a ik" vctvq o^a p{

¹ C"v^Ån²uv" 4: p crrcn" c"ur>t^axcn" x² i |gv^vrtqxqm^aek>"wv^ap" ²tv²mgnv²m⁰. "c|^{3/4}uu|gu" tcp^fq o k |^anv^ancvⁿ dem²gt²ok^atc" r q|kv^vx" xqnv" c" mg|gn²u" gn v^v. "c" mg|gn²uv" c"vguv j o²tu²mngv" u|k i p khk m^apu" o gi g o gnmgf²ug" *CT255" xk|ui^ancv⁺xc i {"c" r tqvgm^vx" cpvk i²p" gngmvtqmg o knw o kpgu|gpek^au" xk|ui^ancv^apcm" r q|kv^vx" gtgf o²p{g" *CR426" ²u" CR424" xk|ui^ancv⁺gugv²p" mg|f v²m" gn⁰

⁴ C"r²-tv²k 1 qnfcⁿÅ" Dque j nq-vgu|v^{*}Dgt i gt–Boos- o >fqu^va ucn. " o ku|gtkp^v i c o c = 2.223+gtgf o²p{g" rncegd>xcn" xcn>"^{3/4}uu|g jcuqpn^va ucn

³ C"v^Ån²uk"ct^ap{qm" m^Ån^{3/4}pd² i²pgm" gi |cmv; 7' -qu" o gid² |jcv>u^a ik" vctvq o^a p{c

⁶ C"v^Ån²uv" 4: p crrcn" c"ur>t^axcn" x² i |gv^vrtqxqm^aek>"wv^ap" ²tv²mgnv²m⁰

€ Uvcvku|vkmck" u|k i p khk m^epek^a pcm" hgngn" o gi" c" 2.247-^{3/4}u" u|kpvgp

I {gt o gmgm"2u"ugtfÄn m

C|"Gwt»rck" I {»i {u|gtÄi {p³mu²i" c"i {gt o gmgm" gugu²p"gi {"xc i {"v³dd" mqtqu |v^an {p^an" jncu |v^auv" gpigf²n {g|c|P [ZVJTCEKU xk|ui^ancvk"gtgf o²p {gkpgm" dgp {Älv^auk"m³4vngg |gvvu²i²v" kmgv gp"Dceknwu" qmq|vc" hgtv |²u"mg |gn²u²dgp" *n^auf"604 rqp. "i {gt o gmi {»i {^au |cvk"cmcn o c|^autc"xqpcvmq|»" kphqt o^aek»m+0@

G|v" c" i {»i {u|gtv"šmkx²vnggu"m³4tÄn o²p {gmö"m³4|³4vv"gpigf²n {g|v²m. "c ok" c|v"lgngpvk. "jqiy a gygyszer cmcn o c|^au^atc"xqpcvmq|»cp"– c"dgvg i u²i "tkvmc"gn hqtfwn^auc" o kcvv²u"gvkmck"qmqmd»n"mkhq {»nci² pg o" ngjvgv"vgnlgu"m³4t "kphqt o^aek»v" i { lvgpk0

C|"Gwt»rck" I {»i {u|gtÄi {p³mu²i" o kpfgp"tgpfngm |²u²tg" dqu^avqv"Äl" kphqt o^aek»v²xgpgv hgnÄn xk|ui^an. " ²u u|Ämu²i" gugu²p" o» fqu|vlc" c| "cmcn o c|^auk"gn {t^auv0

5.2 Hct o cmqmpgvkmck"vwncl fqu^a i qm

Hgnu|f{x»f^au

C|"qdknvqczk o cd"het o cmqmpgvkm^alc"nkp^atku" c"6 o ilmi "*c"ngimkugdd"lcxcuqv" cfc i "2.47-u|³4t³4ug+²u" c" 16 o ilmi "m³4|³4vfk" f»|kuvctq o^ap {dcp"gi {u|gtk"kpvtcx²p^au" dgc f^auv"m³4xgv gp."gi²u|u²igu" xk|ui^ancvk" cncp {qmp^an0" C|"qdknvqczk o cd"38 mg/kg-qu" cfc i l^apcm"gi {u|gtk"kpvtcx²p^au" dgc f^au^av"m³4xgv gp" gi²u|u²igu" h²thkmp^an²u"p mp²n" c" E_{ocz} ²u" c| "CWE_{kph} ^avnc ic"622 ±; 3.4 okmtqitc o lon. "kmgv xg" 7392 ± 1360 okmtqitc o perl on" xqnv0" C|"qdknvqczk o cd" hngv²uk" kfglg" m³4tÄndgnÄn"42 pcr" xqnv" *^avnc i +0

Eloszl³2

C|"qdknvqczk o cd" ^avnc i qu" o gi qu |n^auk" v²thq i cvc" fkc o kmwu" gi {gpuÄn {k^a nncr qvdc p"9; .9 ± 3; .4 ml/kg xqnv²u" o gi jenc fvc" c" rnc | o cxqnv o gpv. "c ok"cttc" wvcn. "jq i {"dgm³4xgv mg |km" dk |qp {qu" o²tv²m "u|³4xgvk" gnqu|n^au0

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C|"qdknvqczk o cddcn"pg o "x²i g |vgm" hqt o^anku" cp {c i eugt g-xk |ui^ancvqmcv0
C" o qpqmnp^anku" cpvkvguvgm" fku |rq |fex»lc c|qpdc p"tgpfu |gtkp" c"xcuewnc tku" hqn {c f²mv²tg p"m|^aÄn k" gnqu|n^auucn" ²u"cm^at" c"u|³4xgv mgd g"v³4tv²p "hgnx²vgn gn"l^at. "xcnc o kpv" rtqvg^a |qm^ancvk" mcvc dqnk |o wu" t²x²p" mku" rgrvk fgm²u" c o kpxcxc m"l³4ppgm" n³vtg. "c o gn {gm" g |v"m³4xgv gp" c| "gp fqi²p" m²u |ngv gm" t²u |²x²" x^ancm" xci {"mkÄtÄnpgm0

Gnk o kp^aek»

C|"qdknvqczk o cd" ^avnc i qu" engctcpeg-²tv²mg"5.57 ± 2. ;54 onlper lmi" xqnv²u"u|^a o qvwx gp" gn o ctc fvc" i nq o gtwn^atku" hknvt^aek»u" t^av^av»n. "c ok"cttc" wvcn. "jq i {"c| "qdknvqczk o cd" i {cmqtncvkc i" pg o "ÄtÄn" c" xgu²p" mgtgu |vÄn0

MÄn³png i gu" dvg i euqrqtvm

C"pg o. "c|²ngvmt" ²u" c" tcuu| "jcv^auck
C|"qdknvqczk o cd"het o cmqmpgvkm^al^av" gi {"rqrwn^aek»u"het o cmqmpgvkmck" gng o |²udgp" ²tv²mgv²m"592" qn {cp" gi²u|u²igu" xk|ui^ancvk" cncp {"u|²tw o kpv^akxcn. "cmkm" gi {u|gtk"kpvtcx²p^au" f»|kuv" mcrvc m"6" mnpk mck" xk|ui^ancvdc p0" G|gp" gng o |²u" cncr l^ap" c" pg o *p "xc i {"h²thk. "c" tcuu| *pg o "hgj²t" d t "xc i {"hgj²t" d t + "xc i {"c|²ngvmt" *kf ugm"xc i {"hkvcncqm+ "pg o "hglvgv" mk"lgngpv²mgp {"jcv^auqmcv" c| "qdknvqczk o cd" het o cmqmpgvkmck" rctc o²vgtgktg0" C|"qdknvqczk o cd" mnpk mck" xk|ui^ancvckdep" c|qpdc p" pg o "xgvv" t²u |v" gng i gpf "u|^a o Ä"87²xgu" ²u" kf ugdd" u|go²n {"c ppcm" o gi^a nncr {v^au^ajq |. "jq i {"c| "het o cmqmpgvkm^alwm" gnv²t-g" c" hkcvcncdd" t²u |vxgx m²v n0" C|"qdknvqczk o cd" mnpk mck" xk|ui^ancvckdep" t²u |v" xgvv"542" h "m³4|Än" ;.6 ' *542152+ "xqnv"87²xgu" ²u" kf ugdd. "o {i"4 ' *54218+ "xqnv"97²xgu" ²u" kf ugdd0

