

Vaistinis preparatas neberegistruotas

I PRIEDAS

RTGRCTCVQ"EJCTCMVGTUVM "UCPVTWMC

X{mfqoc"rerknfqoc"-kq"xckuvpkq"rtgrctcvq"uvgd ugpc0"Vck"ref u"itgkvc"pwuvcv{vk"pcwl "ucwiwoq" kphqt o cekl 0"Uxgkmcvqu"rtkgflk tq"urgenkuvck"vwtk"rtcpq-vk"crkg"dgv"mqmku" vetk o cu"pgrc igkfcwlc o cu" tgcmeclu0"Crkg"vck."mckr"rtcpq-vk"crkg"pgrc igkfcwlc o cu"tgcmeclu."flt0 60: um{tkwlg0

1. XCKUVKPKQ"RTGRCTCVQ"RCXCFKPKOCU

P [ZV J TCEKU 100 o i l o n"mqpepvtcvu"kphw|kpkc o "vktrenwk

2. MQM [DKP "KT"MKGM [DKP "UWF VKU

Kiekviename mililitre koncentrato yra 100 o i "qdknvmucmuk o cdq0"
Viename 6 ml flakone yra 600 o i "qdknvmucmuk o cdq0

Obiltoksaksimabas k-iwpc o cu" k- rgnk " I U-PU2" o kgnq o qu"n uvgnk . "tgmq o dkpepvpk u" FPT"
vgejpqiklqu" d fw0

Rci cndkp " o gfflk i c."mwtkqu" r q x g k m k u" f l k p q o c u

Kiekviename mililitre koncentrato yra 36 o i "uqtdkvqnkq0

Xkuqu" rci cndkp u" o gfflk i qu" k-xctf {vqu"803"um{tkwlg0

3. HCTOCEKP "HQTOC

Mqpepvtcvu" kphw|kpkc o "vktrenwk"*uvgtknwu"mqpepvtcvu+0"

P [ZV J TCEKU - vck"umckftwu"ctdc"qrcnguewqlcpvku."dgurcnxku."ignuxcu"ctdc"twuxck"ignuxcu"vktrenku."
mwtk o g"i c n k" d v k"-kgm"vkgm"rgt o cvq o "ctdc"denv "dcnv { o k p i "mkgv l "fengnk "*lqu"dwu"rc-cnkpvcu"
pewfqlep"v" kphw|klqu"nkplqu"hnkvt + "kt"mwtkq" r j " { t c " 7 . 7 . " q " q u o q n k c t k - m w o c s - 2 7 7 - 5 2 : o Q u o l m i o

4. MNKPKMKP "KPHQTOCEKLC

4.1 Vgtrckp u"kp f k m c e k l q u

P [ZV J TCEKU umtkc o cu"mctw"uw"cvkvpmc o cku"cpvkdcmvgtkpkcku"vaistiniais preparatais."xku "c o flkcwu" i t w r k " r c e k g p v c o u . " i { f c p " B a c i l l u s a n t h r a c i s u w m g n v " k p j c n k c e k p " l w q f n k i " * f l t 0 7 0 3 " u m { t k + 0

P [ZV J TCEKU umtkvcu" xctvqvk"xku "c o flkcwu" i t w r k " r c e k g p v c o u " k p j c n k c e k p " l w q f n k i " u " r t q h k n c m v k m c k " r q " u n { k q " u w " k p h g m e k l q u " - c n v k p k w . " m c k " m k v q u " i { f { o q " r t k g o q p u " p g v k p m c " c t d c " v q m k " r t k g o q p k " p t c 0 * f l t 0 7 0 3 " u m { t k + 0

4.2 Fq|cxk o cu"kt"xctvqlk o q" o gvqfcu

P [ZV J TCEKU vwt v "d vk"uwnk-kpvcu" "xgp "pgfgnukcpv."gucpv"mnkpkmkp o u"kp f k m c e k l q o u 0

Xtucku"cvxglcku"vwt v "d vk"rcuktgpivc"vckm{vk"cvkvpmc o "i { f { o "kt"rtkgflk t ."lgkiw"uwnk-kpwu"

P [ZV J TCEKU rcekgpvwk"rcuktgkm-v "cpchknucmkp "tgcmeklc0

Fq|cxk o cu

Tgmq o gpfwqlc o c" N [ZV J TCEKU fq| "uwcwiwukg o u" rcekgpv c o u . " u x g t k c p v k g o u " p g " o c f l k c w " m c k r " 6 2 m i . " y r a v i e n a 1 6 o i l m i " m p q " u x q t k q " * M U + " k p v t c x g p k p " k p h w | k l c 0 " T g m q o g p f w q l c o c " P [Z V J T C E K U f q | " u w c w i w u k g o u " r c e k g p v c o u . " u x g t k c p v k g o u " o c f l k c w " p g k " 6 2 m i . " { t c " x k g p c " 4 6 o i l m i " m p q " u x q t k q " * M U + " i n v t c x g p k p " k p h w | k l c 0

Prieš atliekant P [ZV J TCEKU kphw | kl . "tgmq o gpfwqlc o c" r t g o g f k m c e k l c " c p v k j k u v c o k p k p k w " x c k u v k p k w " r t g r c t c v w " * f l t 0 6 0 6 " k t " 6 0 : " u m { t k w u + 0 "

Mckr "mqtgi wqvk" fq | " r c u k t g k - m w u " u w " k p h w | k l c " u w u k l w u k q o u " t g c m e k l q o u " * U K U T + . " f l t 0 1 n g p v g n l g 0

1 ngpvgn 0" Qdknvqmucmuk o cdq" fq | u"mqtgi csk o cu" r c u k t g k - m w u " u w " k p h w | k l c " u w u k l w u k q o u " t g c m e k l q o u 0

UKUT"uwpmw o cu"	Fq u"mqtgi csk o cu
1-3 laipsnio uw"kphw klc" uwuklwuk"tgcmeklc	Tgkm v " r g t v t c w m v k " q d k n v q m u c m u k o c d q " k p h w k l " k t " v c k m { v k " r e i c n d k p g u " r t g o q p g u 0 Rkt o " m c t v " r c u k t g k - m w u " 5 " n c k r u p k q " - x q m - v k o w k . " d t q p e j " u r c o c o u " c t d c " i g p g t e n k w q v e k " w t v k m e t k l e k . " q d k n v q m u c m u k o c d q " k p h w k l " t g k m k c " x k u k - m e k " p w v t c w m v k 0 Rcukmctvqlwu"4"nckrupkq"-xqm-vk o wk"ct"wtvkmctklek"ctdc"rcukmctvqlwu"dgv"mwtkc o "5" nckrupkq"uk o rvq o wk."qdknvqmucmuk o cdq"kphw kl "tgkmkc"xluk-mek"pwtcwmvk0" Rtkg-kpiw"cvxglw."xluk-mek"p{mwu"uk o rvq o c o u ."kphw kl "t c n k o c " c v p c w l k p v k . " x c k u v k p " r t g r c t c v n c - k p e p v " r g t r w u " n k c w " p g k " k m k " p w t c w m k e p v " k p h w k l 0 " P g u c p v " u w " k p h w k l c " u w u k l w u k " u k o r v q o . " v a i s t i n i s p r e p a r a t a s k p c o c u " 5 " n g p v g n l g " p w t q f { v w " i t g k k w 0 " Vwt v " d v k " c v n k m v c " r t g o g f k m c e k l c 0
4 laipsnio uw"kphw klc" uwuklwuk"tgcmeklc	Qdknvqmucmuk o cdq"kphw kl "tgkmkc"pgfgnukcpv"pwtcwmvk0 Vwt v " d v k " v c k m q o q u " r e i c n d k p u " r t g o q p u 0 Qdknvqmucmuk o cdq"kphw kl "tgkmkc"xluk-mek"pwtcwmvk0"

[r c v k p i q u " r q r w n k c e k l q u

Senyviems pacientams

87" o g v " k t " x { t g u p k g o u " r c e k g p v c o u " m q t g i w q v k " v a i s t i n i o p r e p a r a t o f q | u " p g t g k m k c " * f l t 0 7 0 4 " u m { t k + 0

Xckm "rqrwnkceklc

Tgmq o gpfwqlc o c" fq | " x c k m c o u " p w u c v q o c " r e i c n " m p q " u x q t . " m c k r " p w t q f { v c " v q n k e w " r c v g k m v q l g " 4 " n g p v g n l g 0

2 ngpvgn 0" Tgmq o gpfwqlc o c" qdknvqmucmuk o cdq" fq | "xckmc o u" r e i c n " m p q " u x q t +

M p q " u x q t u " j m i _	Fq "] o i l m i " M U _
>40	16
@37-40	24
37 ctdc" o c f l k c w	32

Xctvqlko q" o g v q f c u "

Qdknvqmucmuk o cdcu"uwnckpco cu" "xgp "rgt";2" o k p w k 0

Cyuctiwoq"rtkgoqp u."mwtk "tgkmkc"kovku"rtkg-"twq-kcpv" - "xckmckp "rtgrctcv "ctdc"cvnkgmcpv"lq"kphw/kl

Hncmqpp"pgicnk o c"mctv { vk0"Rtkg-"nc-kpepv"qdknvqmucmuk o cd " "xgp .1 "tgkmkc"rtcumkguv"pcvtkq"ejnqtkfq" ; o i l o n " * 2 . ; r t q e 0 + " k p l g m e k p k w " v k t r c n w " * f l t 0 8 0 8 u m { t k + 0 "

Rtcumkguv "qdknvqmucmuk o cdq"kpvtcxgpku u"kphw | klqu"vktren "tgkmkc"uwnckpvk" "xgp "rgt";2" o k p w k . " 5 " n g p v g n l g " p w t q f { v w " k p h w | k l q u " i t g k k w . " p c w f q l c p v " k p h w | k p " o c k - g n " c t d c " k p h w | k p " - x k t m - v " k t " 2 . 4 4 " o k m t q p " k p h w | k l q u " n k p k l q u " h k n v t 0 "

Xku "kphw | klqu"nckm "kt"pg" o cflkew"mckr"xcncpf "rq"lqu"tgkmc"cvkfflck"uvgd vk."ct"rcekgpvc o u"pgrcuktgk-mkc" rcfkf lwukq"lcwvto o q"rqfl{ ock"kt"uk o rvq o ck"*ft0 606"um{ tk +0"Uw"kphw | klc"uwuklwukcu"tgcmeklcu"tgkmc" mqpvtqkwqvk"vckr."mckr"pwtqf {vc"3"ngpvgn lg0

Kpvtcxgpkp u"kphw | klqu"rcdcki qlg"kphw | klqu"nkpl "tgkmc"rtcrncwk"pcvtq"ejnqtkfq"; o ilon"*2.; rtqe0+ kplgmekpkw"vktrenw0

3 ngpvgn 0"Qdknvqmucmuk o cdq"fq| .dgpftcu" "xgp "nc-kpc o q"vktrenq"mkgmku"kt"kphw | klqu"itgkku"rcien" m pq"uxqt

