

ANEKS I

CHARAKTERYSTYKA PRODUKTU LECZNICZEGO

Produkt leczniczy bez ważnego pozwolenia na dopuszczenie do obrotu

Pkpkglu|{"rtqfwmv"nge|pke|{"d f|kg"fqfcvmqyq"oqpkvtqycp{"W o q nkyk"vq"u|{dmkg"
|kfgpv{hkmqycpk"pqy {ej"kpht o cel"q"dg|rkgelg uv ykg0"Quqd{"pcng eg"fq"ncejqygiq"rgtuqpgnw"
ogf{e|pgiq"rqykpp{"i"fcu|c "yu|gnmkg"rqfgl|gycpg"f|kfcpc"pkgrq fcpg0"Cd{"fqykgf|kg "uk ".lcm"
|fcu|c "f|kfcpc"pkgrq fcpg"-rcvt|"rwpmv"60:0

1. NAZWA PRODUKTU LECZNICZEGO

P [ZV J TCEKU 322" o i l o n"mqpepvtcv"fq"urqt| f|cpkc"tq|vyqtw"fq"kphw|lk

2. UM/CF"LCMQ EKQY ["K"KNQ EKQY [

Jeden o n"mqpepvtcvw" |cykgtc"322" o i"qdknvqmucmu{ ocdw0"
Lgfpc"hkqmc"q"qdl vq ek"8" o n" |cykgtc"822" o i"qdknvqmucmu{ ocdw0

Qdknvqmucmu{ ocd"lguv"y {vyct|cp{"y" o {ukej"mq o »tmcej"u|rke|cmc" I U-PUZ" o gvqf "tgmq o d kpcelk"
FPC0

Uwduvpcel"rq o qepke|c"q"|pcp{ o "f|kfcpkw

3" o n"mqpepvtcvw" |cykgtc"58" o i"uqtdkvqnw0

Rgfp{"y {mc|"uwduvpcel"rq o qepke| {ej."rcvt|"rwpmv"8030

3. RQUVC "HCTOCEGWV [E \ PC

Mqpepvtcv"fq"urqt| f|cpkc"tq|vyqtw"fq"kphw|lk"mqpepvtcv"lcfqy {+0"
P [ZV J TCEKU o c"rquvc "rt|g|tqe|{uvgiq"nwd"qrcnk|wl eg iq."dg|dctypgiq."dnf q »»vgiq"nwd"
dnf qdt |qycyq »»vgiq"tq|vyqtw."mv»t{"o q g|cykgtc "pkgykgm "nke|d "rt|g|tqe|{uv{ej"nwd"dkc{ej"
e| uvgm"dkcmqy {ej"qfhkvtqy {ycp{ej"y"vtcmekg"rqfycpkc+."q"r J"y {pqu| e{ o 7.7"qtc|
qu o qncpq ek"y {pqu| egl"499-52: o Quolmi0

4. U \ E \ G I ~ / Q Y G " F C P G " M N K P K E \ P G

4.1 Wskazania do stosowania

P [ZV J TCEKU lguv"yumc|cp{"fq"uvquycpkc"y"umqlct|gpkw|"qfrqykgfpkok"ngmco k"
rt|gek y dcmvgt{lp{ok"yg"yu|{uvmkej"i twrcej"ykgm qy {ej"y"nge|gpkw"y inkmc"y |kgypgiq"y {yqfepgiq"
rt|g|"dcmvgtk "*Bacillus anthracis* *rcvt|"rwpmv"703+0

P [ZV J TCEKU lguv"yumc|cp{"fq"uvquycpkc"y"yg"yu|{uvmkej"i twrcej"ykgm qy {ej"y"tc ocej"
rtqhkncmv{mk"rqgmurq|{e{lpgl"y inkmc"y |kgypgiq."mkgf{"kppg"o gvqf{"nge|gpkc"u "pkgqfrqykgfpgk"nwd"
pkgfqv rpg"rcvt|"rwpmv"703+0

4.2 Dawkowanie i sposób podawania

P [ZV J TCEKU pcng {"rqfycy "qf"tc|w"rq"rqlykgpkw"uk "yumc|c "mnpke|p{ej0

Qfrqykgfpg"leczenie k"pcf|»t"ogf{e|p{"rqykpp{"|cyu|g"d{ "fqv rpg"pc"y {rcfgm"y {uv rkgpkc"
tgemel"cpchkmv{e|pgl"rq"rqfcpkw"rtqfwmv"nge|pke|giq"P [ZV J TCEKU0