C"vguv o²tgvgv n³4uu|ghÄi i "jcv^auqm

C"engctepg"pci {"vguv³/₄ o gi *32; mi+"gugv²p^m34tÅndgnÅn"5: ' -mcn"xqnv" o ci cucdd." o kv^ac"tghgtgpek" rqrwn^aek>dcpl"Vguv³/₄ o g igp"cnrwn>"cfcicq^au^a*38 o ilmi+"gtgf o 2p{gm²p^vc|"CWE_{lph} 34 ' -kal g o gnm g fkm."c o k"mnkpkmcnci"pg o "lgn g p v u 0

I {gt o gmgm²u"ugt f Ån m

C | "qdknvqczk o cd"htc o cmqmkpgvkm^a1^av" i {gt o gmgm²n"pg o "xk | u i ^anv^am⁰"C"40 v^adn^a | cvdep^{*}604 rqp^v+ o g i c f q v " c f c i c q ^a u k " c l ^a p ^a u q m " r q r w n ^a e k > u " h c t o c m q m k p g v k m c k " o g i m ³/₄ | g n ^v ² u u g n " x ² i | g v v " u | k o w n ^a e k > m d > n " u | ^a t o c | p e m . " c o g n { g m g v " Å i { " v g t x g | v g m . " j q i { " o g i h g n g l g p m c " | " q d k n v q c z k o c d " 3 8 o i l m i " c f c i l ^a p c m c m c n o c | ^a u c m q t " h g n p v g m p ² n " m k c n c m w n > " g z r q | { e k > p c m 0

5.3 A preklinikai biztonságosági vizsgálatok eredményei

C"jci {q o ^a p {qu – hct o cmq n > i k c k " d k | v q p u ^a i q u u ^a i k . " k u o ² v g n v " c f c i c q ^a u Å " f > | k u v q z k e k v ^a u k . " t g r t q f w m e k > t c " 2 u " h g l n f ² u t g " m k h g l v g v " v q z k e k v ^a u k " – x k | u i ^a n c v q m d > " u | ^a t o c | > " p g o - m n k p k m c k " l g n g i " c f c v q m " c | v " k i c | q n v ^a m . " j q i { " c " m ² u | { v o ² p { " c m c n o c | ^a u c m q t " j w o ^a p " x q p c v m q | ^a u d c p " m Å n ³/₄ p n g i g u " m q e m ^a | c v " p g o " x ^a t j c v > 0

M³/₄ | r q p v k " k f g i t g p f u | g t k " M K T + " n ² | k > m c v " * d c m v ² t k w o q m . " i { w n c f ^a u . " x ² t | ² u " ² u " c m c n o c p m ² p v " p g e t q u k u + " ² u | n g n v g m " q n { c p " c p v j t e z u | c n " h g t v | ³/₄ v v " ² u " c | v " v Å n " p g o " ² n " P \ Y " p { w n c m p ^a n " ² u " o c m ^a m > o c l o q m p ^a n . " c o g n { g m " q d k n v q c z k o c d q v " * 6 o i l m i + " x c i { " m q p v t q m " m ² u | { v o ² p { v " m c r v c m " k p v t c x ² p ^a u c p " c " d g v g i u ² i " k i c | q n ^a u c m q t 0 " C | " q d k n v q c z k o c d d c n " m g | g n v . " c " h g t v | ² u v " v Å n " p g o " ² n " ^a n c v q m p ^a n " ² u | n g n v " o k m t q u | m > r q u " g n x ^a n v q | ^a u q m c v " c | " g z v t c x c u e w n c t k u " d c m v ² t k w o q m " q m q | v ^a m . " p g o " r g f k i " c | " q d k n v q c z k o c d " j c v ^a u c " o k c v " l ³/₄ v v g m " n ² v t g 0 " C | " c i { " m > t u | ³/₄ x g v c p ^a v " k n g v g p " p g o " c | q p q u " v q v c m " f > | k u - t g c m e k > " ³/₄ u u | g h Å i i ² u v 0 " P g o " o w v c v c m " m k " c " m g | g n ² u u g n ³/₄ u u | g h Å i i " c i { k " n ² | k > m c v " c p v j t e z u | c n " h g t v | ³/₄ v v " ² u " c | v " v Å n ² n v " P \ Y " p { w n c m p ^a n " * c " 4 : 0 p e r q p + " x c i { " o c m ^a m > o c l o q m p ^a n " * c | " 7 8 0 p e r k i + " c | " q d k n v q c z k o c d " 3 8 m g / k g - k i " k n n 0 " 5 4 m g / k g - k i " v g t l g f " f > | k u c k p e m " g i { u | g t k " c m c n o c | ^a u ^a v " m ³/₄ x g v g p 0 " C p v j t e z u | c n " h g t v | ³/₄ v v " ² u " c | v " v Å n ² n " o c m ^a m > o c l o q m p ^a n " c | " q d k n v q c z k o c d d c n " ³/₄ u u | g h Å i i ² u d g p ^a m > " x k u g n m g f ² u p g w t q n > i k c k " j c v ^a u q m c v " p g o " ² u | n g n v g m " c | " q d k n v q c z k o c d - m g | g n ² u v " m ³/₄ x g v g p 0

C | " g o d t { q h q g v e n k u " h g l n f ² u t g " m k h g l v g v " j c v ^a u " g i { g n g p " x k | u i ^a n c v ^a v " x g o j g u . " g i ² u | u ² i g u " P \ Y " p { w n c m m c n " x ² i g | v ² m . " c o g n { g m " 6 " k p v t c x ² p ^a u . " 5 4 m g / k g - k i " v g t l g f " f > | k u d c p " m c r v c m " q d k n v q c z k o c d q v " * g | " o i l m i " c n c r l ^a p " c | " g o d g t k " c f c i " m ² v u | g t g u g + " c " 8 0 . " c " 3 2 0 . " c " 3 5 0 " ² u " c " 3 9 0 i g u | v ^a e k > u " p e r q p 0 " P g o " h k i { g n v g m " o g i " q n { c p " d k | q p { v ² m q v . " c o g n { " c " x g o j g u " p u v ² p { " x c i { " c " o c i | c v q m " q d k n v q c z k o c d " o k c v d g m ³/₄ x g v m g | " m ^a t q u q f ^a u ^a t e " w c v n " x q p c l " C " m w o w n c v " x " g z r q | { e k > " P \ Y " p { w n c m p ^a n " * 3 2 0 0 0 o k m t q i t c o o x p e r l o n + " c | " c f c i q m ² p v " 5 4 o i l m i " P Q C G N " u | k p v g p " * p = 6 " c f c i + . " C W E ₀₋₃₇ p e r " c n c r l ^a p " j q | | ^a x g v n g i g u g p " m ² v u | g t g u g p " o g i j c n c f v c " c " 3 8 m g / k g - q u " m n k p k m c k " k p v t c x ² p ^a u " f > | k u " g u g v ² p " m k c n c m w n > " n ² t h k " ² u " p k " m q o d k p ^a n v " j w o ^a p " C W E - v 0 " C " E _{o c z - 2} t v ² m g " 5 4 o i l m i " f > | k u v " m ³/₄ x g v g p " 3 3 : 2 o k m t q i t c o o x p e r l o n " x q n v 0

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803 Segítséganyagok felsorolása

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s | q t d k v " * G 6 4 2 +
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804 Inkompatibilitások

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9 2x

Jfi"fvqv"qnfcv"kpHÀ|k»u"|u"amdep

C|"kphÀ|k»u"|u"amdep"x2i|gvv"jfi"fv"uv"m3/4xgv gp" c|"cnmnc o c|"a"u"gn vvk"m2 o kck."hk|kmcck"2u" o kmtqdk"anku" uvcdknk"u": »t"p"mgtgu|vÄn"ki c|qnvcp"hgpp o c t c f"u|qdcj o 2tu2mngvgp"*42 ÅE – 47 ÅE+"xci {" j v u|gmt2p{dgp"*4 ÅE – : ÅE+0

O kmtqdkqn» i kck"u|g o rqpvd»n."mkx2xg."j c" c"hgnp {kv"uklhgnqnf"auklj"fi"fv"uk" o »fu|gt"mk|"a"tlc" c" o kmtqdkqn» i kck" u|gpp {g| f2u"mqem" a|cv"v."c"vgt o 2mgv" c|qppcn"hg n"mg n" jcu|p"anpk0

J c" c"m2u|fv o 2p {"pg o "mgtÄn" c|qppcn"hg n" jcu|p"an" utc."c|"cnmnc o c|"a"u"gn vvk"v"aqn"uk"kf 2tv"2u" m3/4tÄn o 2p {gm2tv" c"hg n" jcu|p"an»" c"hg n" u0

Jfi"fvqv"qnfcv"kpHÀ|k»u"hg eumgpf dgp"