M pq"uxqt"Jmi_ *fq cxk o cu rcien"m pq"uxqt	Dgpftcu" "xgp "nc-kpc vktrenq"mkgmku"Jo_n_ Jkphw kpk" o ck-gnku"ctdc" -xktm-vcu_	Kphw klqu"itgkku]onJ_
> 40 mi"ctdc"uwewiwu{uku"*38 o ilmi"MU+		
> 40	472	167
> 15 mi"- 40 mi"*46 o ilmi"MU+		
31-40	472	167
16-30	100	67
15 mi"ctdc" o cflkew"*54 o ilmi"MU+		
11-37	100	67
7-10	72	55.5
5.3-6. ;	47	17
4.3-3	20	35.5
3.3-2	37	10
3"ctdc" o cflkew	7	6.9

Xckuvkpkq"rtgrctevq"umkgfk o q"kt"kphw | kpk" o ck-gnku"ctdc" xktm-vq"pcwfqlk o q"rtkg-"xctvqlcpv"kpvtwmeklc" rvcgkmc o c"808 um{ tkwlg0

4.3 Mqpvtckpflmceklqu

Rcfkf 1 u"lcwvto o cu"xgkmmckek"ctdc"dgv"mwtlck0803 um{ tkwlg"pwtqf {vck"rcicndkpgk" o gfflckick0

4.4 Urgekcn u" ur lko ck"kt"cvuctiw o q"rtkg o qp u

Cvugmc o wo o cu

Ukgmkcpv"rcigtcpvk"dkqai kpk "xckuvkpk "rtgrctev "cvugmc o wo ."tgkmc"ck-mkck"vflask"to vaistinio rtgrctevq"rexckfko "kt"ugtklqu"pwogt 00

Uw"kphw | klc"uwuklwukcu"tgcmeklcu."rcfkf 1 u"lcwvto o cu"kt"cpchknemukle

Uw"kphw | klc"uwuklwukcu"*rcfkf lwukq"lcwvto o q+"tgcmeklcu"dwxq"fcflpek"uvgd o qu"cvngmcpv" qdknvqmucmuk o cdq"mnkpkmkpkwu"v{tk o wu"uw"uxgkmcu"vktkc o ckukcku0"Fn"uwpmk "tgcmekl "ct"cpchknemuklcu" rexqlcu"qdknvqmucmuk o cd "uvgd o qlg"crnkpmqlg"vwt v "nc-kpvk"ftcdwvqlck."o qmcpv{u"kt"vwtkpv{u" tgkmc o cu"rtkg o qpqu"cpchknemuklc"uwxcnf {vk0"Rcekgpvc"vwt v "d vk"cvkfflck"uvgd o k"xku "kphw | klqu"nckm "kt" dgpv"xcncpf "rq"lqu0

Mcfepik"mnkpkmkpkck"v{tk o ck"dwxq"cvngmco k"uw"uxgkmcu"ucxcpqtckcu."rcuktgk-mwu"dgv"mqmkck"tgcmeklai qdknvqmucmuk o cdq"kphw | klqu"dwxq"pwtcwmke o qu0"tg o kcpvku"uw"mkvcu" o qpqmmqpkpkcu"cpvkm pcku."mwtkg" pcwfqlck o k"i { fcpv"uwpmcku"nkicu."uwuklwuk"rcvktvk o k."vcpmco ck"mqpvtqkwqvc"pvtv"rtqegf t ."rcrtcuvc" kphw | klcu"icnk o c"wfldck i vk0"Uw"kphw | klc"uwuklwukcu"tgcmeklcu"tgkmc"mqpvtqkwqvk"vckr."mckr"pwtqf {vc"3" ngpvgn lg0

Rtkg-"nc-kpcpv"qdknvqmucmuk o cd ."tgmq o gpfwqlc o c"cvngmck"rtg o gfkckekl "cpvjkuvc o kpkpkw"xckuvkpkw" rtgrctevw."rx | 00"fkhgpkj kftc o kpw"*ft0 604"um{ tk +0"Cvngmcpv"qdknvqmucmuk o cdq"mnkpkmkpkwu"v{tk o wu fkhgpkj kftc o kpcu"dwxq"ngkfflck o cu"rcekgpvc o u"nkmwu"52" o kpw k "kmc"qdknvqmucmuk o cdq"kphw | klqu0" Cvngmwu"

rtg of g f k m c e k l " c p v k j k u v c o k p w . " c p c h k n c m u k l c " x k u " v k g m " i c n k " r c u k t g k m - v k . " v c k r " r e v " l k " i c n k " w f l o c u m w q v k " c t d c " c v k v q n k p v k " r c f k f l w u k q " l e w w t w o q " u k o r v q o w u 0

Lwqfnki u"uwmgncvu" o gpkpikvcu

Qdknvqmucmuk o edcu " p g r t c u k u m x g t d k e " r t q " m t c w l q - i c n x q u " u o g i g p " d e t l g t " k t " l w q " p g i c n k o c " w f l m k t u v k " m g n k q " c t " k - i { f { v k " l w q f n k i u " u w m g n v q " o g p k p i k v q 0 "

Xckm "rqrwnkceklc

Qdknvqmucmuk o edcu " u c w i w o q " c t d c " h e t o c m q m k p g v k p k " v { t k o " u w " x c k m " r q r w n k c e k l c " p g c v n k m v c " * f l t 0 7 0 4 " u m { t k + 0

Rqxgkmku " h c d q t c v q t k p k " v { t k o " t g | w n v c v o u

P [Z V J T C E K U i c n k " k - m t c k r { v k " u g t q n q i k p k " v { t k o " f n " l w q f n k i u " t g | w n v c v w u 0

Uqtdkvqнку

Kiekviename P [Z V J T C E K U m i l i l i t r e y r a 3 6 o i " u q t d k v q n k q " * f l t 0 4 " k t " 8 0 3 " u m { t k w u + 0 " x g p m g u v k " x c k u v k p k c k " r t g r c t e v c k . " m w t k " u w f v { l g " { t e " u q t d k v q n k q . " i c n k " d v k " o k t v p k i e n t a m s . " m w t k g o u " f k c i p q | w q v c u " i k o v c u h t w m v q | u " p g v q n g t c x k o c u " * H P + 0 " Q d k n v q m u c m u k o e d c u " p g i c n k o c " x c t v q v k " p a c i e n t a m s . " m w t k g o u " f k c i p q | w q v c u " H P . " p g d g p v " { t e " x k u m " p w u x g t k e p v k " m k p k m k p " d v k p { d " k t " p t e " m k v q " r c u k t k p m k o q 0 " P r i e š s k i r i a n t š i o v a i s t i n i o p r e p a r a t o . " d v k p c " u w f l k p q v k " k - u c o k " m k g m x k g p q " r c e k g p v q " c p c o p g | " f n " H P 0

M f k m k e o u " k t " o c f l k g o u " x c k m c o u " * l e w p g u p k g o u " p g k " 4 " o g v + " m { n c { r e " f k f g n k u " r e x q l w u . " p g u " l k g o u " H P " i c n k " d v k " f c t " p g f k c i p q | w q v c u 0 "

Natris

Kiekviename šio vaistinio preparato 6 o n " l m c m d p g " { t e " o c f l k c w " k a i p 1 o o q n " * 4 5 o i + p c v t k q . " v 0 { 0 " l k u " d g x g k m " p g v w t k " t g k m - o u 0 "

4.5 U x g k m c " u w " m k v c k u " x c k u v k p k c k u " r t g r c t e v c k u " k t " m k v q m k c " u x g k m c

Ekr tqh n q m u c e k p c u

C v n k g m c p v " u x g k m q u " v { t k o " q d k n v q m u c m u k o e d c u " * x k g p c " l q " f q | + " x k g p c u " c t d c " m e t v w " u w " e k r t q h n q m u c e k p w " d w x q " u w n c - k p c o c u " 6 2 " v k t k c o | 0 " F g x { p k c u " f k g p c u " f x k f g - k o v " v k t k c o 1 " d w x q " n c - k p c o c u " x k g p c u " q d k n v q m u c m u k o e d c u . " f x k f g - k o c k c k - " q d k n v q m u c m u k o e d c u " m e t v w " u w " e k r t q h n q m u c e k p w 0 " 3 8 o i l m i " o d k n v q m u c m u k o e d c u " n c - k p c p v " " x g p " r t k g - " e k r t q h n q m u c e k p q " k p v t e x g p k p " k p h w | k l " c t d c " m e t v w " u w " l w q " f w " m e t v w u " r g t " r c t " x c t v q l c p " e k r t q h n q m u c e k p q " i g t k c o 1 " v c d n g v . " q d k n v q m u c m u k o e d c u " h e t o c m q m k p g v k m c " p g r c u k m g k v 0 " Q d k n v q m u c m u k o e d c u " r g t " d w t p " c t d c " x g p " x c t v q l c o q " e k r r o f l o k s a c i n o f a r m a k o k i n e t i k o s t a i p p a t p g r c m g k v 0

M k v " u x g k m q u " v { t k o " p g c v n k m v c 0 " M c f c p i k " q d k n v q m u c m u k o e d c u " { t e " o q p q m n q p k p k u " c p v k m p c u . " u x g k m q u " t k | k m c " { t e " p g f k f g n 0

608 X c k u k p i w o c u . " p - v w o q " k t " f l k p f { o q " n c k m q v c t r k u

P - v w o c u

F w q o g p " c r k g " q d k n v q m u c m u k o e d c u " x c t v q l k o " p - v w o q " o g v w " p t e . " v c k e w " f l k p q o c . " m c f " f l o q i c w u " K i I " r t c u k u m x g t d k e " r t q " n c e g p v q u " d e t l g t 0 C v n k g m c p v " v { t k o w u " u w " i { x p c k u . " v k g u k q i k p k q " c t " p g v k g u k q i k p k q " f l c n k p i q " r q x g k m k q " t g r t q f w m e k p g k " u k u v g o c k " p g p w u v c v { v c " * f l t 0 7 0 5 " u m { t k + 0 C v u c t i w o q " u w o g v k o c k u " p - v w o q " o g v w " P [Z V J T C E K U i g t k c w " p g x c t v q v k 0

flkpf{ocu

Pgflkpf{ocu."ct"qdknvmucmuk o cdcu"l-ukumtkc" " o qvppqu"rkgp 0"flkpf{ocu."mcf"flo qicwu"Ki I "l-ukumtkc" " o qvppqu"rkgp "rkt o cu"rctcu"rq"xckmq"i k o k o q"kt"rq"vq"lq"mqpegpvtceklc"i t gkvck"uw o cfl lc"kmk"pgfkfgn u0" Vqf n"-kwq"vtw o r w nckmqvctrkw"pgi cnk o c"cv o guvk"rcxqlcwu"flkpf{ocu"m fkmkc o u"i cnk o {d u0"X nkew" i cnk o c"cruxctuv{vk"i cnk o {d "xctvqv"qdknvmucmuk o cd "flkpf{ocu"nckmqvctrkw."dgv"vkm"gucepv"mnkpkmkpkc o" rqtgkmmk0

Xckukpiwo cu

Xckukpiwo q"v{tko "uw"qdknvmucmuk o qv{vnmkvc0

4.7 Rqxgkmku"igd lko wk"xctwqv"kt"xcnf{vk"ogejcpk|owu

Qdknvmucmuk o cdcu"i cnk"uknrpck"xgkmv"igd lko "xctwqv"kt"xcnf{vk"ogejcpk|owu"pgu"rq" P [ZV J TCEKU kphw |klqu"i cnk"rcuktgk-m-vk"i cnxqu"umcwu o cu."i cnxqu"uxckiko cu."pwqxctiku"kt"x o k o cu" *ft0 60:"um{tk +0