Fcymqycpkg

\cngcepg"fcymqycpkg"rtqfwmvw"nge|pke|giq"P [ZVJTCEKU w"fqtuqf{ej"rcelgpv»y"q"o cukg"ekcfc"eq"
 pcl o pkgl"62"mi"vq"rqlgf{pe|c kphw|lc fq {npc 38 o ilmi"o cu{"ekcfc"* o e0+0" \cngcepg"fcymqycpkg"
 rtqfwmvw"nge|pke|giq"P [ZVJTCEKU u dorouf{ej"rcelgpv»y"q"o cukg"ekcfc"rqpk gl"62"mi"vq"
 pojedynczc kphw|lc fq {npc 46 o ilmi o e0"

Rt|gf"rqfcpkg o"rtqfwmvw"nge|pke|giq"P [ZVJTCEKU |cngce"uk "rtgogf{mcel "ngmkg o"
 rt|geky jkuvc o kppy {o"*rcvt|"rwpmv{"606"k"60: +0"

Urqu»d"o qf{hkmcelk"fcymk"y"rt|{rcfmw"tgcmelek"|yk |cp{ej|"kphw|l ."rcvt|"vcdgnc"30

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Nasilenie tgcmelek"	Oqf{hkmcelk"fcymk
Tgcmelek" yk cpg" "kphw l uvqrpkc"3-5	Pcng {"rt gtyc "kphw l qdknvqmucmu{ ocdw" "cuvquqyc leczenie yurqocicl eg0 Rt {"rkgtyu {o"y{uv rkgpkw" yku e egig"qffgejw"umwte w"qumt gnk"nwd" wqi»npkqpgl"rqmt {ymk"uvqrpkc"50 pcng {"pc"uvefg"qfuvc yk "qdknvqmucmu{ ocd0 Y"rt {rcfmw"pcytqvw" yku e egig"qffgejw"nwd"rqmt {ymk"uvqrpkc"40 d f " pcytqvw"lcmkejmqnykgm"qdlcy»y"uvqrpkc"50 pcng {"pc"uvefg"qfuvc yk " qdknvqmucmu{ ocd0" Y"rq quvcf{ej"rt {rcfmcej"rq"ecfmqy"y"o"uwv rkgpkw"qdlcy»y"kphw l oq pc" y pqyk "u {dmq ek "q"50% o pkglu pk "rt gf"lej rt gtycpkg o 0" Y" rt {rcfmw"dcmw"qdlcy»y yk cp{ej "kphw l u {dmq "infuzji qrkucpq"y" vcdgnc"50" Pcng {" cuvquqyc "rtgogf{mcel 0
Tgcmelek" yk cpg" "kphw l "uvqrpkc"60	Pcng {"pcv{ej okcuv"rt gtyc "kphw l qdknvqmucmu{ ocdw0 Pcng {" cuvquqyc nge gpk"yurqocicl eg0 Pcng {"pc"uvefg"qfuvc yk "qdknvqmucmu{ ocd0"

Urgelcnpq"i twr {"rcelgpv»y

Quqd|"y"rqfgu/€{o"ykgmw

W"rcelgpv»y"y"ykgmw"×87"ncv"fquvquqycpkg fcymk"pkg"lguv"mqpkge|pe *rcvt|"rwpmv"704+0

F/kgek"koefq/kg

\cngcepc"fcymc"w"fkgek"koefq/kg {"cng {"qf"o cu{"ekcfc."lcm"rqmc|cpq"y"vcdgnc"4"rqpk gl0

Vcdgnc"40" \cngcepc"fcymc"qdknvqmucmu{ ocdw"wf|kgek"koefq/kg {"*fcyma y"|cng pq ek qf"o cu{"ekcfc+