C"jfi"fvqv" P [ZV J TCEKU qnfcvqv"gnm2u|fv2ug"vv"p" c|qppcn"dg"mg n" c f p k" pg o "u|cdcf"v"aqn"pk0" C"hg n"pg o " jcu|p"an"m2u|fv o 2p {"mk"mg n" f q d p k0

806 MÄn3/4p ng i gu"v"aqn"uk"gn ft"auqm

J v u|gmt2p{dgp"*4 ÅE – : ÅE+"v"aqn"cp f»0

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€ C"mqpegpvt"v"v o "qnfcvqu" kplgmek»j q|"m2u|fv o 2p {"v" c" d g c f" a u" g n v v" u|g o t g x 2 v g n g | 2 u u g n" o g i" m g n n" xk|u"i"anpk."jqi {"pkpeu-g"gnu|fpg| f x g."kmgv x g" p g o "vctvcn o c|-g"u|g o e u 2 m g v0" C|"P [ZV J TCEKU "v"v"u»"xci {"qrcngu|m"an»."u|fpvgngpv n"jcnx"ap {u"ati"aki"xci {"jcnx"ap {"dctp"uu"ati"aki"vgtlgf "u|fp " qnfcv."c o g n {"p2j"ap {"a"v g v u| "xci {"hgj2t"u|fp ."hgj2tlgu|gt "t2u|geum2v"vctvcn o c|jcv"*g|gket a dg2r"fvv"u|t "gnv"axqnf"vlc+0

€ Fqdlc"mk" c|"kplgmek»u"Äxgi gv."j c" c|"qnfcv" gnu|fpg| f3/4v"xci {"kfgi gp"t2u|geum2mgv"vctvcn o c|"n"u" f" 50 rqpvd+0

€ P g"t" a | | c"hg n" c|"kplgmek»u"Äxgi gv#

Gn m2u|fv2u"2u"jfi"fv"u"kpHÀ|k»u"|u"amdep"

30 U|"a o qnlc"mk" c|"qdknvqzecz o cd"u|Ämu2i gu" o gpp {ku2i2v"Äi {"jqi {"o gi u|qtq| |c" c"40 v"dn" a|cvdcp" *n"u" f"604 rqpvd+"lcxcuqnv." o i l m i -d e p" m k h g l g | g v v" f »|k u v" c|"c f q v v" d g v g i" m k n q i t c o o d e p" m k h g l g | g v v" v g u v 3/4 o g i 2 x g n0

40 U|"a o qnlc"mk" c|"qdknvqzecz o cd"mqpegpvt"v"v o "qnfcvqu"kpHÀ|k»j q|" o knknkvgt dgp"mkg l g | g v v" u|Ämu2i gu"v2thqicv"v"2u" c|"c f c i" d g c f" a u" a j q|"u|Ämu2i gu" kplgmek»u"Äxgi gm"u|"a o"v0" G j j g|"q u u|c"gn" c" m k u|"a o q n v." o k n n k i t c o o d e p" m k h g l g | g v v" c f c i q v"*30 n2r2u+"c"mqpegpvt"ak»xcn."c o k"322 o i l o n0

Okpfgp"gi {gu"klplgmek»u"Äxgi"8 o n"qdknvqzczk o cd"mqpepvt^avw o "qnfvcqu"kpHÀ|k»jq|"dgcfa^au^av"
vgu|k"ngjgv x²0
50 X^ancuu|qp"mk"gi {" ; o il on"2.; ' +p^avtkw o -mnqtkf"qnfvcqu"klplgmek»v"vctvcn o c |»." o gi hngn " o²tg v "
kpHÀ|k»u" | u^amqv⁰"Xgi {gp"mk"cl"kpHÀ|k»u" | u^amd»n"emmqtc"v²thqicv^a"qnfvcqv."c o gpp{kv"mku|^a o qnv"
o knknkvgt dgp"cl"qdknvqzczk o cdte"xqpcvmq | »cp"chgpvk"40 n²r²u"uqt^ap⁰"Fqdlc"mk"cl"kpHÀ|k»u" | u^amd»n"
mkxgvv"qnfvcqv⁰
60 Xgi {g"mk"cl"qdknvqzczk o cd"mqpepvt^avw o "qnfvcqu"kpHÀ|k»jq|"u | Ämu²i gu"v²thqicv^a*c o gn {gv"e"
40 n²r²udgp"u|^a o qnv"mk+"cl" P [ZVJTCEKU kplgmek»u"Äxgi²d n"xc i {"Äxgi gkd n⁰"Fqdlc"mk"cl"
P [ZVJTCEKU kplgmek»u"Äxgi*gm+dgp" o ctcfv"qnfvcqv⁰
70 Xki {g^av"cl"qdknvqzczk o cd"mqpepvt^avw o "qnfvcqu"kpHÀ|k»jq|"u | Ämu²i gu" o gpp{ku²i²v" c"
mkx^ancu|vqv"kpHÀ|k»u" | u^amdc⁰"
80 ~ xcvqcp"htqicv^av"cl"kpHÀ|k»u" | u^amqv."jq i {"c|"qnfvcv³uu|gmgxgtgflgp⁰"Pg"t^a | |c"hg n#
90 C|"kpHÀ|k»v"; 2 rgtc"cnv"mgm" dgc fpk"e"50 v^adn^a | cvdcp"dg o wvcqv"ugdgu²i i gn"*n^auf"604 rqp v+."
2.44 o kmtqpqu"dg²r"vqv"u| t v"cnmca o c|xc⁰"
:0 C|"gnm²u|vqv"qnfvcv": »t^ap^av"uvcdkn"u|qdcj o²tu²mngvgp"*42 ÄE"2u"47 ÄE"m³/₄v v+"xc i {"
j v u|gmt²p{dgp"*4 ÄE"2u": ÄE"m³/₄v v+"v^atqnc"gi {ct^ap⁰"

Gn m²u|v²u"2u"j|i^au"kpHÀ|k»u"hg eumgpf dgp

30 U|^a o qnlc"mk"cl"qdknvqzczk o cd"u | Ämu²i gu" o gpp{ku²i²v"Äi {" .jq i {" o gi u|qtq| |c"e"40 v^adn^a | cvdcp"
*n^auf"604 rqp v+"lcxcuqnv." o ilmi-dcp"mkhglg | gvv" f» | kuv"cl"cfqv"dgvgi"mknqitc o o dcp"mkhglg | gvv"
vguv³/₄ o gi²xgn⁰
40 U|^a o qnlc"mk"cl"qdknvqzczk o cd"mqpepvt^avw o "qnfvcqu"kpHÀ|k»jq|" o knknkvgt dgp"mkhglg | gvv"
u | Ämu²i gu"v²thqicv^a*2u"cl"cfci" dgcfa^au^ajq|"u | Ämu²i gu"klplgmek»u"Äxgi gm"u|^a o^av⁰"Gjjg|"quu|c"gn"e"
mku|^a o qnv." o knknqitc o o dcp"mkhglg | gvv"cfciqv"*30 n²r²u."c"mqpepvt^aek»xcn."c o k"322 o il on⁰"
Okpfgp"gi {gu"klplgmek»u"Äxgi"8 ml P [ZVJTCEKU mqpepvt^avw o "qnfvcqu"kpHÀ|k»jq|"dgcfa^au^av"
vgu|k"ngjgv x²0
50 X^ancuu|qp"e" dgc fcpf»"kpHÀ|k»³/₄uu|gu"vqv" o gpp{ku²i²pgm" o gi hngn " o²tg v "hg eumgpf v⁰
60 C"mkx^ancu|vqv"hg eumgpf "2u"gi {"2.44 o kmtqpqu"dg²r"vqv"u| t "ugi^av²i²xgn"xi {g"mk"cl"
qdknvqzczk o cd"mqpepvt^avw o "qnfvcqu"kpHÀ|k»jq|"u | Ämu²i gu" o gpp{ku²i²v" *c o gn {gv"e"40 n²r²udgp"
u|^a o qnv"mk+"⁰"Fqdlc"mk"cl" P [ZVJTCEKU kplgmek»u"Äxgi*gm+dgp" o ctcfv"qnfvcqv⁰
70 Xgi {gp"mk"e"40 v^adn^a | cvdcp" o gi jcv^atgqv"vgnlg"kpHÀ|k»u"v²thqicvpcm" o gi hngn " o gpp{ku²i "
; o il on"2.; ' +p^avtkw o -mnqtkf"qnfvcqu"klplgmek»v⁰
80 ~ xcvqcp"ngi {vug"cl"qnfvcqv⁰"Pg"t^a | |c"hg n#
90 C|qppcn"cfic"dg"cl"gnm²u|Änv"j|i^avqv"qdknvqzczk o cd"qnfvcqv⁰"Pg v^atqnlc"cl"qnfvcqv"e"
hg eumgpf dgp#"C"hg n"pg o"jcu|p^anv"m²u|v⁰ o²p{v"ug o o ku"vug" o gi⁰