4.8 Pgrcikfcwlc o cu"rqxgkmku

Ucwiwo q"fwqogp ucptcwmc

Qdknvmucmuk o cdq"ucwiwo cu"vktvcu"vkm"uw"uxgkmku"ucwiwo wukcu"vktkc o ckukcu0

Qdknvmucmuk o cdq"ucwiwo cu"dwxq"xgtvpc o cu"cvnkgmcpv"vtku"mnkpkmkpkwu"v{tko wu."mwtkwqug"fcn{xcxq"542" uxgkm "vktkc o l "*pwq"3:"kmk"9; ogv "c o flkcuw+."mwtgou" "xgp "dwxq"uwn-c-kpvc"xkgpc"ctdc"fxk"38 o ilmi" fq| u0"

K-"xkuq"472"vktkc o l "k-"542"uwnkguvc"xkgpc"38 o ilmi"qdknvmucmuk o cdq"fq| 0"Uw"rcfkf lwukw"lcwvtw o w" uwukwukqu"pgrcikfcwlc o qu"tgemklqu"* umckvcpv"k-d tk o +"rcuktgk-m"rtqe0"*44"l-"472+"-k "vktkc o l ." umckvcpv"xkgp "cpchknckmklqu."mwtk"rcuktgk-m "kphw|klqu"ogvw."cvxgl 0"Fn"rcfkf lwukw"lcwvtw o w"ct cpchknckmklqu"kphw|klc"dwxq"pwvtcwmc"5 rtqe0*:"k-"472+"vktkc o l 0"

Fcfpkcwukqu"pgrcikfcwlc o qu"tgemklqu."crkg"mwtku"rtepg-vc."dwxq"i cnxqu"umcwu o cu"*rcuktgk-m " 4 rtqe0.";"k-"472"vktkc o l "+"pkglw"rtqe0.";"k-"472+"kt"wtvkmctklc"*4 rtqe0."8"l-"472+0

Rgt"rkt o cu"vtku"xncpfcu"pwq"kphw|klqu"rtcfklqu"fcfpkcwukck"pwuvvcq o qu"pgrcikfcwlc o qu"tgemklqu" dwxq"pkglwn{u *p?9="4.: rtqe0+."wtvkmctklc"*p?8="4.6 rtqe0+."i cnxqu"umcwu o cu"*p?6="3.8 rtqe0+."k-d tk o cu" *p?5="3.4 rtqe0+."mqwn{u *p?5="3.4 rtqe0+."i cnxqu"uxckiko cu"*p?5="3.4 rtqe0+*"crk o c"i cnxqu"uxckiko "kt" rquvwtcnkp "i cnxqu"uxckiko +0"

TMkqu"uwpmkqu"pgrcikfcwlc o qu"tgemklqu"rcuktgk-m "rgt"rkt o cu"vtku"xncpfcu"rq"kphw|klqu"wtvkmctklc" *p?3."2.6 rtqe0+."pkglwn{u *p?3."2.6 rtqe0+"kt"pwictqu"umcwu o cu"*p?3. 2.6 rtqe0+0

Per 3-46"xncpfcu"pwq"kphw|klqu"rtcfklqu"fcfpkcwukck"pwuvvcq o c"pgrcikfcwlc o c"tgemklc"dwxq"i cnxqu" umcwu o cu"*p?5="3.4 rtqe0+

Pgrcikfcwlc o "tgemkl "ucptcwmc"ngpvgn lg"

6"ngpvgn lg"rcien"qticip ukuvgo mncu "kt"fcflp "rcvgnkko qu"pgrcikfcwlc o qu"tgemklqu" " qdknvmucmuk o cd ."mwtkqu"dwxq"pwuvvc{vqu"vktcpv"472"uxgkm "vktkc o l ."mwtgou" "xgp "dwxq"uwnkguvc" viana 16 o ilmi"qdknvmucmuk o cdq"fq| 0

Pgrcikfcwlc o o poveikio fcfpkc"crkd flkpc o cu vckr<"ncdck"fcflpasu"*x3132+."fcflpas *pwq"x31322"kmk" >3132+"kt"pgfcflpas *pwq"x313"222"kmk">31322+0"Mkgmxkpgqlg"fcflpkq"i twr lg"pgrcikfcwlc o as poveikis pwtqf{vcu o cfl lcp kq"uwpmw o q"vxctmc0"

4 ngpvgn 0"Uxgkmg o u"uwewi wukg o u"vktkc o kgukg o u"pwuvcv {vqu"pgrc igkfcwlc o qu"tgcmeklqu

OgfFTC"qticip ukuvg o mncu	Fcfpcu	Pgfclpcu
K o wpkp u"ukuvg o qu"uwvtkmk o ck		Cpchncmukp "tgcmeclc" Rc fkf l u"lcwttwo cu
Pgtx "ukuvg o qu"uwvtkmk o ck	I cnxqu"umcwu o cu	I cnxqu"uxckiko cu Rquvwtcnkpku"i cnxqu"uxckiko cu Jkr guvg klc
Cmk "uwvtkmk o ck		Hqvghqdklc
Cwu "kt"ncdtktpv "uwvtkmk o ck		Pg o cnqp u"rql kck"cwu {ug
Mtcwlc i {unk "uwvtkmk o ck		Flebitas
Mx rexk o q"ukuvg o qu."mt vkp u" n uvqu"kt vctrwrncw kq"uwvtkmk o ck	Mquwn {u	I gtmn u"uwfkt ikpk o cu" Fkuhqpklc" Ukpwu "wfdwtmk o cu" Fkurp lc
Xkt-mkpk o q"vtcmvq"uwvtkmk o ck		N r "umcwu o cu
Qfqu"kt"rqqf kpkq"cw f kpkq"uwvtkmk o ck	Pkgflwn {u."wtvkmctklc. k-d tk o cu	Cngt ikpku"fgt o cvkvcu" I gpgtck wqvcu" k-d tk o cu" Qfqu"nwr o cuku
Mcwn ."tcw o gp "kt lwpik o qlq"cw f kpkq"uwvtkmk o ck		I on pk "umcwu o cu" Tcw o gp "urc o ck" Tcw o gp "vt m kqlk o cu" fcp f kmcwnkq"umcwu o cu"
Dgp ftkglk"uwvtkmk o ck"kt xctvqlk o q"xkgvqu" rcfk f k o ck	Umcwu o cu" kphw klqu xkgvqlg	Umcwu o cu" Pg o cnqp u"rql kck"mt vkp u"utkv {lg" TMcnvmt vku" Pwqxct i ku" Rcvkpk o cu" kphw klqu" xkgvqlg" Uw -kt f k o k"pguwukl u"mt vkp u"utkvkqu" umcwu o cu" Nkg kepv"ct"urcwfflcpv"lwpvc o cu" umcwu o cu" Umcwu o cu" f tqk "mtcwlci {un " xkgvqlg

Cvtpmv "pgrc igkfcwlc o "tgcmecl"crkd f kpk o cu"

Rc fkf l u"lcwttwo cu"kt"cpchncmuklc

C-vwqpkg o u"vktkc o kgukg o u."mwtkg o u"qdknvqumucmuk o cdq" kphw |klc" dwxq"pwttewmve" f n" ien k o q" rcfkf lwukq"
lcwttwo q."pwuvcv {vqu"-kqu" pgrc igkfcwlc o qu"tgcmeklqu" wtkmctklc."k-d tk o cu."mquwn {u." pkgflwn {u." i cnxqu"
uxckiko cu." igtmn u"uwfkt ikpk o cu." fkuhqpklc." fkurp lc"kt" pg o cnqp u"rql kck"mt vkp u"utkv {lg" Mkvkg o u"
vktkc o kgukg o u."mwtkg o u"rcuktgk-m "rc fkf l u"lcwttwo cu." fewikewuke"rcuktgk-m "uw"qfc"uwukl "uk o rvq o ck."
kaip antai pkgflwn {u"kt" k-d tk o cu."kt"8"vktkc o kgukg o u"rcuktgk-m "mquwn {u"0"Cpchncmuklqu"tgk-mkp {u"rcuktgk-m "
fkfflk l "m pq"fen ." umckvcpv" mcmn ."mt vkp ."pwict ."lwqu o gp ."tcpmcu"kt" mqlcu." cr o wukw" fkhw |k-mw
pkgfl lko "uwngkncp kw." "fkni nkp "repc-kw" k-d tk o w."vckr"rcv"fwuwnkw"kt"mquwnkw0

Pgdwxq "lqmk " rql {ok ." mcf" rcfkf lwukq" lcwttwo q" tgcmeclcu" kt" k-d tk o wu" d v " uwm n u" ekvqmkp "
k-ukum {tk o cu="mnpk-mck"tgkm-o kpi "ekvqmkp "mqpegpvtceklqu"rqm { k "pgpwuvcv {vc0

Kowpqi gpk-mw o cu

Xkukg o u"vktkc o kgukg o u."mwtkg o u"vkl "mnpkmpkpk "v {tk o " o gvw"dwxq"uwngkuvc"xkgpc"kt" f xk"qdknvqumucmuk o cdq"
fq| u."dwxq"cvnkmyk"v {tk o ck" f n"cpvkm p "rtkg-"qdknvqumucmuk o cd "uwukfct {o q0"C-vwqpkg o u"vktkc o kgukg o u"
*4.7 rtqel.": "k-"542+."mwtkg o u" "xgp "dwxq"uwngkuvc"dgpv"xkgpc"qdknvqumucmuk o cdq"fq| ."pwuvcv {vcu" k o wpkpku"
atsakas - i {f {o q" ogvw" uwukfctkwuk " i {f q o l " rqxgkm " pgwvtcnk |wqlcp k " cpvllm anti- *cpin
vjgtergwwke"cpvkdqff+0" Mkgm {dkpkck"vkvtck" dwxq"pgfkfgnk"kt" ux {tcxq"pwq" 3<42"kmk" 3<5420" Vktkc o kgukg o u."
mwtkg o u" pwuvcv {vcu" vqmu" k o wpkpku" cvucmcu." remkvwukqu" hct o cmqmkpgvkmqu" etdc" remkvwuk " vqmu-mw o q"
ejctcmvgtkuvkm " rql {ok "pgpwuvcv {vc0

Pranešimas apkg" vctkc o cu"pgrc igkfcwlc o cu"tgcmeclcu

Uxctdw"rtcpg-vk"crkg" vctkc o cu"pgrc igkfcwlc o cu"tgcmeclcu"rq"xckuvkpkq"rtgrctevq"tgi kувtceklqu."pgu"vck" ngkfflkc"pwqncv"uvgd vk"xckuvkpkq"rtgrctevq"pcwfqu"kt"tk|kmqu"ucpv{m 0"Uxgkmcvqu"rtkglk tq"urgekcnkuvck"vwtk" prang-vk"crkg"dgv"mqmku" vctkc o cu"pgrc igkfcwlc o cu"tgcmeclcu"pcwfqfc o [Lgufiede](#) pwtqf{vc" nacionaline pranešimo sistema)

4.9 Rgtfq|cxko cu

Rgtfq|cxwu"xckuvkpkq"rtgrctevq."tgm v "uvgd vk."ct"rcekpvc o u"pgrcuktgk-mkc"pgrc igkfcwlc o q|rqxgkmkq" rqlf{okck"ct"uk o rvq o ck)