O cuc"ekcfc"jmi_	Fcymc"j o ilmi"o e0_
@"62	38
@37"fq"62	46
37"nwd"o pkgl	54

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Pkg"pcng {"rqvt| uc "hkqnm 0"Rt|gf"rqfcpkg o"infuzji fq {npjg qdknvmucmu{ ocd"pcng {"tq|ekg e|{ "y" tq|vyqt|g"ejnqtmw"uqfw"fq"yuvt|{mky c "quv gpkw"; o i l o n"2.; ' +"*rcvt|"rwpmv"808+0"

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Rt|g|"ecf{"e|cu"vt ycpkc"infuzji k"rt|g|"eq"pcl o pkl"iqf|kp "rq"lgiq"|cmq e|gpkw"rcelgpv»y"pcng {" wyc pkg"o qpkvqtqyc y"egnw"y {mt{ekc rt|gf okqvqy {ej"krqf okqvqy {ej"qdlcy»y"pcf ytc nk y q ek" *rcvt|"rwpmv"606+0"Y"rt|{rcfmw"tgcme|k"yk|cp{ej|"kphw|l pcng {"rquv rquc "lqfpgk"}" y {v{e|p{ok|cyctv{ok"y"vcdgnk"30"

Rq|"cmq e|gpkw"infuzji fq {npjg |guvcy"kphw|{lp{"pcng {"rt|grfwmc "tq|vyqtg o"ejnqtmw"uqfw"fq" yuvt|{mky c "quv gpkw"; o i l o n"2.; '+0"

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>40 mi"nwd"fq tq nk"38 o ilmi"o e0+		
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>15 mi"fq"62 mi"46 o ilmi"o e0+		
53"fq"62	472	389
38"fq"52	100	89
15 mi"nwd"o pkl"54 o ilmi"o e0+		
11 do 15	100	89
5 do 10	50	55.5
5.3"fq"6.;	47	39
4.3"fq"5	42	35.5
3.3"fq"4	15	10
3"nwd"o pkl	9	6.9

, "kpuvtwme|c"fqv{e| ec"tq|ekg e|cpkc"rtqfwmw"nge|pke|g iq"qtc|"w {ekc"yqtmc"kphw|{lpgiq"nwd" uvt|{mcy mk"fq"kphw|lk"rt|gf"rqfcpkg o."rcvt|"rwpmv 8080"

4.3 Rt|geky yumc|cpkc

Pcf ytc nk y q "pc"uwduvcpel "e|{pp "nwd"pc"mv»t mqn y k gm"uwduvcpel "rq o qepke| "y {o kgpkqp "y" rwpmekg"8030"

4.4 Urgelcnpq"quvt|g gpkc"k" tqfmk"quvtq pq ek"fqv{e| eg"uvquqy cpkc

Kf g p v { h k m q y c n p q

W celu rqtfc y k g p k c "k f g p v { h k m q y c n p q ek"dknq i ke|p{ej"rtqfwmw»y"nge|pke|{ej"pcng {"e|{vgnpkg" |crkuc"pc|y "k"pw o gt"ugtkk"rqfcycpgiq"rtqfwmw0"

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infuzje |cucfpke|q"oq pc"y»ye|cu"wmq e|{ .lg ni yftq {"uk "qfrqykgfpg"rquv rquycpk0"Y"
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|crqdkgic"cpchknemulk"oq g"ocumqyc "nwd"qr» pkc "y{uv rkgpkq qdlcy»y"pcf ytc nk yq ek0

Y inkmqyg"|"crcngpkq"qrqp"o»|iqyq-tf|gpkqy{ej

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F|kgek"|"ofqf|kg

Pkg"rt|grtqycf|qpg"dcfc "fqv{e| e{ej"dg|rkge|g uvyc"cpk"htc ocmqmkpgv{mk"qdknvqmucmu{ ocdw"w"
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Y r{y"pc"y{pkmk"dcfc "ncdqtcvqt|lp{ej

Gmurq|{elc"pc"rtqfwmv"nge|pke|{"NYXTHTCEKU oq g"y r{y"pc"y{pkmk"dcfc "ugtqnqike|p{ej"pc"
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Uqtdkvqn