Ogiug o oku^av²u

D^at o kn {gp"hg n"pg o"jcu|p^anv"i {" »i {u|gt."knngvxg"jwmcf²mcp{ci" o giug o oku^av²u"e"i {" »i {u|gtgmtg"
xqpcvmq| »gn "t^auqm"u{gkpv"mgm"x²i t g jclvcpk⁰

7. A HQT ICNQODCJQ \ CVCNK"GP IGF ; N ["LQ IQUWNVLC

UHN"Rjct o cegwkecnu" Fgwwuejncpf" I o d J
Octkg-Ewtkg-Uvtcuug":
9;75: N³ttcej
P² o gvtu|^a i

8. C"HQT ICNQODCJQ \ CVCNK"GP IGF ; N ["U \ f OC*K+

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**9. C"HQT ICNQODCJQ \ CVCNK"GP IGF ; N ["GNU "MKCF fUfPCM"
OGI-L[~]VfUfPCM" F fVWOC**

C"hticnq o dcjq|cvcnk"gpigf2n{"gnu "mkcf^au^apcm"fa^avwoc<42420"pqxg o dgt"3:

10. C"U\ "XGI"GNNGP T\ ;U;PGM"FfVWOC

C"i {>i {u|gtt n^t2u|ngvgu"kphqt o^aek>"c|"Gwt>rck" I {>i {u|gtÁi {p³mu²i"kpvtgpgvgu"jqpncl^ap"
* [jwr<ll y y0g oc0gwtqrc0gw+](#)>²u" c|"cfqw"vci^amc o"i {>i {u|gtjcv>u^ai^apcm"kpvtgpgvgu"jqpncl^ap"*kpm+@"
vcn^anjcv>0

A gyógyszerk.sztm.ny forgalomba hozatali enged.lye megszünt

II. MELLÉKLET

- A. C"DKQN~ IKCK"GTGFGV "JCV~ CP [C] I [fTV~ LC" ; U"C"
I [fTVfUK"V ; VGNGM"X ; IHGNU\CDCP~VfUf ; TV"
HGNGN U" I [fTV~
- D) HGNV ; VGNGM"XCI ["MQTNfVQ\ fUQM"C\ "GNNfVfU" ; U"
JCU\ PfNCV"MCREUfP
- C. C"HQTI CNQODC JQ\ CVCNK"GP IGF ; N ["GI [; D"
HGNV ; VGNGK" ; U"M" XGVGNO ; P [GK
- D. HGNV ; VGNGM"XCI ["MQTNfVQ\ fUQM"C" I [~ I [U\GT"
DK\ VQPUf IQU" ; U" JCV ; MQP ["CNMCNOC\ fUfTC"
XQPCVMQ\ ~ CP
- E. HQT I CNQODC" JQ\ CVCNV" M" XGV "KPV ; \MGF ; UGM"
VGNLGU~V ; U ; TG"XQPCVMQ\ ~ "URGEKfNKU"
M" VGNG\GVVU ; I "C"MKX ; VGNGU" M" TONO ; P [GM"
M" \ ; W"OG ICFQVV"HQT I CNQODC JQ\ CVCNK"
GP IGF ; N ["GUGV ; DGP

A. C"DKQN ~ IKCK'GTGFGV " JCV ~ CP [CI*QM+ I [fTV ~ LC1I [fTV ~ K' ! U"C
I [fTVfUK"V ; VGNGM"X ; IHGNU \ CDCF ~ V fUf ; TV"HGNGN U" I [fTV ~ *M+

C"dkqn>ikck'gtgfgv "jcv>cp{ci*qm+}i{^tv>l^apcmli{^a tv>kpcm"pgxg"2u"e"og

Nqp|c"Dkqnqikeu."kpe0"
323"Kpvgtpcvkqpcn" Ftkxg
Rqtvu o qwvj."P J"25:23"
C o gtkmck"G i { guÄnv" f nnc o qm

C"i{^a tv^uk"v^2vngnm"x^2ihgnu|cdf{v^a u^2 tv"hgngn u"i{^a tv>*m+"pgxg"2u"e"og

Cegtvrjctoc"D0X0
Dquejuvtccv"73
6:33"IE."Dtgfc
Jqmncpfkc

D0 HGNV ; VGNGM"XC I ["MQTNfVQ \ fUQM"C \ "GNNfVfU" ! U" JCU \ P fNCV"MCREUfP"

Qtxqk"tgpfgnx^2p{ jg | "m^3/4v^4w" i { >> i { u | gt0

C. A HQT I CNQODCJQ \ CVCNK"GP I GF ; N ["G I ["D"HGNV ; VGNGK" ! U"
M " XGVGNO ; P [GK

€ Kf u | cmqu"i { >> i { u | gtdk | vqu^a ik"lgngpv^2ugm"*Rgtkqfke"uchgv{ "wrfcvg"tgrqtv."RUWT+

Gttg"cm^2u | v^o^2p { tg"RUWT-qmcv"42231 : 51GM"kt^ap { gn^329e0"ekmm^2pgm"*9+"dmg | f^2u^2dgp"
og i^amcr"vqv"2u"cl" gwt>rck kpvgtpgvgu"i { >> i { u | gtrqtv^anqp"p { knx^a pquu^a i tc"jq | qv"wpk>>u"tghgtpekc"
kf rqpvm"nkuv^a lc"*GWT F"nkuvc+. "kngvxg"cppcm"dt o gn { "m^2u ddk"htkuu"vqv"v^a nvq | cvc"u | gtkpvk"
m^3/4xgvgn o^2p { gmpgm"og ihgngn gp"mgm"dgp { Älvcpk0

D. HGNV ; VGNGM"XC I ["MQTNfVQ \ fUQM"C" I [~ I [U \ GT"DK \ VQPUf I QU" ! U"
JCV ; MQP ["CNMCNOC \ fUfTC"XQPCVMQ \ ~ CP""

€ Kockzatkezelési terv

C"htqicnq o dcjq | cvcnk"gpigf^2n { "lqiquwnvc"*OCJ + "m^3/4vng | k"oci^a v."jq i { "c"htqicnq o dcjq | cvcnk"
gpigf^2n { "30:04 o qfwnl^3dcp"ng{tv."l>>x^a jci { qv"mqem^a | cvmg | gn^2uk"vgtxdgp."kngvxg"cppcm"
l>>x^a jci { qv"htkuu"vqv"v^a xgt | k>>kdep"t^2u | ngvg | gvw."m^3/4vng | "hct o cmqxi kncepk"v^2mgp { u^2 i gmgv"2u"
dgexcvmq | ^a uqmcv"gnx^2 i | k0

C"htkuu"vqv"v^a mqem^a | cvmg | gn^2uk"vgtx" dgp { Älvcpf>>"c"m^3/4xgvmg | "gugvmdgp<

€ jc"o" "Gwt>rck" I { >> i { u | gtdk | vqu^a ik"lgngpv^2ugm"*Rgtkqfke"uchgv{ "wrfcvg"tgrqtv."RUWT+

€ jc"o"mqem^a | cvmg | gn^2uk"vgtx" dgp { Älvcpf>>"c"m^3/4xgvmg | "gugvmdgp<
kphqt o^a ek>>"2tmg | km."c o gn { "c" | gn p { lmqem^a | cv"rtqhn"lgngpv u"x^a nvq | ^a u^a j q | "xg | gyjgv."kngvxg"*c"
dk | vqu^a i qu"i { >> i { u | gtcnmcn o c | ^a utc"xc i { "mqem^a | cv- o kpk o cnk | ^a n^a utc"kt^a p { wn>>+"Älcdd."
og i jcv^a tq | >>"gtgf o^2p { gm"u | Ängvpgm0

E. HQT I CNQODC" JQ \ CVCNV" M" XGV " KPV \ MGF \ UGM" VGNLGU~V \ U \ TG" XQPCVMQ \ ~ "URGEKfNKU" M" VGNG \ GVVU \ I "C" MKX \ VGNGU" M" T@NO \ P [GM" M" \ " VV" OGICFQVV" HQT I CNQODC JQ \ CVCNK" GP IGF \ N ["GUGV \ DGP