5. HCTOCMQNQIKP U"UCX[D U

5.1 Hct o cmqfkpc o kp u"ucx{d u

Hct o cmqvgtcrkp "i twr - k o wpkpkc"ugtw o ck"kt"ko wpq inqdwkpkc."urgekhpck"ko wpq inqdwkpkc."CVE" kodas - L28DD440

Xgkmo q"ogejcpk|o cu

Qdknvqmucmuk o cdcu"{tc"o qpqmnpkpkcu"cpvkm pcu."mwtku"rtkuklwpik"B. anthracis crucwikip "cpvki gp " *CC+0"Qdknvqmucmuk o cdcu"unqrkpc"CC"lwpiko uk"rtkg"n uvgnk "rcxkt-kwlg"gucep k "lq"tgegrvqtk ".vckr" pngku fco cu"lwf nki u"ngvncpkc o "hcmvqtkwk"kt"fg o qu"hcmvqtkwk"- hgt o gpvc o u."mwtkg"{tc"vqmukpq" uwfgfc o qukqu"fen{u"kt"{tc"cvuencpkik"wfl"revqigpkp "lwf nki u"vqmukpq"rqxgkm "- revgmvk" "n uvgn u"xkf 0

Farmakodinaminis poveikis

Obinvqmucmuk o cdcu"rtkuklwpik"nckux l "CC. gucpv"2.55"pO"chkpk-mw o q"rwukcwux{tqu"fkuekceklqu" mquvcpvc0"

Kp"xkvtq qdknvqmucmuk o cdcu"lwpikcuk"rtkg"Ames."Xqmw o ir Sterne rcfgtok "B. anthracis CC0"V{tko " cvcumckvqug"pwtqf{v "rcfgtok "B. anthracis CC"grkvrcu. rtkg"mwtk "lwpikcuk"qdknvqmucmuk o cdcu." wflmqpugtqwqlc o cu)

Kp"xkvtq v{tko ck"uw"n uvgn "dcpfkpkw."pcwfqlcpv"rgnk "o cmtqhc i wu."ngkfflkc"o cp{vk."mcf" qdknvqmucmuk o cdcu"pgwvtenk|wqlc"vqmukp "ngvncpkq"vqmukpq"rqxgkm ."CC"kt"ngvncpkq"vqmukpq"fgtkp 0"

Kp"xkxq vgmuk o kpiwo q"v{tko cku"uw"pcwlqkqu" \ gncpflku"denckukcu"*P \ D+"vkw-keku"kt"mtcdc f o ku" o cmcmq o ku."mwtkg o u"dwxq"fwqc" mx rvk"Ames"gt o u"B. anthracis urqt ."rq"i{f{ o q" qdknvqmucmuk o cdcu"dwxq"pwuvcv{vcu"pwq"fq| u"rtkmncwuq o cu"i{xgpc o w o cu0"Rq"wflmt vk o q"B. anthracis urqt o ku"CC"mqpegpvteckle"P \ D"vkw-k "kt"mtcdc fflk "o cmcm "ugtw o g"fkf lq0"Rq"i{f{ o q" qdknvqmucmuk o cdcu"CC"mqpegpvteckle"uw o cfl lq"fcw iwo qu"i{xgpwuk "i{x p "ugtw o g0"CC" mqpegpvteckle"i{x p ."mwtkg o u"dwxq"ngkfflkc o cu"rncegdcu."ugtw o g"fkf lq."mqn"lkg"pwick-0

Xgkmu o kpiwo cu

Mcfepk|pg o cpq o c"kt"pggvk-mc"cvnkmvk"mqpvtknwqlc o wu"mnkpkmkpkwu"v{tko wu"uw"kpjcnkeckpg"lwf nki g" ngticp kcku"flopp o ku."qdknvqmucmuk o cdcu"o qpqvgtcrklqu"xgkmu o kpiwo cu"i{fcpv"kpjcnkeckp "lwf nki " *xckuvkpk "rtgrctevkpcpv"uw"rncegdw+"rcit uvcu"xgkmu o kpiwo q"v{tko cku"uw"P \ D"vkw-keku"kt" mtcdc f o ku"o cmcmq o ku0"

Cvngmcpv"-kwqu"v{tko wu."i{x pck"dwxq"wflmtg keok"cgtd|qnk|wqvq o ku"*Ames rcfgt o u"B. anthracis urqt o ku."pcwfqlcpv"o cffcw i"422zNF72 fq| ."kt"x nckw"umtkvpiaku"nckmq"o o gpcvku"rtcfgfco k"i{f{vk" qdknvqmucmuk o cdcu0"Cvngmcpv"kpjcnkeckp u"lwf nki u"i{f{ o q"xgkmu o kpiwo q"v{tko wu."i{x pck"dwxq" rtfcfgfco k"i{f{vk"rcuktgk-mwu"ukuvgo kp u"lwf nki u"mnkpkmkpkc o u"rqlf{okc o u"ctdc"uk o rvq o c o u0" Cvngmcpv"rtqhkncmvkmqu"rq"u n{ kq"uw"kphgmeklqu"-cnvkpw"xgkmu o kpiwo q"v{tko wu."i{x pck"dwxq"

rtcfgfco k"i {f {vk"rq"u n { kq"uw" *B. anthracis* -cnvkpw."dgv"kmk" k-ukx {uvcpv"uk o rvqoco u⁰"Mtedc f u" o cmcmqu"dwxq"rtcfgfco qu"i {f {vk"icxwu"vgkiko "ugtw o q"gnmvtqejgo knkw okpuegpepkq"GEN+v {tk o q" f n" *B. anthracis* CC"tg|wnvcv ."rtc lwu"xfwvwpk-mck" o cflfcwi"62 xcncpf "rq"wfimt vk o q" *B. anthracis*0" Cvnkgmcpv" P \D"vkw-k "i {f {o q"xgkmu okpiwo q"v {tk o wu."i {x pck"dwxq"rtcfgfco k"i {f {vk"icxwu" vgkiko "GEN"v {tk o q" f n" *B. anthracis* CC"tg|wnvcv "ctdc"rq"knicnckmq"rtcfkp u"m pq"vgo rgtcv tq" refkf lko q."rtc lwu"xfwvwpk-mck" o cflfcwi"52"xcncpf "rq"wfimt vk o q"K-i {xgpc o w o cu"dwxq"xgtvkpc o cu" rtc lwu"4:"retq o u"rq"wfimt vk o q" *B. anthracis* cvnkgmcpv"vqnkw"crtc-{vwu"v {tk o wu⁰

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5 ngpvgn 0"K-i {xgpc o w o q"tqfkmnk"cvnkgmcpv"qdknvqmucmuko cdq"*38 o ilmi+" o qpqvgterklqu" xgkmu okpiwo q"v {tk o wu

V {tk o q"rcdcki qlg" k-i {xgpwuk "vktko i {x p "fcuku *rtqe ⁰ "k-i {xgpqlp++		Rncgdcu	Qdknvqmucmuko cdq" 38 o ilmi"	r"tgkm-o ²	95 rtqe ⁰ "RK ³
I {f {o cu"- Pcwluqu" \gnepfklqu"dcnvgkl"vkw-kck					
V {tk o cu"CT255 ¹	2"*2135+		83.7 rtqe ⁰ "*:135+	2.2235,	*2.4;2."2.:83+
I {f {o cu"- mtedc f u" o cmcmqu					
V {tk o cu"CR426 ¹	6 rtqe ⁰ "*3138+		68.9 rtqe ⁰ "*9137+	2.228: ,	*2.2: ;".2.8:3+
V {tk o cu"CR424 ¹	2"*2139+		53.5 rtqe ⁰ "*7138+	2.22:7,	*2.29;".2.7:9+"
Rtqhknemvkm"rq"u n { kq"uw"kpghmeklqu"-cnvkpw" mtedc f u" o cmcmqu					
V {tk o cu" CR523 ⁴	3: xcno rq"u n { kq" uw" kphgmeklqu" -cnvkpw	2"*218+	100 rtqe ⁰ "*818+	2.2234,	*2.693."3.222+
	24 xcno rq"u n { kq" uw" kphgmeklqu" -cnvkpw	--	:5 rtqe ⁰ "*718+	2.2264,	*2.452."2.; ;8+
	36 xcno rq"u n { kq" uw" kphgmeklqu" -cnvkpw	--	72 rtqe ⁰ "*518+	2.2567	*-2.259."2.: :4+

RK"rcukmncwvkcuku"kpvgtxcncu

¹ K-i {xgpc o w o cu"xgtvkpcu"rtc lwu"4:"retq o u"rq"wfimt vk o q"urqtq o ku."xkukg o u"tcpfqok |wqvkgo u" i {x pc o u"rtkg-"i {f {o "dwxq"rcvxtkvpc"dcnvgtkgoklc."i {f {o cu"rtcf vcu"u o ctmck"refkf lwu"m pq" vgo rgtcv tck"v {tk o cu"CT255+"ctdc"guv"vgkiko o o "crucwikipk "cpvki gp " gngmvtqejgo knkw okpuegpepkq"v {tk o q"tg|wnvcvwk"v {tk o ck"CR426"kt"CR424+0

² R"tgkm-o "pwuvcv"vc"vckmcpv"xgprwu "Dque"intgkl "rcmqtg i wq v"vckmcpv"ic o c"2.223"tqfkmn ." rci cn"Berger-Dqu o gvqf +."n {ikpcpv"uw"rncgdw⁰

³ Vkmunwu"K-i {xgpc o w o q"tqfkmnk "umktvw o q";7 rtqe⁰"rcukmncwvkcuku"kpvgtxcncu⁰

⁴ K-i {xgpc o w o cu"xgtvkpcu"rtc lwu"4:"retq o u"rq"wfimt vk o q"urqtq o ku⁰

ε Tqfq"uvcvkup "tgkm-okpiwo "guv"2.247"n {ikwk⁰

Xckm "rqrwnkceklc

Gwtqrqu"xckuv "cigpv tc"cvkf lq" ukretgkiqlk o "rcvglmvk" P [ZV J V C B K U w "xkgpc"ct"fcwikcw" xckm "rqrwnkceklqu"rqitwrk "i { fcpv"dcmvgtkp "kphgmekl "tg|wnvcvwu"*xctvqlk o q"xckmc o u"kphqt o ceklc" rvcgkmc o c"604 um { tkwlg+0

"ku"xckuvkpku"rtgrctevcu"tgi kuvtwqvuc"u"vkv o ku"u n { i q o ku0"Vck"tgk-mkc."mcf" f n"nki qu"tgvw o q"kt" f n" etkpk "rtkgflec k "icwvk"xkuqu"kphqt o ceklqu"crkg"- "xckuvkp "rtgrctev "pgdwxq" o cpq o c" Gwtqrqu"xckuv "cigpv tc"mcu o gv"rgtflk t u"pcwl "kphqt o cekl "crkg"- "xckuvkp "rtgrctev ."lgiw"lqu"dwu."kt" rtktgkmwu"cvpcwlkpu"-k "REU0