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rcelgpvqo"|"f|kgf|ke|p "pkgvqngtcpel "htwmvq|{"0"Pkgo"pcng {"uvquyc "qdknvqmucmu{ ocdw"w"rcelgpv»y"|" "
f|kgf|ke|p "pkgvqngtcpel "htwmvq|{."e|{dc" g"lguv"vq"dg|y|in fpkgo"mqpkge|pg"|"mnkpk|pgiq"rwpmvw"
ykf|gpkc"|"pkgo"o"cpk"y"oq nk yq ek0"Rt|gf"|"cuvquycpkgo"vgiq"rtqfwmv"nge|pke|giq"w"rcelgpv»y"|" "
qdlcyco"|"f|kgf|ke|pgl"pkgvqngtcpel"htwmvq|{"pcng {"rt|grtqycf|k "u|e|gi»eqy{"y{ykcfo

Pkgoqyn vc"ko"cfg"dzieci *y"ykgmw"rpkp gl"4 ncv+u "u|e|gi»npg"pctc qpg."rqpkgy c "dziedziczn
pkgvqngtcpelc fruktozy oq g"pkgo"dc {"lgu|e|g"wpkej"tq|rq|pcpc0"

U»f

Vgp"ngm"|"cykgtc"o"pkgl"pk "3"o oqn"uqfw"45"o i+"pc"lgfp "hkqnm "q"qdl vq ek 8"on."vq"|"pce|{"ngm"w"pclg"
uk "c"š yqnp{"qf"uqfw0

4.5 Kpvgtcmelg"|"kpp{ok"rtqfwmvcok"nge|pke|{ok"|"kppg"tqf|clg"kpvgtcmelk

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38 o ilmi oeo y"infuzji fq {npej rt|gf"rqfcpko"e|rtqhnqmuce{p{"y"infuzji fq {npej lub przed
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e|rtqhnqmuce{p{"rqfycppl"fqwvupkg"nwd"fq {npgk0

Pkg"rt|grtqycf|ppq" cfp{ej"kp{ej"dcfc "fqv{e| e{ej"kpvgtcme{k0"Rqpkgy c qdknvqumucmu{ o cd"lguv"
rt|gek yekfcg o " o qppqmmqpcnp{ o . "t{ | {mq"kpvgtcme{k"lguv" o cfcg0

608 Y r{y"pc"r{qfpq .ek "k"ncmvcel

Ek c

Nie oc fcp{ej fqv{e| e{ej uvquycpkc"qdknvqumucmu{ o cdw"w"mqdkgv y"ek {."ykefcq o q"lqfpcm." g
nwf|mc"Ki I"rt|gpkmc"rt|g|"dctkgt "fc {umqy 0
Dcfcpc"pc"|ykt| vcej"pkg"y {mc|cfc| dg|r q tgfpgiq"cpk"rq tgfpgiq"u|mqfnygiq"y r{y"pc
reprodukcł *rcvt|"rwpmv"705+0
Y"egnw"|cejqycpkc quvtq pq ek"|cngec"uk "wpkmcpkg"uvquycpkc"rtqfwmvw"nge|pke|giq"P [ZVJ TCEKU
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Mct okgpkc"rkgtuk

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fq" o ngmc"nwf|mkgiq"y"rkgt yu| {ej"fpkcej"rq"rqqtqf|kg."c"ymt>>veg"rqvg o "lgl"uv gpkg"uk "| o pkglu|c0"
W|yk |mw|"v{ o "pkg"o q pc"y {mnwe| { "t{ | {mc"fn"pkg o q yn v"mct okqp{ej"rkgtuk "y"v{ o "mt>>vmko"
qmtguk0"Rq"v{ o "e|cukg"o q pc"tq|yc { " |cuquycpkc"qdknvqumucmu{ o cdw"y"vtcmekg"mct okgpkc rkgtuk ."
cng"v{nmq"y"rt| {rcfmcj"v|cucfpkqp{ej"mnpke|pkg0

R{qfpq

Pkg"rt|grtqycf|ppq"dcfc "qdknvqumucmu{ o cdw"fqv{e| e{ej"r{qfpq ek0

4.7 Y r{y"pc"|fqpq "rtqycf|gpkc"rqle|f>y"qdufwiky cpk"o cu|{p

Qdknvqumucmu{ o cd"o q g"y {ykgte "pkgyknmk"y r{y"pc"|fqpq "rtqycf|gpkc"rqle|f>y"qdufwiky cpk"
o cu|{p."rqpky c "rq"rqfcpkw"rtqfwmvw"nge|pke|giq"P [ZVJ TCEKU oqi "y{uv rk "d>n"ifqy {."
|cytqv{"ifqy {."| o e|gpkg"ky {okqv{"*rcvt|"rwpmv"60:+0