Okwv^ap^g|v^ci {> i {u|gtv c"mkx²vgngu"m³4tÅn o²p {gm"hgpp^ann^auc" o kcvv"j c i {v^am"l>>x^a"c"948142261GM" tgpfgngv"360"ekmm²pgm"*: + "dmg | f²ug"u | gtpv" c" hqt i cnq o dcjq | cvcnk"gp i gf²n { "lq i quwnvl^apcm" c" o g i c f qv" jcv^atkf p" dgnÅn" o g i "mgnn"vgppkg" c | "cn^a ddk"kp^v2 | mgf²ugmgv<

Lejz	Lejzat napja
<p>C "qdknvqzczk o cd"RM-I^apcm" jwo^ap"u ²tw o dcp"v³4tv²p " o g i jcv^atq ^au^atc"u qn i ^an»" o » fu gt" * I EN-382+ "xcnkf^an^au^a j q "c" hqt i cnq o dcjq cvcnk"gp i gf²n { "lq i quwnvl^apcm"dg"mgnn"p { Àlvcpkc" c" xk ui^ancvk" o » fu gt"xcnkf^an^au^apcm"gtgf o²p {gkv" c"m³4xgvmg mtg" xqpcvmq »cp." o kgn v"gnx² i g p²m" c "C J 723"mnkpkmcck" xk ui^ancv" o kpv^akpcm"ngn o ²u²v" g gn" c" o » fu gttgn<"RC"^ancnk"kpvgthgtgpekc"*85" ²u": 5+. "GH. "NH"²u"CFc-m."xcnc o kpv" c" xk ui^ancvk" o » fu gt" vgnlgv"v o²p {g" jcg o qn { vkewu"²u"nkr g o k^au"u ²tw o dcp0"R^atjw c o quu^a ik" xk ui^ancvq"mgnn"x² i g pk" c "vgtxg gvv." p { "nv" gntgpf g ²u "C J 723" vgtgrk" xk ui^ancvd»n"u ^at o c »" o kpv^ammcn0</p> <p>C"mnkpkmcck"x^ancu ."dk vqpu^a i quu^a i "²u"vqngt^an j cv»u^a i "*"dgn²tvxg" c" dvgv i u² i "nghqn { ^au^av²u" c"vÅn²n²uv"kp j cn^aek»u"vÅf -+ "cpv j tezu cn" i { cp"v j cv»nci."xcn»u "p ng i"xc i { "k i c qnvcp" hgtv ³4v"2u" qdknvqzczk o eddcn"mg gn"v" xk ui^ancvk"cnep { qmp^an+²tv²mgⁿ2u² j g "c" hqt i cnq o dcjq cvcnk"gp i gf²n { "lq i quwnvl^apcm"gi "o g i dgu ²nv" xk ui^ancvk"vgtx"u gtpv"gn"mgnn"x² i g pkg" c"KX0 h^a kuÅ." p { "nv" gntgpf g ²u "C J 723"vgtgrk" xk ui^ancvq" cmmgt." c o kmqt"n²rhgpgl^atx^ap { " Åvk" hgn" c hgl²v" c qmdcp" c "qtu ^a i qmdcp." c o gn { gmdgp" c " qdknvqzczk o cd"gp i gf²n { g gvv"²u"gn²tjgv" ." o clf"dg"mgnn"p { Àlvcpkc" c" xk ui^ancvq"ng ^at»"lgn²pv²uv0</p>	<p>C "C J 723" xk ui^ancv" ^at»" mnkpkmcck"lgn²pv²u²xgn"gi { Åvv" mgnn" dgp { Àlvcpk</p> <p>Dgp { Àlvcpf »²xgu" lgn²pv²ugm"</p> <p>C"ng ^at»"lgn²pv²uv" ng i hgnlgdd"34 j »pcrrcn" c " qdknvqzczk o cd"vqnu»" dgc f^au^av"*xkuu" c o gp ng i gu" cfcvi { lv²u" gugv²p"rgfki" c " vqnu»" cfcvi { lv²uv+ " m³4xgv gp"mgnn" dgp { Àlvcpk</p>

A gyűjtemény kiadásának jogszabályi engedély nélkül nem lehetséges.

A gyógyszerkészítmény forgalomba hozatali engedély megszerzését

III. MELLÉLET

Ez OMGU\ "XGI"!UDGVG IV\FL!MQ\VCV~

A gyógyszerkészítmény forgalomba hozatali engedély megszerzését

A. EOMGU\ "XGI

C"MONU "EUQOCIQNFUQP"HGNV©PVGVPF "CFCVQM

FQDQ\

1. C" I [~ I [U\GT"PGXG

P [ZVJTCEKU 100 o i l o n"uvgtkn"mqpepvt^avw o
qdknvqzck o cd"

2. JCV ~ CP [CI*QM+"OGIPGXG\ ;UG

1 o n"322 mg qdknvqzck o cd0

3. UGI ;FCP [CIQM"HGNUQTQNfUC

Ugi²fcp{ciqm<jku|vkfkp."u|qtdkv."G655."u>ucx."p^avtkw o -jkftqz kf."kplgmek>>jq|"xcn>>x"|0

4. I [~ I [U\GTHQTOC" ;U"VCTVCNQQ

Mqpepvt^avw o "qnfcvqu"kpH|k>>jq|
600 mg/6 ml
1 fd"kplgmek>>u"Åxgi

5. C\"CNMCNOC \ fUUCN"MCREUQNCYQU"VWFPKXCN ~ M" ;U"C\"CNMCNOC \ fU"
O ~ FLC*K+

Jcu|p^ancv"gn w"qnxcuuc"gn" c" o gmn²mgnv"dgigi v^al²mq|vcv>>v#
Kx0"j|i"v^au"ww^ap0
Mk|^at>>nci"gi {u|gtk"cnmcn o c |^autcl
Ne r~~z~~a fel!

ST"m>>f"dgknngu|vgpf "-"y xyqdknvqzck o cd-uhn0gw

80 M©N" P"HKI [GNOG\ VGV ;U."OGN ["U\GTKPV"C" I [~ I [U\GTV"
I [GTOGMGMV N"GN\ fTXC"MGNN"VCTVCPK

7. VOXfDDK"HKI [GNOG\ VGV ;U*GM+."COGPP [KDGP"U\ ©MU ; I GU

8. NGLfTCVK"KF

EXP

9. M©N" PNGIGU"VfTQNfUK'GN ~TfuQM

J v u|gmt²p{dgp"v^atqncpf>>0"

Nem fagyasztható

C"h2p{v n"xcn»"x2fgng o "2tfgm2dgp" c | "gtgfgvk" euq o ci qn^audcp"v^atqncpf»0

10. M@N" PNG I GU" ~ XKP V ; \ MGF ; UGM" C" HGN" PGO" JCU \ P f NV" I [~ I [U \ GTGM" XCI ["C \ "KN [GP" VGTO ; MGMD N" MGNGVMG \ GVV" JWNNCF ; MCP [C I QM" f TVCNO CVN CPP f" V ; VGN ; TG." J C" KN [GPGMTG" U \ ©MU ; I" XCP

11. C" HQT I CNQODCJQ \ CVCNK" GP I GF ; N ["LQ I QUWNVL f PCM" PGXG" ; U" E ÖG

UHN" Rjcto cegwvkecnu" Fgwvuejncpf" I odJ

Octkg-Ewtkg-Uvtcuug":

9;75; N³/ttcej

P² o gvqtu |^a i

12. C" HQT I CNQODCJQ \ CVCNK" GP I GF ; N ["U \ f OC* K+"

GW13142136:7/001

13. C" I [f TV f UK" V ; VGN" U \ f OC

I {0u |0<

14. C" I [~ I [U \ GT" TGPF GNJGV U ; IG

15. C \ "CNMCNOC \ f UTC" XQPCVMQ \ ~ "WVCU" V f UQM

380 DTCKNNG" T f UUCN" HGNV ©PVG VGVV" KPHQTO f EK ~ M

Dtcknng- f t^a u" hgnv² apvgv² ug" cn» n" hgn o gpvxg0

17. GI [GFK" C \ QPQU" V ~ ~ - 4F" XQPCNM ~ F

Gi {gfk" c | qpqu" v» | A 4F" xqpcnm» f fcn" gnn^a vxcl

18. GI [GFK" C \ QPQU" V ~ ~ "QNXCUCJCV ~ "HQTO f VWOC

RE"

UP"