5.2 Hct o cmqmkpgvkv u"ucx{d u

Cduqtdeklc

Rq"xkgpqu"kpvtcxgpkp u"kphw|klqu"uxgkmg o u"vktkc o kgug o u"qdknvqmucmuk o cdq" hct o cmqmkpgvkmc" { tc" vkgukp ."mck"fq| "ux{twqlc"pwq"6 o ilmi"*6"mctvwu" o cflgup "wfl" o cflkcwuk "fgmq o gpfwqlc o "fq| +"kmk" 16 o ilmi0"Uxgkmg o u"vktkc o kgug o u"x { tc o u"kt" o qvgtk o u" xgp "uwnc-kpwu" xkgp "38 o ilmi" qdknvqmucmuk o cdq"fq| ."xkfwvkp "E_{ocz} kt" C W E_{inf} dwxq"cvkvkpmc o ck"622+;3.4 Û il o n"kt"7 170 ± 1 360 Û i" fl o n0"Qdknvqmucmuk o cdq" r wukp u"gnk o kpceklqu"nckmcu"dwxq" o cffcw i"42"ret "*"xkfwtmku+0

Pasiskirstymas

Xkfwvkpku"pwukuvqx l wu"rwukcwsvyrai qdknvqmucmuk o cdq"rcukumktuv { o q"v tku"dwxq"9; .9 ± 4 o n l m i"kt" xkt-klq" rnc | o qu"v t ."q"vck"ngkfflkc" fct { vk" k-xcf ."mcf"-kgm"vkgm"vaistinio preparato"mktuv "kt" " cwfkpku0

Dkvtcpuhqt o ceklc

Qhkecnk "qdknvqmucmuk o cdq" o gvcdqnk | o q"v { tk o "pgcvmkmvc0 Vc kcw" f n"ucxq"ejctcmvgtkuvkm " o qpqmnapkpkck"cpvkm pck"r r t e u v c k" r e u k u m k t u v q" w f l" m t e w l c i { u n k " t k d ." m w t " i c n k" e d u q t d w q k u " c w f k p k w u . " k t " r t g v c k | k " m e v e d q n k | w q l c o k " v t w o r w u " r g r v k f w u " k t " c o k p q t i - v k u . " m w t k g " x n k c w " v t e w m k c o k " g p f q i g p k p " l " x k u w o " c t d c " r e - c n k p c o k " k - " q t i c p k | o q 0

Gnk o kpceklc

Xkfwvkp u"qdknvqmucmuk o cdq" mktgpuc" xgtv u"dwxq"5.57 ± 2. ;54 o n l f l m i"kt" f c w i" o c f l g u p u" w f l" i n q o g t w n " h k n v t c e k l q u" i t g k v ."q"vck"tgk-mkc."mcf"qdknvqmucmuk o cdcu" k-"gu o u"pgrcuk-cnkpc" rgt" kpmuvwu0

[rcvkpiqu"rqrwnkceklc

N{vkgu."c o flkcwu"kt"tcu u" vcmc Qdknvqmucmuk o cdq" hct o cmqmkpgvkv u"ucx { d u"dwxq"xgtvkc o qu"cvnkgmcpv"rqrwnkcekp "hct o cmqmkpgvkv " cpenk | ."pcwfqlcpv"592"uxgkm "vktkc o l ."mwtkg o u"6"mnkpkmkpk "v { tk o " o g w w " x g p " d w x q " u w n g k u v e " x k g p c " vaistinio preparato fq| ."ugtw o q" o kpkwu0" T g o k e p v k u " - k c " c p e n k | g . " n { v k u " * o q v g t k u " k t " x { t e u + . " t e u " * m e w m e | k g k " k t " p g " m e w m e | k g k + " k t " c o f l k w u " * x { t g u p k u " k t " l e w p e u " c o f l k w u + " p g v w t " l q " t g k m - o k p i q u " v e m q u " hct o cmqmkpgvkpkc o u"qdknvqmucmuk o cdq" rctc o gvte o u0" Vc kcw" "mnkpkmkpkwu"qdknvqmucmuk o cdq v { tk o w u" d w x q " v t e w m v c " p g r e m c p m e o c k " 8 7 " o g v " k t " x { t g u p k " v k t k c o l ." m e f " d v " i c n k o c " p w u v e v { v k . " l q i " v a i s t i n i o " p r e p a r a t o h c t o c m q m k p g v k p u " u c x { d u " l " q t i c p k | o g " u m k t c u k " p w q " l " l e w p g u p k " v k t k c o l " q t i c p k | o g 0 " k - " 5 4 2 " m n k p k m k p k w q u g " q d k n v q m u c m u k o c d q " v { t k o w q u g " f c n { x e x w u k " v k t k c o l . ; . 6 r t q e 0 " * 5 2 " k - " 5 4 2 + " d w x q " 8 7 " o g v " k t " x { t g u p k " k t " 4 r t q e 0 " * 8 " k - " 5 4 2 + " d w x q " 9 7 " o g v " k t " x { t g u p k 0

M pq"uxqtka" vcmc

Gucpv"fkfgnkc o"m pq"uxqtka" *32; mi+."vaistinio preparato mktgpucu"dwxq" o cffcw i"5: rtqe0" fkgfupku" pgk"tghgtgpek" lg"rqrwnkceklqlg0" Mck"vaistinis preparatas fq| wqlc o cu"rcicn"uxqt " *38 o ilmi+."GWE rcfkf lc"34 rtqe0."q"vck"p tc"mnkpk-mck"tgkm- o kpicu"rcfkf lk o cu0

Xckm "rqrwnkceklc

Qdknvqmucmuko cdq "hct o cmqmkpgvkv u"ucx {d u"pgk-vktvqu"xckm "rqrwnkceklq|g0"4"ngpvgn Ig"*604"um {tkwlg+
rcvqkmvqu"tgmq o gpfceklqu" f n"xckuvkpkq"rtgrctevq"fq|cxk o q"rcit uvqu"uk o wnkceklq o ku"rcicn"rqrwnkcekp "
hct o cmqmkpgvkv "o gqf .mwtkqu"uwrtqlgmvwvqu"vckr."mcf"cvkvkv "pwuvcv {v "qdknvqmucmuko cdq"
gmurq|kekl "uwcwiwuk "vktko l "qti cpk| o g"uwngkfwu"38 o ilmi"fq| 0

5.3 Kmkmnkpkmkpk "ucwiwoq"v{tko "fwqogp{u

rtcuu "hct o cmqmq i kpkq"ucwiwoq."mctvqvkpk "fq|k "vmuk-mwoq"dgk"vmukpkq"rqxgkq"tgrtqfwmeklck"kt"
x {uv {o wkuk"mkmnkpkmkpk "v{tko "fwqogp {u"urgekhkpkq"rcxqlcwu"floqiwk"pgrctqf 0

Lwqfnki g"wflukmt vwukgou"pgk-i {xgpwukgou"P\D"vkw-kcou"kt"mtcdc f ou"ocmcmqou."mwtkgou" "xgp "
dwxq"uwngkuvc"qdknvqmucmuko cdq"*6 o ilmi+."ctdc"mqpvtknkpkeou"i {x pcou"nki qu"fcvktkpk o q"o qogpww"
dwxq"pwuvcv {vc"egpvtkp u"pgtx "ukuvgo qu"*EPU+"rcflgkfk o "dcmvgtklqu."wflgik o cu."jgoqtciklc"kt"
tgvmet kcu"pgmtq| +0"Okmtqumqrkpkwu"rqm { kwu."mwtkg"pwuvcv {vk"pgk-i {xgpwukgou"qdknvqmucmuko cdw"
i {f {vkgou"i {x pcou."uwm n "wfl"mtcwlci {unk "tkd "dwxwukqu"dcmvgtklqu."q"pg"qdknvqmucmuko cdq"rqxgkmu0"
Fq| "u" uclqu"uw"icnxqu"uogigp "jkuvqrcvqni klc"pgpwuvcv {vc0"K-i {xgpwukgou"lwqfnki g"wflukmt vwukgou"
P\D"vkw-kcou"*rtc lwu"4:"rtqou+"ctdc"mtcdc f ou"ocmcmqou"*rtc lwu"mkk"78"rct +."mwtkgou"
cvkvkpmc o ck"dwxq"uwngkuvc"xgpc"pg"fkfgup "mckr"38 o ilmi"fq| "kt"pg"fkfgup "mckr"54 o ilmi"fq| ."
pgpwuvcv {vc"lqmk "uw"i {f {ow"uwuklwuk "icnxqu"uogigp "rcflgkfk o "Rq"i {f {o q"qdknvqmucmuko cdw"
k-i {xgpwukgou"lwqfnki g"wflukmt vwukgou"mtcdc f ou"ocmcmqou"pgpwuvcv {vc"lqmk "uw"qdknvqmucmuko cdw"
uwuklwuk "pgwtqni kpk "kt"gnigukq"rcmkvko 0

Vienas poveikio embriono ir vaisiawu"x {uv {o wkuk"v{tko cu"dwxq"cvnkmcu"uw"vkw-kpi q o ku."uxgkmo ku"
P\D"vkw- o ku."mwtkgou"8- .32- .35- "kt"39- "iguvceklqu"fkgp " "xgp "dwxq"uwngkuvqu"mgvwtkqu"mkk"
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Qdknvqmucmuko cdq"flenkpi q"rqxgkq"vkw-kpi q o u"rcvq ou"kt"l "xckukw"rqfl {ok "pgpwuvcv {vc0"
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fq| u+"cvkvkq"pgrcvgd vq"pgkiko q"rqxgkq"tkd "PQCGN+."tgo kcpvku"CWE₀₋₃₇- "flgp ."dwxq"ocflfwi"
fw"mctvwu"fkfgup "wfl"flopp ou"- x {tcou"kt"o qvgtkou"mctvw"- pwuvcv {v "CWE"xkfwtm ."xgp "uwngkfwu"
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Pqnuqtdevcu": 2"*G655+
Vandenilio chlorido t i-vku"*G729."umktvcu"r J"mqtg i wqvk+
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805 Vkpme o wo q"nckmcu

Neatidarytas flakonas

7 metai

Rtcumkguvcu"vktrencu"kphw|kpkc o g" o ck-gn{lg

Mc o dctkq"vg o rgtcv tqlg"*42 ÅE"-47 ÅE+"kt"-cnf{vwxg"*4 ÅE"-: ÅE+"kphw|kpkc o g" o ck-gn{lg"rtcumkguvcu"vktrencu"ejg o k-mck."hk|k-mck"kt" o kmtqdkqni k-mck"uvcdknwu"nkgmc": "xcncpfcu0

O kmtqdkqni kpkw"rqflk tkw."xckuvkp "rtgrctev "tgkm v v'antoti pgfgnucpv."pgdgpv"hnemqpcu"cvkfctq o cu"kt vaistinis prepatvcu"twq-ke o cu"ct"umkg fflk o cu"pgmgncpv" o kmtqdkqni k p u"vct-qu"tk|kmqu0

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€ Prieš xctvqlcpv."mqpegpvtcv" kplgmekpkc o "vktrenwk"tgkmkc"crflk t vk."ct"lc o g"pguk o cvq"mkgv I " fcngk "kt"ct"pgrcmkvwuk"l "urcnc"0 P [ZV J TCEKU - vck"umckftwu"ctdc"qrcnguewqlcpvku."dgu rcnku."