NN

C"MKU"M" \XGVNGP"EUQOC IQNfUK"G I [U; IGMGP"OKPKO fNKUCP"HGNV©PVGVPF " CFCVQM

KPLGMEK ~ U"©XGI"E~OMG

1. C" I [~ I [U\GT"PGXG";U"C\"CNMCNOC \ fU"O ~ FLC*K+

P [ZVJTCEKU 100 o i l o n"uvgtkn"mqpepvt^aw o
qdknvqzecz ocd"
kx0 dgcf^autc. j*i* v^au" w^ap0

2. C\"CNMCNOC \ fUUCN"MCREUQNCVQU"VWFPKXCN ~ M

Mk|^at>>nci"gi {u|gtk"cnmcn o c|^autc0

3. NGLfTCVK"KF

EXP

4. C" I [fTVfUK"V; VGN"U \ fOC

I {0u|0<

5. C"VCTVCNQO"U—N [TC."V; THQICVTC."XCI ["GI [U; I TG"XQPCVMQ \ VCVXC

600 mg/6 ml

80 GI [; D"KPHQTO fEK ~ M

A gyógyszerk.sztm.ny forgalomba hozatali enged.lye megszfnt

A gyógyszerkészítmény forgalomba hozatali engedély megszerzését

D0 DGVGIVfLlMQ\VCV~

Dgvgi v^al²mq | vcv >> < "kphqt o^a ek > m" c" dgvgi "sz²ta

P [ZVJTCEKU 100 o ilo n"mqpegpvt^avw o "qnf cvqu" kphA | k > j q |

qdknvqzck o cd

G | "c" i { > i { u | gt "hmq | qv "hgnA i { gngv "cncv" ^a m. " o gn { "ng j gv x² vgu | k" c | "A l" i { > i { u | gtdk | vqu^a i k" kphqt o^a ek > m" i { qtu" c | qpqu^a v^a u^a v⁰ "G j j g | " " p" ku" j q | | ^a l^a twn j cv" c" vwf q o^a u^a t c" lww > " d^a t o kn { gp" o gnm² m j cv^a u" dglgnp v² u² xgn⁰ "C" o gnm² m j cv^a uqm" lgnp v² u² pgm" o > flck t > n" c" 6⁰ r qpv" x² i² p" * O gnm² m j cv^a uqm" dglgnp v² u² g^a vcn^a n" vqx^a ddk" v^a l²mq | vcv^a uv⁰

Okgn v"gmng | fk" cmcn o c | pk" g | v" c" i { > i { u | gtv. "qnxcuuc" gn" hki { gn o gugg" c | "cn^a ddk" dgvgi v^a l²mq | vcv > v. " mert az " p" u | ^a t c" hqpqu" kphqt o^a ek > mcv" vctvcn o c | 0

- Vctvcn" o gi" c" dgvgi v^a l²mq | vcv > v. " o gtv" c" dgppg" u | gtrn "kphqt o^a ek > mtc" c" m² u ddk" gmdgp" ku" u | A mu² i g" ng j gv⁰
- Vqx^a ddk" m² t f² ugkxgn" hqt fwnlqp" mg | gn qtxqu^a j q | . i { > i { u | gt² u | ² j g | "xc i { "c" i qpfq | ^a u^a v" x² i | " gi² u | u² i A i { k" u | cmg o dgt j g | 0
- J c" " pp² n" d^a t o kn { gp" o gnm² m j cv^a u" lgnpvmg | km. " v^a l²mq | vcuuc" gtt n" mg | gn qtxqu^a v. " i { > i { u | gt² u | ² v" xc i { "c" i qpfq | ^a u^a v" x² i | " gi² u | u² i A i { k" u | cmg o dgtv⁰ G | "c" dgvgi v^a l²mq | vcv > dcp" hgn" pg o "uqtqnv" d^a t o kn { gp" ng j gv² i gu" o gnm² m j cv^a utc" ku" xqpcvmq | km⁰ "N^a uf" 6⁰ r qpv⁰

A betegt² hoztat² artalma:

- 30 Okn { gp" v^a l²mq | vcv > v. " i { > i { u | gt" c | "P [ZVJTCEKU 2^u o kn { gp" dgvgi u² i gm" gugv² p" cmcn o c | j cv > A
- 40 Vwfpxcn > m" c | "P [ZVJTCEKU cmcn o c | ^a uc" gn vv
- 50 Jqi { cp" mgn" cmcn o c | pk" c | "P [ZVJTCEKU-vA
- 60 Ngjgv² i gu" o gnm² m j cv^a uqm"
- 70 Jqi { cp" mgn" c | "P [ZVJTCEKU-t v^a tqnpkA
- 80 C" euq o ci qn^a u" vctvcn o c" ² u" gi { ² d" kphqt o^a ek > m

1. Okn { gp" v^a l²mq | vcv > v. " i { > i { u | gt" c | "P [ZVJTCEKU 2^u o kn { gp" dgvgi u² i gm" gugv² p" cmcn o c | j cv > A

C | "P [ZVJTCEKU jcv > cp { ci c" c | "qdknvqzck o cd⁰ "C | "qdknvqzck o cd" o qpqmnqp^a nku" cpvkvgv. "xc i { ku" gi { "qn { cp" hg j² tlg. "c o gn { "j q | | ^a mcreuqn > fkm" c" n² rhgp² v" qmq | > " dcmv² tkw o qm" ^a nvcn" vgt o gnv" o² tgi cp { ci qm j q | " * vqzpqm j q | +² u" j cv^a uvcncp" vlc" * kpcmvkx^a nlc + " c | qm cv⁰

C | "P [ZVJTCEKU-v" cpvkdkvknw o qmmcn" gi { A v" cmcn o c | | ^a m" hgnp vvgm" ² u" i { gt o gmgm" mg | gn² u² tg" qn { cp" n² rhpgg" gugv² p. "c o gn { gv" c" dcmv² tkw o "dgn² i | ² ug" qmq | qv" * vA f cpvtcz +⁰

C | "P [ZVJTCEKU cmnqt" ku" cmcn o c | jcv > . " j c" " p² tkpvmg | j gygv" c" n² rhgp² v" qmq | > " dcmv² tkw o o cn" xc i { "cppcm" ur > t^a kxcn. " fg" pkpeugpgm vApgvgk. "xcnc o kp v" j c" pg o " ^a nn" tgp f gnmg | ² utg" xc i { "pg o " cmcn o c | jcv > " o^a ukm" mg | gn² u⁰

2. Vwfpxcn > m" c | "P [ZVJTCEKU cmcn o c | ^a uc" gn vv

Pg o "mer jcv" P [ZVJTCEKU-t

- Jc" cmngt i k^a u" c | "qdknvqzck o cdte" xc i { "c" i { > i { u | gt" * 8⁰ r qpv dcp" hgnuqtqnv + " gi { ² d" ³ / 4 u u | gygx l² tg⁰

Hki { gn o g | vgv² ugm" ² u > xkp v² | mg f² ugm"

C | "P [ZVJTCEKU alkalmaz² ta gn v" dgu | ² n lgp" mg | gn qtxqu^a xcn. " i { > i { u | gt² u | ² xgn" xc i { "c" i qpfq | ^a u^a v" x² i | " gi² u | u² i A i { k" u | cmg o dgttgn <

- ha c" dgvgi " * vg j^a v " p" xc i { " i { gt o gmg + ³ / 4 t³ / 4 mngvgu" htwmv > | kp vqngtcpek^a pcm" pgxg | gvv" tkvmc" i gpgvkmck" dgvgi u² idgp" u | gp xgf. "xc i { " j c" pg o " hqi { cu | v j cv" ewmtqu" ² vngmgv" xc i { "kvcnqmcv. " o gtv" tquu | wn" ² t | k

oci^a.v.j^ap{ "xci { "qn { cp"mgng o gvnpg v"Ápgvgm"lgnpgvmg | pgm"p^anc." o kpv" c" jcurwhhcf^au."
i { qo qti ¾teu"xci { "jcu o gp²u0

C | "P [ZVJTCEKU-mg | gn²u"vv^apk" gugvng i gu" cngt i k^au" tgcme k> m" p² j c" uÁn { qucm"ng j gvp gm0" Ng j gvu² i gu."
jqi { "c | "cngt i k^au" tgcme k> m"mqem^a | cv^apcm"eu¾mmgpv²ug² t fgm²dgp"cpvkjku | vc o kpv"mcr" c | "P [ZVJTCEKU
dgc f^auc" gn vv0