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€ K- o gumkv g"hnemq p .lgkiw"vktrenq"urcnc"rcmkvwuk"ctdc"lc o g" o cvq o k"uxgvk o m pkc"*flto 5"um{tk +0

€ Pgmtcv{mkvg"hnemqpcu0

Retwq-k o cu"kt"umkgfk o cu"kphw|kpkc o g" o ck-gn{lg"

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70 Uwngkumkvg"tgkmc o "qdknvmucmuk o cdq"mqpegpvtcvq"kpwh|kpkc o "vktrenwk"mkgm " reuktcpmv "kphw|kp " o ck-gn 0"

80 Rcnipi xc"crxgtumkvg"kpwh|kp " o ck-gn .mcf"vktrencu"k-uk o ck-{v 0"Pgmtcv{mkvg0

90 kphw|kp "vktren "tgkmc"uwnc-kpvk"rgt";2"okpw k .5"ngpvgnlg"um{tk +}pwtqf{vw"kpwh|klqu" i tkg kw."pcwfqlcpv"2.44" o kmtqp "kphw|klqu"nkpklqu"hknvt 0"

:0 Laikomas 20 ÅE"-47 ÅE"mc o dckq"vg o rgtecv tqlg"ctdc"4 ÅE"-: ÅE"vg o rgtecv tqlg"-cnf{vwxg." rctwq-vcu"vktrencu"k-nkgmc"uvcdknwu": "xcncpfcu0

Retwq-k o cu"kt"rtcumkgfk o cu"kpwh|kpkc o g"-xktm-vg

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40 Crumck kwqmkvg"tgkmc o "qdknvmucmuk o cdq"mqpegpvtcvq"kpwh|kpkc o "vktrenwk"mkgm " o knkvtcku"kt" vqmkck"fq|gk"tgkmcnpi "hncmqp "umck k ."oknkitc o cku"crumck kwq "fq| "3"flkipku+"rcfncpfc o k" k-"mqpegpvtceklqu"*322 o ilon+"k-"xkgpq"hnemqpp"icnk o c"uwngkuvk"8 ml obiltoksaksimabo koncentrato iphw|kpkc o "vktrenwk0

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60 Pcwfaqc o k"reuktcpmv "-xktm-v "kt"2.44" o kmtqp "kphw|klqu"nkpklqu"hknvt ."rtkvtcwmkvg"tgkmc o " qdknvmucmuk o cdq"mqpegpvtcvq"kpwh|kpkc o "vktrenwk"mkgm " *crumck kwq "4"flkipu{lg+0" P [ZVJTCEKU flakone *-wqug+"nkmwuk "pguwxtcvq mapegpvtcvq"fcn "k-o gumkvg0"

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80 Rcnipi xc"k-o ck-{mkvg"vktren 0"Pgmtcv{mkvg0

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Cvngm "vxctm{ o cu

Pguwxtcvq "xckuvp "rtgrctcv "ct"cvngmcu"tgkmc"vxctm{vk"nckmcpvku"xkgvcpk "tgkmcncxk o 0

7. TGIKUVTWQVQLCU

UHN"Rjct o cegwkecnu" Fgwuejnepf" I o d J
 Octkg-Ewtkg-Uvtcuug":
 9;75;"N3/attcej
 Xqmkgvklc

8. TGIKUVTCXKQ"RCfi [O LKOQ"PWOGTKU"*-KCK+"

GW13142136:71223

9. TGIKUVTCXKQ 1 RGTG I KUVTCXKQ"FCVC

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10. VGMUVQ"RGTfiK TQU"FCVC

K-uc o k"kpht o ceklc"crkg"- "xckuvp "rtgrctcv "revgkmc o c"Gwtqrqu"xckuv "cigpv tqv"vkpmncncr{lg" [jwr<ll y y 0g o c 0gwtqrc0gw kt](#)}xcnuv{d u"pet u"cigpv tqv"rexcfkpk o cu"*pwqtqfc+;"uxgvcp lg0

II PRIEDAS

- A. DKQNQ IKP U"XGKMNKQUKQU" OGF ĦKCIQU" I COKPVQLCU"
KT" I COKPVQLCU."CVUCMKP I CU"WĦ"UGTKL "K^MNGKFKO
- B. VKGMKOQ"KT"XCTVQLKOQ"U N[IQU"CT"CRTEKDLKOCK
- C. MKVQU"U N[IQU"KT"TGKMCNCXKOCK"TG I KUVTWQVQLWK
- D. U N[IQU"CT"CRTEKDLKOCK"UCW IKCO"KT"
XGKMUOKP I CO"XCĦVVKPKQ"RTGRCTCVQ"XCTVQLKOWK"
WĦVKMTKPK
- E. URGEKHKPKU" RCTGK I QLKOCU" X[MF [VK"
RQTG I KUVTCEKPGU"WĦFWQVKU"TG I KUVTCEKLQU"
K^MKOVKP OKU"U N[IQOKU"CVXGLW

**A. DKQNQIKP U *-K + "XGKMNKQUKQ L + "OGFfKCIQU *- + "ICOKPVQLCU *-CK+"KT"
ICOKPVQLCU *-CK+."CVUCMKP I AS *-K+"Wfi"XCUVQ"UGTKLQU"KTMNGKFKO**

Dkqnqikp u *-k + "xgkmmkqukqu *-k l + "ogffkciqu *- + "icokpvqlq"rcxcfkpkocu"kt"cftgucu

Nqp|c"Dkqnqikeu."Kpe0"
323"Kpvgtpcvkqpcn" Ftkxg
Rqtvu o qwj."P J"25:23"
LCX

Icokpvqlq *- +."cvucmkp i q" wfi"ugtkl "k-ngkfk o ."rcxcfkpkocu *-ck+"kt"cftgucu *-ck+

CegtvkRjctoc"D0X0
Dquejuvtccv"73
6:33" I E."Breda
Qncpfklc

B. VKGMKOQ"KT"XCTVQLKOQ"U N[IQU"CT"CRTKDQLKOCK"

Tgegrvkpku"xckuvkpku"rtgrctevcu0

C. MKVQU"U N[IQU"KT"TGKMCNCXKOCK"TG I KUVTWQVQLWK

€ **Rgtkqfk-mck"cvpewkpc o k"ucwiwo q"rtqvqmnek"RCUR+**

™kq"xckuvkpkq"rtgrctevq"RCUR"rcvgkmo q"tgkmcncxkock-k-f uv{vk" Fktgm v{xqu"42231:51GD"
107c straiptsnio 7 fcn{lg"pwocv{vcog"U lwpiqu"tghgtgpepk "fcv "u tc-g"GWTF"u tc-g+."mwtku"
umgndkocu"Gwtqrqu"xckuv "vkpmncncr{lg0

**D. U N[IQU"CT"CRTKDQLKOCK."UMKTVK"UCW I KCO"KT"XGKMUOKP I CO"XCUVKPKQ"
RTGRCTCVQ"XCTVQLKOWK"WfiVKMTKPKV"**

€ **Tk|kmqu"xenf{ o q"rncpcu"TXR+**

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Cvpewkpvku"tk|kmqu"xenf{ o q"rncpcu"vwtk" d vk"rcvgkmcv<

€ retgkmcncxwu"Gwtqrqu"xckuv "cigpv tck=

€ mck"mgk keoc"tk|kmqu"xenf{ o q"ukuvgo c."{rc "icxwu"pcwlqu"kpht o ceklqu."mwtk"icnk ng o vk"fkfgn "
pcwfgqu"kt"tk|kmqu"ucpv{mkq"rqm{v "ctdc"reukgmwu"uxctd "hctocmqnqikpkq"dwftwo q"ct"tk|kmqu"
ocflkpk o q+"gver 0

**E. URGEKHKPKU" RCTGKIQLKOCU" X [MF [VK"RQTG I KUVTCEKPGU"WfiFWQVKU"
TG I KUVTCEKLU"KTMKOVKP OKU"U N[IQOKU"CVXGLW**

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fcnk o k."tgikvwtvqvlcu"pwuvv{vku"vgt o kpcu"vwtk" x{mf{vk"-kcu"wlffwqvk<

Crtc-{o cu	Vgt o kpcu
<p>Ukgmfcocu"xcnkfwqvk"qdknvqmucmukoedq"hetoemqmkpgvypkq"v{tkoq" floqicwu"ugtwog"ogvqf"*IEN-382+."tgi kvtwqqlcu."rtkg-" pcwqfco cu"dcpfkp"okpk"cpenk gk"mnpkmpkq"v{tkoq"CJ723" vkmuncu."vwtv"rcvgkmvk"dcpfkp"xcnkfeclqu"tg wnvcwu."uwuklwukwu"uw" -kcu"curgmvcu<"CC"*85"kt":5+."GH."NH"kt"cpvkm p"rtkg-xckuv" *CRX+kpvgtgtgpekle"kt"dcpfkpq"pcwqfkoq"vktkcpv"jgoqnvkp"kt" nkrgek"ugtwog"oikpwu"ejctcmvgtkuvkmq"ku0"Retcngk oq" dcpf{o wu"tgkm v"cvnkmyk"uw"pwocv{vq"cvxktq"ncwmq"v{tkoq"CJ723" ogw"rcokvcu"okpkcu0</p> <p>Ukgmfcocu" xgtvkvk"mnpkmpk"cvucm ."ucwiwo"kt"vqngtwqlcowo." umckvcpv"nki qu"gi"kt"qdknvqmucmukoedw"i{f{v"vktko"l."mwtg" vctvc."ocp{vc."mcf"icnk"d vk."ctdc"rcvxtkvpvc"kpjcnkecp"lwqfki" k-i{xgpcowo."tgi kvtwqqlcu"vwtv"."reicn"uwvctv"rtqvqmgn"."evnkmyk" 6"hc u"cvxkt"ncwmq"v{tko"CJ723."x{mwu"kpjcnkecp"u"lwqfki"u" rtqvt"mkwk"vqug"-cn{ug."mwtkqg"qdknvqmucmukoedcu"tgi kvtwqvcu"kt"lq" icnkoc"uki{vk."kt"rcvgkmvk"icnwkpu"cvcumckvqu"tg wnvcwu0</p>	<p>Rcvgkmvk"mctvw"uw"icnwkpg" mnpkmpkq"v{tkoq"CJ723" cvcumckvc0</p> <p>Ogvp u"cvcumckvqu."mwtkcu" reikia pateikti</p> <p>Icgvkwp"cvcumckvc"dwu" rcvgkmvc"pg"xncw"mckr" rte"lwu"34"o"pguk"rq" rcumwvku" qdknvqmucmukoedq"kphw klqu" ctdc"rcumwvkvkq"fwogp" tkpmkoq."lgkiw"dwu"tgpmeok" retrospektyviniai fwogp{u0</p>

Vaistinis preparatas neberregistruotas

Vaistinis preparatas neberegistruotas

III PRIEDAS

ŪGPMNKPKOCU"KT"RCMWOV U"NCRGNKU

Vaistinis preparatas neįregistruotas

A. **FIGPMNKPKOCU**

KPHQTOCEKLC"CPV"K™QTKP U"RCMWQV U

F fiwv

1. XCKUVKPKQ"RTGRCTCVQ"RCXCFKPKOCU

P [ZV J TCEKU 100 o i l o n"uvgtknwu"mqpegpvtcvu
obiltoksaksimabas

2. XGKMNKQLK *-KQU+"OGFfiKCI C *-QU+"KT"LQU *- + "MKGMKCK+

1 o n"322 o i"qdknvqmucmuk o cdq0

3. RCICNDKPK "OGFfiKCI "U TC™CU

Rci endkp u" o g f f i k c i q u < " j k u v k f k p c u . " u q t d k v q n k u . " G 6 5 5 . " v a n d e n i l i o c h l o r i d o f i - v k u . " p c v t k q " j k f t q m u k f c u . "
kplgmekpku"xcpfwq0

4. HCTOCEKP "HQTOC"KT"MKGMKU"RCMWQV LG

Mqpegpvtcvu"kpwh | kpkc o "vktrcnwk
600 o i l 8 m l
1 flakonas

5. XCTVQLKOQ"OGVQFCU"KT"D FCU *-CK+

Rtkg-"xctvqlk o " r g t u m c k v { m k y g " r c m w q v u " n c r g n 0
Rtcumkgfwu"ngkuvk" "xgp 0
Vkm"xkgpmetvkpkc o "xctvqlk o wk0
Pgmtcv { vk0

ST"mqfcu"dwu"pwtqf {vcu" y y y 0qdknvqzck o cd-uhn0gw

80 URGEKCNWU" UR LKO CU."MCF"XCKUVKPK "RTGRCTCV "D VKPC"NCKM [VK"
XCKMCOU"PGRCUVGDK OQLG"KT"PGRCUKGMKCOQLG"XKGVQLG

7. KITAS *-K+"URGEKCNWU *- U+" UR LK"OGULG"TGKMK+

8. VKPMCOWOQ"NCKMCU

Vkpmc"kmk

9. URGEKCNKQU"NCKM [OQ"U N [IQU

Nckm { vk" -cnf { vwxg0"

Pgicnkoc"wfl-cnf{vk0"

Nckm{vk"icokpvqlq"rcmwqv lg."mcf"vaistas d v "cruwivqvcu"pwq"-xkququ0

10. URGEKCNKQU"CVUCTIWOQ"RTKGOQP U"F N"PGUWXCTVQVQ"XCKUVKPKQ"
RTGRCTCVQ"CT"LQ"CVNKGM "VXCTM[OQ"*LGK"TGKMKC+

11. TGIKUVTWQVQLQ"RCXCFKPKOCU"KT"ADRESAS

UHN"Rjcto cegwkecnu" Fgwwuejncpf" I od J
Ockg-Ewtkg-Uvtcuug":
9;75;"N3/4ttcej
Xqmkgvklc

12. TGIKUVTCEKLQ"RCfi [O LKOQ"PWOGTKU"*-KCK+"

GW13142136:71223

13. UGTKLQ"PWOGTKU

Ugtklc

14. RCTFCXKOQ"*KTMFCXKOQ+"VXCTMC

15. XCTVQLKOQ"KPUVTWMEKLC

380 KPHQTOCEKLC"DTCKNKQ"TCTMVW

Rtkk ovcu"rc i tkpfk o cu" kphqt o ceklq" Dtcnkq"tc-vw" pgrcvgkmvk0

17. WPKMCNWU"KFGPVKHKMCVQTKWU - 4F"DT MTMPKPKU"MQFCU

4F"dt m-pkpu"mqfcu"uw" pwtqf {vw"wpkmcnw"kf gpvk hkmcvqtkw o k0

18. WPKMCNWU"KFGPVKHKMCVQTKWU - fiOQP OU"UWRTPVCOK"FWQOGP[U

RE<"
UP"
PP"

OKPKOCNK"KPHQTOCEKLC"CPV"OCfi "XKFKPK "RCMWQ K
HNCMQPQ"GVKMGV

1. XCKUVKPKQ"RTGRCTCVQ"RCXCFKPKOCU"KT"XCTVQLKOQ"D FCU"*-CK+

P [ZV J TCEKU 100 o i l o n"uvgtknwu"mqpegvtevcu
obiltoksaksimabas
Rtcumkgfwu"ngkuvk" "xgp 0

2. XCTVQLKOQ"OGVQFCU

Vkm"xkgpmctvtpkc o "xctvqlk o wk0

3. VKPMCOWOQ"NCKMCU

GZR

4. UGTKLQU"PWOGTKU

Lot

5. MKGMKU"*OCU ."V TKU"CTDC"XKPGVCI+

600 o i l 8 ml

80 KITA

Vaistinis preparatas neberegistruotas

Vaistinis preparatas neįregistruotas

B. RCMWQV U"NCRGNKU

Remwqv u"ncrgnku<kphqt o cekle" r cekpvwk

P [ZVJTCEKU 100 o il o n"mqpegvptcvu" kphw|kpkc o "vkt rcnwk obiltoksaksimabas

X{mfqoc"rerknfjoc"-kq"xckuvq"uygd ugpc0"Vck"rcf u"itgkvc"pwuvv{vk"pcwl "ucwiwoq" kphqt o cekl 0" Owou"icnkvg"rcf vk"rtcpq-fcok"crkg"dgv"mqm "Lwo u"rcuktgk-mkcpv "-cnwvkp "rqxgkm 0"Crkg"vck."mckr" rtcpq-vk"crkg"-cnwvkp "rqxgkm ."fit0 4 um{tkcwu"redckiqlg0

Cvkfflck"rgtumkv{mkvg"xku "- "ncrgn ."rtkg-"rtcf fcok"xctvqvk"xckuv ."pgu"lcog"rcvgkmc o c"Lwo u" uxctdk" kphqt o cekle0

- P gk-ogumkvq"-kq"ncrgnkq."pgu"x n"icnk"rtktgkvmk"l "rgtu"fnk0
- Lgkiw"mknv "fcwkw"mncwuko ."mtgkrmkv u" "i{f{vql ."xckuvkpkpm "ctdc"uncwi{vql 0
- Lgkiw"rcuktgk-m "-cnwvkpku"rqxgkmku"*pgv"lgkiw"lku"-kc o g"ncrgn{lg"pgpwtqf{vau+. mtgkrmkv u" " i{f{vql ."xckuvkpkpm "ctdc"uncwi{vql 0"fit0 4 um{tk 0

Crkg"m "te-q o c"-kc o g"ncrgn{lg

- 30 Kas yra P [ZVJTCEKU kt"mc o "lku"xctvqlc o cuA
- 40 Mcu"flkpvkpc"rtkg-"Lwo u"uwngkfllkcpv" P [ZVJTCEKU
- 50 Kaip P [ZVJTCEKU dwu"uwngkuvcu
- 60 Icnk o cu"-cnwvkpku"rqxgkmku"
- 70 Kaip laikyti P [ZVJTCEKU
- 80 Remwqv u"vwtkp{u"kt"mkvc" kphqt o cekle

1. Mcu" {te" P [ZVJTCEKU kt"mc o "lku"xctvqlc o cuA

P [ZVJTCEKU uwf v{lg" {te"xgkmmkqu" o gfflck"qu"qdknvqmucmuk o cdq0"Qdknvqmucmuk o cdcu" {te" o qpqmnpkpkpku"cpvkm pecu"-vc o "vkmqtu"t -kgu dcnv{ o cu."mwtku"lwp ikeuk"rtkg"vqmukp ."mwtkwqu"ic o kpc" lqwfnki "uwmgkncp kqu"dcmvgtklqu."kt"lqw"kpemv{xkpc0

P [ZVJTCEKU umktc o cu"metvw"uw"cpvdkvkmcku." i{fcpv"uwcw i wukwqukwu"kt"xckmwu."mwtkg"uwukti q" lqwfnki g" mx r "dcmvgtkl " *kpcnkcekpg"lqwfnki g+0

P [ZVJTCEKU vckr"rcv"icnk"d vk"xctvqlc o cu" x{mwu"u n{ kwk"uw"lqwfnki u"dcmvgtklq o ku"ctdc"urqtq o ku." dgv"fct"pgrcuktgk-mwu"nki qu"uko rwo o c o u"ctdc"lgkiw"p te"mkv "ctdc"vkpmc o "xckuv 0

2. Mcu"flkpvkpc"rtkg-"Lwo u"uwngkfllkcpv" P [ZVJTCEKU

Lwo u"pgicnk o c"ngkuvk" P [ZVJTCEKU

- lgkiw" {te"engtiklc"qdknvqmucmuk o cdwk"ctdc"dgv"mwtck"rcicndkpgk"-kq"xckuvq" o gfflck"ic" *lqu" išvardytos.6 um{tkwlg+0

ur lk o ck"kt"cvuctiwoq"rtkg o qp u"

Reukvotmkg"uw"i{f{vqlw."xckuvkpkpmw"ctdc"uncwi{vqlw."rtkg-"rtcf fcok"xctvqvk" P [ZVJTCEKU<

- lgkiw"Lwo u"*ctdc L u "xckmwk+"fki pq|wqvcu"tgvcu"i ppgvkpkpku"uwtkmko cu" ik d o m v q | u" p g v q g t e x k o c u " * H P + " c t d c " L u " x c k m e u " p g d g i c n k " x c t v q v k " u c n f f l k " o c k u v q " r t q f w m v " c t " i t k o . " p g u " p w q " l " l c o " r e u k f e t q " d n q i c . " l k u " x g o k e . " l c o " r e u k t g k - m k e " v q m k g " p g o c n q p u " t g k - m k p k c k " m e k r " r k n x q r v k o c u . " r k n x q " u r c | o c k " c t " x k f w t k e x k o c u 0

Mck"mwtckku"cvxglcku"engtikp u"tgcmeklqu."mwtkqu"icnk"rcuktgk-m"rq"i{f{ o q" P [ZVJTCEKU."icnk"d vk" uwpmkqu"htq o qu0"Ukgmkcpv"uw o cflkpvk"engtikpk "tgcmekl "tk|km ."rtkg-"cvnkmgcpv" P [ZVJTCEKU kphw|kl ." Lwo u"icnk"d vk"reskirtas antihistamininis vaistas0

Mkvk"xckuvck"kt"P [ZV J TCEKU

Lgkiw"xctvqlcvq"ct"pgugpkck"xctvqlqvg"mkv "xckuv "ctdc" f n"vq"pgucvg"vkmtk."crkg"vck"rcuem{mkvg"i { f {vqlwk"ctdc"xckuvkpkpmwk0
Lwou"icnk"d vk"rcumktvk"cpvkdkqvmck"*rx|0."ekrtqhqmucekpcu+"kpjcnkcekpgk"lwqfnkigk"i { f {vk0

P -vw o cu"kt"flkpf { o cu

Lgkiw"guvcg"p - ke."flkpfqvg"m fkm ."o cpqvg."mcf"icnd v"guvcg"p - ke"ctdc"rnepwqlcvq"rcuvqvk."rtkg-"Lwou"uwngkflkcpv"-kq"xckuvq."rcukvetmkvg"uw"i { f {vqlw0

Pgflkpq o c."ct"P [ZV J TCEKU icnk"rcmgpmvk"fct"pgik o wuko "xckmwk"ct"pg0"

Pgflkpq o c."ct"P [ZV J TCEKU k-ukumtkc" "o qvkpqu"rkgp 0"L u"kt"L u "i { f {vqlcu"pwurt ukvg."ct"L u"vwt vw o vg"flkpf {vk"rq"P [ZV J TCEKU kphw|klqu"ct"pg0

Xcktxk o cu"kt" o geje pk | o "xcnf { o cu

P [ZV J TCEKU icnk"uwmgnvk"vqmkwu"-cnwvtpk"rqxgkmq"tgk-mkpkwu."mckr"icnxqu"umcwu o cu."icnxqu"uxckik o cu."pwqxctiku"kt"x o k o cu0"Vck"icnk"vwt vk"vemqu"L u "igd lko wk"xcktwqvk"kt"xcnf {vk"o geje pk | o wu0