Egy²gy²yszerek ¾az P [ZVJTCEKU

Hgnv²vngpÁn"v^al²mq | vcuuc"mg | gn qtxqu^av"xci { "i { > i { u | gt²u | ²v" c" lgnpgng i "xci { "pg o t² ikdgp"u | gfgm"
xcnc o kpv"u | gfpk"vgtxg | gw"gi { ²d i { > i { u | gtgkt n0
Ng j gvu² i gu." jqi { "cpvkdkqvk mw o qm cv" *rn0" ekr tqhmqzcekpv+ "mcr." c o gn { gm"ugi { vk m" c" vÁf cpvtcz"mg | gn²u²v0

Vgtjguu² i "2u"u | qrv cv^au

Jc" " p" vgtjgu"xci { "u | qrv cv." kmngv xg" j c" hgpp^amn" " pp²n" c" vgtjguu² i "ng j gv u² i g" xci { "i { gt o gm gv"u | gtgvpg." c"
i { > i { u | gt" dgc f^auc" gn vv" dgu | ²n lgp" mg | gn qtxqu^axcn0

Pg o "ku o gtv." jqi { "c | "P [ZVJTCEKU m^a tqv" vj cvlc-g" c" o ci | cvq v0"

Pg o "ku o gtv." jqi { "c | "P [ZVJTCEKU ^avlwv-g" c | "cp { cvgl dg0" " p" ²u" mg | gn qtxquc" m¾ | ¾ugp" gn f¾pvkm." jqi { "
hq n { vcj cvlc-e a szoptat ¾ az P [ZVJTCEKU dgc f^au^av" m¾ xgv gp0

C"m²u | v o ²p { "jcv^auck" c" i²rl^ato xg | gv²ujg | "2u" c" i²rgm" mg | gn²u² jg | "u | Ámu² i gu" m²rguu² i gmtg

C | "P [ZVJTCEKU o gnm²m jcv^auqmcv." r²n f^awn" hglh^al^auv." u | ²fÁn²uv" h^atc fvu^a i qv" ²u" j^ap { ^auv" qmq | jcv0" G | "
jcv^auucn" ng j gv" c" i²rl^ato xg | gv²ujg | "xci { "c" i²rgm" mg | gn²u² jg | "u | Ámu² i gu" m²rguu² i gktg0

Az P [ZVJTCEKU u | qtdkvq v" *G642+ "vetvnc o c |

C"u | qtdkv" c" htwmv> | " *gi { "ewmqthelvc+ " hqt^auc0" Jc" " p" *xci { "i { gt o gm g+ " c | "¾t¾mngvgu"
htwmv> | kpvnqgtcpek^apcm"pgxg | gw"tkvnc" i gpgvkmc k" dgvgv² idgp"u | gpxgf." ng j gvu² i gu." jqi { "mg | gn qtxquc"
Ài { "f¾pv." jqi { " " pp²n" *xci { "i { gt o gm²p²n+ " pg o " cmncn o c | jcv^am" g | v" c" i { > i { u | gtv0" C | "¾t¾mngvgu"
htwmv> | kpvnqgtcpek^adcp"u | gpxgf " dgvg i gm" pg o " vwf^am" ngdqpvcpk" c" htwmv> | v." c o k" uÁn { qu"
o gnm²m jcv^auqm j q | " xg | gv j gv0

C"i { > i { u | gt" alkalmaz ¾ az gn vv^al²mq | vcuuc"mg | gn qtxqu^av" ctt>n." jqi { "c" dgvg i " *vg j^av" " p"xci { "
i { gt o gm g+ "¾t¾mngvgu" htwmv> | kpvnqgtcpek^adcp"u | gpxgf." xci { "j c" pg o " hqi { cu | vjcv" ewmtqu² vngmgv" xci { "
kvncqmcv." o gtv" tquu | wn" ²t | k" o ci^a.v.j^ap { "xci { "qn { cp"mgng o gvnpg v"Ápgvgm"lgnpgvmg | pgm"p^anc." o kpv" c"
jcurwhhcf^au." i { qo qti ¾teu"xci { "jcu o gp²u0

Az P [ZVJTCEKU p^avtkw o qv" vetvnc o c |

C"m²u | v o ²p { "mgxgugdd" o kpv" 3. o o qn" *45 o i+ " p^avtkw o qv" vetvnc o c | "c | "P [ZVJTCEKU egy-egy 6 ml-es
kplgmek>u" Áxg i l²dgp." c | c | "i { cmqncvknc i " šp^avtkw o o gpv gu00

3. Jqi { cp"mgm" cmncn o c | pk" c | "P [ZVJTCEKU-vA

C | "P [ZVJTCEKU-v" mg | gn qtxquc" xci { "c" i qpfq | ^au^av" x² i | " gi²u | u² i Ái { k" u | cmg o dgt" hqilc" " ppgm"
dgc fpk0" Mg | gn qtxquc" xci { "c" i qpfq | ^au^av" x² i | " gi²u | u² i Ái { k" u | cmg o dgt" c | " " p" *xci { "i { gt o gm g+ "
vguv¾ o gi g" cncr l^ap" u | ^a o vlc" mk" c" f> | kuv0"

Mg | gn qtxquc." c" i qpfq | ^au^av" x² i | " gi²u | u² i Ái { k" u | cmg o dgt" xci { "i { > i { u | gt²u | g" m²u | vk" gn " c"
i { > i { u | gtv" c" dgc f^auj q | 0"

C | "P [ZVJTCEKU qnfvcqv" eugr rkphÀ | k> dcp" cfl^am" dg"; 2 rgte" nghqti^auc" cncv." lgnmg o | gp" a kar gi { km
x² p^al^adc0" Hqn { c o cvqu" o gi hki { gn²u" cncv" vctvl^am" " pv" c | "P [ZVJTCEKU dgc f^auc" m¾ | dgp." xcnc o kpv"
ng i cñ^add" gi { " > t^a p^av" c | " kphÀ | k> " dgc f^au^av" m¾ xgv gp0"

C | "P [ZVJTCEKU dgc f^auc" gn vv" tgp fu | gtpk v" i { > i { u | gtgm gv" hqi" mcrpk" c | "cngt i k^au" tgcme k> m"
o gi gn | ²u²tg" xci { "gp { j^av²tg0"

Jc" d^ato kn { gp" vqx^a ddk" m²tf²ug" xcp" c" i { > i { u | gt" cmncn o c | ^au^axcn" mc reuqncv dcp." m²tf g | g" o gi"
mg | gn qtxqu^av." i { > i { u | gt²u | ²v" xci { "c" i qpfq | ^au^av" x² i | " gi²u | u² i Ái { k" u | cmg o dgtv0

4. Ng jgvu² i gu" o gnm² m jcv^a uqm

Okpv" o kpf gpi i { > i { u | gt. " i { " g | " c" i { > i { u | gt " ku" qmq | jcv" o gnm² m jcv^a uqmcv. " c o gn { gm" c | qpdc p" pg o " o kpf gpnkp² n" lgn gpv mg | pgm0

C | qppcn" u | > n lqp" mg | gn qtxqu^a pcm" xci { " c | " kphÀ | k > v" " ppgm" dgc f > " u | g o ² n { pgm. " j c" c" m³ / xgv mg | o gnm² m jcv^a uqm" d^a t o gn { km² v" vcr cu | vcnlc <

Xku | mgv² u. " mk² v² u. " n² i u | q o l" xci { " u | rqn > " n² i | ² u" - g | gm" cngtik^a u" tgcme k > " v² n² t | ² mgp { u² i + " lgn g" lgn g jgv pgm0

Az P [ZV J TCEKU vxq^a ddk" o gnm² m jcv^a uck" m³ / ² vctvq | pcm <

Gyakori *32-d n" ng ihgnlgdd" 3 dvgigv² tkpvjgv+

- Hglh^a 1^a u
- M³ / j³ / i² u
- H^a 1 fcnq o " c | " kphÀ | k > " dgc f^a uk" j gn { ² p
- Xku | mgv² u. " d tmk² v² u. " dng² tvxg" c" xku | mgv . " mkg o gnm g f " mk² v² u gmgv" eucn^a pmk² v² u+

Pgo " i { cmqtk *322-d > n" ng ihgnlgdd" 1 dvgigv² tkpvjgv+

- Cmg tik^a u" tgcme k > m
- U | ² f² n² u
- \ ukddcf^a u
- C" u | g o " h² p { ² t | ² mgp { u² i g" * hqvqh > dkc +
- Mgnng o gvn gp" ² t | gv" c" h² n dgp
- Vqtqmkttkv^a ek >
- Tgm gfv" j cpi
- O gnm² m² tgi - fwiwn^a u
- N² i u | q o l
- Clcmh^a 1 fcnq o
- Gme² oc. " j^a o n > " d t
- K | q o t^a pi^a u. " k | q o i³ / 4 teu³ / 4 m
- H^a tcfv^a i
- Jkfgingn² u" * jkfgi² t | gv+
- O gnm² m² tgi - fwiwn^a u
- f nvcn^a pqu" h^a 1 fcnq o . " xcac o kpv" c" x² i vci qmcv. " c" o gnm² m² tgi - fwiwn^a u. " c | " a n n m c r e u q v. " c | " k | o q m e v. " c" u | c n c i q m e v. " az kpcmcv" xci { " c" euqpvqmcv" ² tkpv " h^a 1 fcnq o "
- C | " kphÀ | k > " dgc f^a u" pcm" j gn { ² p" m k n c m w n v" f w | | c p c v. " h^a 1 fcnq o " xci { " ² t i { w n c f^a u" * h n g d k v k u | +

O gnm² m jcv^a uqm" dglngpv² ug

Jc " " pp² n" d^a t o kn { gp" o gnm² m jcv^a u" lgn gpv mg | km. " v^a 1² m q | vcuuc" mg | gn qtxqu^a v. " i { > i { u | gt² u | ² v" xci { " c" i q p f q | ^a u^a v" x² i | " g i² u | u² i² i { k" u | cmg o dgtv0 G | " c" dvgigv^a 1² m q | vcv > dcp" hgn" pg o " uqtqnv" d^a t o kn { gp" ng jgvu² i gu" o gnm² m jcv^a utc" ku" xqpcvmq | km0" C" o gnm² m jcv^a uqmcv" m³ / 4 | xgvngp² n" c" jcv > u^a i" t² u | ² tg" ku" dglngpvjgvk" e | X0 h^a i i gn² mdgpvcn^a jcv > " gn² t jgv u² i gmgp" mgtgu | v² n0" C" o gnm² m jcv^a uqm" dglngpv² u² xgn" " p" ku" j q | | ^a 1^a t w j cv" c j j q | . " j q i { " o k p² n" v³ / 4 d d" k p h q t o^a ek > " a n l q p" t g p f g n m g | ² utg" c" i { > i { u | gt" dk | v q p u^a i q u" c m c n o c (^a u^a x c n" m c r e u q n c v d c p 0

5. Jqi { cp" mgm" c | " P [ZV J TCEKU - v" v^a tqnpkA

C" i { > i { u | gt" i { gt o gmgmv n" gn | ^a txc" vctvc p f > #

C" f q d q | q p" ² u" c" e | o m² p" hgnv² pvgvgn¹ a tcvk" k f " * G Z R + " w v^a p" p g" c m c n o c | | c" g | v" c" i { > i { u | gtv0" C" ng¹ a tcvk" k f " c | " c f q v" j > p c r " w v q n u > " p c r 1^a t c" x q p c v m q | km0

J v u | g m t² p { d g p" * 4^a E - : ^a E + " v^a t q n c p f > 0"

Nem fogyasztható

C"n²p{v n²xcn>>x²fng o "2tfgm²dgp" c | "gtgfgvk" euq o c i qn^audcp" v^atqncpf >>0

C | "kphÀ | k>>u" | u^am²dcpx² i | gvv" j | i | v^auv" m³/4xgv gp" c | "cnm²o c | a" u" gn vk" m² o kck. "hk | kmck" ²u" o kmtqdk^anku" uvcdknk^au": >>t^ap" mgtgu | v^an^ak i c | qnvcv" hgpp o c t c f" u | qdcj o ²tu²mngvgp" *42 ÅE - 47 ÅE+ " xci { " j v u | gmt²p { dgp" *4 ÅE - : ÅE+0

C | "P [ZVJTCEKU kphÀ | k>>u" hgeumgp f dgp" v³/4tv²p " j | i | v^auc" v^ap" c | qppen" dg" mgn" c f p k" c" m²u | v o ²p { v. " pg o " u | cdcf" gntcmv^atq | pk0" C" hgn" pg o " j cu | p^anv" m²u | v o ²p { v" mk" mgn" f q d p k 0

80 A csomagoló tartalmáról egy információt

Mit tartalmaz az P [ZVJTCEKUA"

- C"m²u | v o ²p { " j cv>>cp { c i c" c | " qdknvqz czk o cd0" C" m q p e g p v t^a v w o " o k n k n k v g t g p m² p " 322 mg qdknvqz czk o cdqv" vctvcn o c | 0" Gi { " 8 ml-gu" kplgmek>>u" Åxgi" 822 o i" qdknvqz czk o cdqv" vctvcn o c | 0
- Gi { " 2d³/4uu | gyvx m" c" j ku | vk f k p. " c" u | qtdkv" *G642+ " c" r q n k u | q t d^a v " : 2 * G 6 5 5 + " c" u >> u c x " * G 7 2 9 + " 2 u" c" p^a v t k w o - j k f t q z k f " * G 7 4 6 + 0 " N^a u f " o ² i " c" 40 r q p v d c p " * Š C | " P [Z V J T C E K U u | q t d k v q v " v c t v c n o c | ö + 0

Milyen az P [ZVJTCEKU m^ang o g" ²u" o kv" vctvcn o c | " c" euq o c i qn^a u

C | "P [ZVJTCEKU ²zn^avu | >>" xci { " qrcngu | m^an>>." u | v p v g n p x c i { j c n x^a p { u^a t i a x c i { " j c n x^a p { " d c t p^a u u^a t i a u | v p " m q p e g p v t^a v w o " q n f c v " m²u | v²u² j g | 0
C | "P [ZVJTCEKU 1 fd" kplgmek>>u" Åxgi g v " v c t v c n o c | >>" e u q o c i q n d c p " m g t Å n " h q t i c n q o d c l 0

C" hqt i c n q o d c j q | e v e n k " g p i g f² n { " l q i q u w v l c

UHN" Rjct o c e g w k e c n u " F g w v u e j n c p f " I o d J
O c t k g - E w t k g - U v t c u u g " :
9 ; 7 5 ; N³ / 4 t t c e j
P² o g v q t u | ^a i

Gy^art²

C e g t v k R j c t o c " D 0 X 0
D q u e j u v t c c v " 7 3
6 : 3 3 " I E . " D t g f c
J q m c p f k c

C" d g v g i v^a l² m q | v c v >> " n g i w v >> d d k " h g n Å n x k | u i^a n c v^a p c m " f^a v w o c

G | v " c " i { >> i { u | g t v " š m k x² v n g u m³ / 4 t Å n o ² p { g m ö " m³ / 4 v v " g p i g f² n { g | v² m . " c o k " c | v " l g n g p w k . " j q i { " c " i { >> i { u | g t " c n m c n o c | ^a u^a t c " x q p c v m q | >> c p - c " d g v g i u² i " t k v m c " g n h q t f w n^a u c " o k c v v " ² u " g v k m c k " q m q m d >> n " m k h q n { >> n c i " - p g o " n g j g v g w " v g n l g u " m³ / 4 t " k p h q t o^a e k >> v " i { l v g p k 0
C | " G w t >> r e k " I { >> i { u | g t Å i { p³ / 4 m u² i " ² x g p v g " h g n Å n x k | u i^a n " o k p f g p . " g t t g " c " i { >> i { u | g t t g " x q p c v m q | >> " Å l " k p h q t o^a e k >> v . " ² u " u | Å m u² i " g u g v² p " g | v " c " d g v g i v^a l² m q | v c v >> v " k u " o >> f q u | v l c 0

Egy^a információról

C" i { >> i { u | g t n " t² u | n g v g u " k p h q t o^a e k >> " c | " G w t >> r e k " I { >> i { u | g t Å i { p³ / 4 m u² i " k p v g t p g v g u " j q p n c r l^a p " v c n^a n j c v >> < " [j v r r l | y y o g o c l o g w t q r c l o g w 0](#) " W i { c p k v v " o^a u . " c " t k v m c " d g v g i u² i g m t g " ² u " m g | g n² u Å m t g " x q p c v m q | >> " k p h q t o^a e k >> v " v c t v c n o c | >> " j q p n c r q m " e " o g k " k u " o g i v c n^a n j c v >> m 0

C" d g v g i v^a l² m q | v c v >> " c | " G W I G I V³ / 4 u u | g u " j k x c v c n q u " p { g n x² p " g n² t j g v " c | " G w t >> r e k " I { >> i { u | g t Å i { p³ / 4 m u² i " k p v g t p g v g u " j q p n c r l^a p 0

V q x^a d d k " k p h q t o^a e k >> m < " [y y o g o c l o g w t q r c l o g w](#) S T m >> f " d g k n g u | v g p f "