P [ZV J TCEKU uwf v {lg" {tc"uqtdkvqkq"*G642+0

Uqtdkvqkq" {tc"htwmvq| u"*vc o "vmtqu"t -kgu"ewmtcwu+"-cnvkpu0"Lgkiw"Lwou"*ct"L u "xckmwk+"vwtas igpgvkpku"uwvkmk o cu" ik o t o m vq| u"pgvqngtcxk o cu"* HP+."i { f {vqlcu"icnk"pwurt uvk."mcf"Lwou"*ct"L u "xckmwk+"-kq"xckuvq xctvqvk"pgicnk o c0"Rcekpv ."mwtkems {tc" HP. qticpk| o as pgicnk"uwumckf {vk"-kq"xckuvq"uwf v {lg"guvcg kqu"htwmvq| u"kt"vck"icnk"uwmgnvk"uwpm "pgreigkfcwlc o "rqxgkm 0
Prieš xctvqlcvq"šio xckuvq."vwtkg"rcuem {vk"i { f {vqlwk."Lgkiw"Lwou"*ct"L u "xckmwk+" {tc" HP"ctdc"L u "vaikas fewikew"pgicnk"xctvqvk"ucnfewu o ckuvq"ct"i tko "f n"evuktpfcv kq"r {mkpko q."x o k o q."ct"pg o cnqpcwu"rqxgkmq"*rkxq"r vk o q."umtcf flkq"fgink "ct"xkfwtkcxk o q+0

P [ZV J TCEKU uwf v {lg" {tc"pvtkq

Šio vaisto 6 o n"hnemqpg" {tc" o cflkw"kaip 1 mmol *45" o i+ natrio."v0 {0"lku"dgxgkm"pgvwtk"tgkm- o u0

3. Kaip P [ZV J TCEKU dwu"uwngkuvcu

P [ZV J TCEKU Lwou"uwngku"i { f {vqlcu"ctdc"uncwi {vqlcu0"L u "i { f {vqlcu"ctdc"uncwi {vqlcu"crumck kwqu"fq| "reicn"L u "*ctdc"L u "xckmq+"m pq"uxqt 0"

L u "i { f {vqlcu arba uncwi {vqlcu"retwq-"xckuv "kphw|klek0"
P [ZV J TCEKU vktrencu"rft ;2" o kpw k "dwu"uwnc-kpvu"Lwou" "xgp "*rertcuvck"nc-kpc o c" "tcpmqu"xgp +0"
Cvngkmpv" P [ZV J TCEKU kphw|kl "kt"pg" o cflkw"mckr"xncpf "rq"lqu"L u"d ukvg"uvgdk o cu *-c+0"
Prieš atliekant P [ZV J TCEKU."rcekpv o u"rertcuvck"fwqfc o c"xckuv "ukgmcpv"k-xgpi vk"cngt ikpk "tgcmekl "ctdc"lcu"uw o cflkpvk0

Lgkiw"mknv "fewikew"mncwuk o "f n"-kq"xckuvq"xctvqlk o q."mtgkrmkv u" "i { f {vql ."xckuvkpkp "ctdc"uncwi {vql 0

4. I cnk o cu"-cnwvtpku"rqxgkmku

"lku"xckuvcu."mckr"kt"xkuk"mkvk."icnk"uwmgnvk"-cnwvtp "rqxgkm ."pqtu"lku"rcuktgk-mkc"pg"xkug o u"fl o qp o u0

Pgfgnu f c o k"rcuem {mkvg"ucxq"i { f {vqlwk"ctdc"kphw|kl "Lwou"cvngkmp kc o "cu o gpkwk."Lgkiw"rcuvgd vw o vg"dgpv"xgpb "k-"-k "-cnwvtpkq"rqxgkmq"tgk-mkpk <

pkgfllko ."k-d tko ."fwuwn "ctdc"-xqm-vk-ovck"icnk"d vk"cngt ikp u"tgcmeklqu"*rcfkf lwukq"lcwvtw o q"tgcmeklc+0

Mkvcu P [ZVJ TCEKU -cnwvkpu rqxgkmu

Fcfpcu *icnk"rcuktgk-vk"tg kcw kaip 1 flo qiwk iš 32+<

- icnxqu"umcwu o cu.
- mquwn{u.
- umcwu o cu"kpwh|klqu"xkgvqlg.
- pkgfl lko cu."qfqu"kd tk o cu." umckvepv"pkgfl lko "uwmngkcpv "k-d tk o "k-mknckcu"urwqignckcu"
*fkni nkp +0

Pgfcfpcu *icnk"rcuktgk-vk"tg kcw kaip 1 flo qiwk" 322+<

- cngtikp u"tgcmeklqu.
- icnxqu"uxckik o cu.
- vkt rwn{u.
- cmk "lcwvtw o cu"-xkguck"*hqvqhdklc+.
- pg o cnqp u"rql kck"cwu{ug.
- igtmm u"uwfktikpk o cu.
- wflmk o k o cu.
- ukpwu "wfldwtmk o cu.
- fwuwn{u.
- n r "umcwu o cu.
- gi |g o c."rngkumcpqlcpvk"qfc.
- tcw o gp "vt m kqk o ck"kt"urc|ock.
- pwqxctiku.
- -cnvmt vku"*-cn kq"rql vku+.
- pg o cnqp u"rql kck"mt vkp u"utkv{lg."
- xkuq"m pq"umcwu o cu"kt"icn pk ."mt vkp u"utkvku"flcpfkmewnq."tcw o gp ."tck- k ."ucwu i {unk "ct"
mewn "umcwu o cu."
- rcvkpk o cu."umcwu o cu"kpwh|klqu"xkgvqlg"ctdc"mgdkvcu"*xgp "wflfgik o cu+0

Rtepg-k o cu"crkg"-cnwvkp "rqxgkmu

Jeiiw"rcuktgk-m "-cnwvkpu"rqxgkmu"*pgv"lgkiw"lku -kc o g"ncrgn{lg"pgpwtqf{vcu+. mtgkrmkv u" "i {f{vql ." xckuwpkpm "ctdc"ucwi i {vql 0"Crkg"-cnwvkp "rqxgkmu"vckr"rcv"icnkvg"rtepg-vk"vkugukikck"pewfqfco kguk"V priede pwtqf{vc"pcekqpenkpg"rtepg-k o g"ukuvgo c0"Rtepg-fc o k"crkg"-cnwvkp "rqxgkmu"icnkvg"owou"rcf vk" icwvk"fewi kcw"kpht o ceklqu"crkg"-kq"xckuq"ucwi w o 0

5. Mckr"nckm{vk" P [ZVJ TCEKU

Nckm{mkvg}- "xckuv "xckmco u"pgrcuvgdk o qlg"kt"pgrcuvgmko qlg"xkgvqlg0

Cpv" f flwv u"šVkpnc"mk0"kt"hnemqpp"gvkmgv u"rq"šGZRō"pwtqf{vc o "vkpmc o w o q"nckmwk"rcukdcki wu."-kq" xckuq"xctvqk"pgi cnk o c0"Xckuvcu"vkpmc o cu"xctvqk"mk"rcumwvkp u"pwtqf{vq"o pgukq"fkppqu0

Nckm{vk"-cnf{vwxg"*4 ÅE"-: ÅE+0"

Pgi cnk o c"wfl-cn f{vk0

Nckm{vk"ic o kpvqlq"rcmwqv lg."mcf"vaistas d v "crucwiqvcu"pwq"-xkguqu0

Mc o dotkq"vg o rgtcv tqlg"*42 ÅE"-47 ÅE+"kt"-cnf{vwxg"*4 ÅE"-: ÅE+"kpwh|kpkc o g" o ck-gn{lg"rtcumkguvas
vkt rncu"ejg o k-mck."hk|k-mck"kt" o kmtqdkqni k-mck"uvcdknwu"k-nkgmc": "xcncpf cu0

P [ZVJ TCEKU rtcumkgfwu"kpwh|kpkc o g"-xktm-vg."1 "tgkmc"pgfgnucpv"uwngkuvk"kt"lq"pgi cnk o c"nckm{vk0"
Pguwxtvqv vaisto fcn "tgkmc"k-rknvk0

80 Rcmwqv u"vwtkp{u"kt"mkvc"kpht o ceklc

P [ZVJTCEKU uwf vku"

- Xgkmnkqk" o gfflkc i c" {tc"qdknvqmucmuk o cdcu0"Kiekviename mililitre koncentrato yra 100 o i" qdknvqmucmuk o cdq0"Xkgpc o g"8 ml flakone yra 600 o i"qdknvqmucmuk o cdq0
- Re icndkp u" o gfflkc i qu" {tc"jkuvfkpcu."uqtdkvqku"G642+."rqnuqtdevcu":2"G655+."vandenilio chlorido t i-vku"G729+"kt"pcvtqj"j kftqmuk fcu"G746+0"Vckr"rcv"flt0"4"um{tk "šP [ZVJTCEKU uwf v{lg" {tc"uqtdkvqkqđ0

P [ZVJTCEKU k-xck|fc"kt"mkgmku"rcmwqv lg

P [ZVJTCEKU – vck"umckftwu"ctdc"qrcnguewqlcpvku."dgurcnxku."ignuxcu"ctdc"twuxck"ignuxcu mqpepvtevcu"vktrenwk0

P [ZVJTCEKU vkgmk o cu"rcmwqv ug"rq"3"hncmqp 0

Tgikvwtqvqlcu

UHN"Rjct o cegwkecnu" Fgwwuejncpf" I o d J

Octkg-Ewtkg-Uvtcuug":

9;75;"N%ttcej

Xqmkgvklc

I c o kpvqlcu"

Cegtvrjct o c"D0X0

Dquejuvtccv"73

6:33" I E."Breda

Qncpfklc

™ku"rcmwqv u"ncrgnu"rcumwvkp "mctv "rgtflk t vcu

™ku"xckuvcu"tgikvwtqvku" k-k o vkp o ku"u n{ i q o ku0"Vek"tgk-mkc."mcf" f n"nki qu"tgwv o q"kt"gvkpk "rtkgflcu k " icwvk"xkuqu"kpht o ceklqu"crkg"- "xckuvkp "rtgrotcv "pgdwxq" o cpq o c0 Gwtqrqu"xckuv "cigpv te"dgpv"mctv "rgt"ogwv"rgtflk t u"pcwl "kpht o cekl "crkg"- "xckuv "kt"rtktgkmwu" cvpcwlkpu"- "ncrgn 0

Mkvk"kpht o ceklqu"-civkpkck

K-uc o k"kpht o cekl"crkg"- "xckuv"rcvgmkc o c"Gwtqrqu"xckuv "cigpv tqu vkpmncncr{lg" [jvwr<11 y y 0 g o c 0 gwtqr c 0 gw0](#)"Lqlg"vckr"rcv"tcukvg"pwqtq fcu" "mkvwu"vkpmncncrkwu"crkg"tgvcu"nki cu"kt"l i { f { o 0

™ku"ncrgnu"rcvgmkc o cu"Gwtqrqu"xckuv "cigpv tqu"vkpmncncr{lg"xkuq o ku"GU1GGG"mcndq o ku0

Rcrknfq o c"kpht o cekl" [y y 0 qdknvqzck o cd-uhn0gw](#) dwu"pwtq f {vcu"ST"mq fcu0"