4.8 F|kfcpc"pkgrq fcpq

Rqfuwoqycpkc"rtqhkndg|rkge|g uvyc

Dg|rkge|g uvyc"uvquycpkc"qdknvqumucmu{ o cdw"dcfcpq"lqf{pkg"v"|ftqy {ej"qu>d"fqqtq{ej0

Dg|rkge|g uvyc"uvquycpkc"qdknvqumucmu{ o cdw"qegpkcpq"v"542"|ftqy {ej"we|gvpkm>y"*y"ykgmw"qf"3:"
fq"9;"ncv+."mv>t{ o "rqfcy cpq"lqf "nwd"fykg"fcymk"fq {npg"38 o ilmi o e0 y"tcocej"vt|gej"dcfc "
mnpke|p{ej0

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38 o ilmi o e0 F|kfcpc"pkgrq fcpq"yk |cpq|"pcfytc nkyq ek "y"v{ o "y {u{rnc+y {uv rk{ "w"; " "
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pcfytc nkyq ek"nwd"cpchknemulky"p|1 rt|gtycpq"v"5' " : 1472+"qu>d0

Pcle| ekgl"ifcu|cp{ok" f|kfcpc ok"pkgrq fcp{ok"d{f{"d>n"ifqy {"*6' .";1472+." yk f"*6' .";1472+"k"
rqmt { ymc"*4' .".8|472+0

Pcle| ekgl"qdugtyqycp{ok" f|kfcpc ok"pkgrq fcp{ok"y"ek iw"rkgt yu| {ej"5"iqf|kp"qf"tq|rqe| ek"
infuzji d{f{<" yk f"*p?9."4.: ' +."rqmt| { ymc"*p?8."4.6' +."d>n"ifqy {"*p?6."3.8' +."y {u{rnc"*p?5."
3.4' +."mculgn"*p?5."3.4' +. |cytqv{"ifqy {"*p?5."3.4' = "y"v{ o "|cytqv{"ifqy { "rqfe|cu" |okcp{"rq| {elk"
ekfc+0

Y"ek iw"rkgt yu| {ej"5"iqf|kp"po infuzji qdugtyqycpq"pcuv rwl eg"ek mkg" f|kfcpc"pkgrq fcpq"
rqmt| { ymc"*p?3."2.6' +." yk f"*p?3."2.6' + "k" d>n"rnge>y"*p?3."2.6' +0

Pcle| uvu| {o" f|kcfcpkc"o"pkgrq fcp{ o"qdugt yqycp{ o"y"e|cukg"qf"5"fq"46"iqf|kp"qf"tq|rqe| ekc" infuzji d{"d»n"i"eqy {"*p?5."3.4 ' +0

Vcdgnct{e|p{y|mc|f|kcfc "pkgrq fcp{ej

Vcdgnc"6"|cykgtc" f|kcfcpkc"pkgrq fcp{gdqkqvqumucmu{ ocdw"qdugt yqycpg"w"472"|ftqy {ej"qu»d."mv»t{" qvt| {o cnk"fq {npkg"qdqkqvqumucmu{ ocd"y"pojedynczej fcyce 38 o ilmi o e0."wu|gtgi yqycpg"ygfwi" mncu{hkmccl"wmfcf»y" k"pct| f»y"qtc|"ygfwi"e| uvq ek"y {uv rqcpcpkc0

E| uvq "y {uv rqcpcpkc" f|kcfc "pkgrq fcp{ej"zdefiniy qycp qcuw rwl eq" dctf|q"e| uvq"*x3132+." e| uvq"*x31322"fq">3132+"k"pkgd|d{v"e| uvq"*x313"222"fq">31322+0"Y"qdt dkg"mc fgl"itwr {"q"fcpgl" e| uvq ek"y {uv rqcpcpkc" f|kcfcpkc"pkgrq fcp{u "y {okgpkqpg" |iqfpgk" |g" |opkglu|cl e| o"uk pcukngpkgo0

Vcdgnc"60" F|kcfcpkc"pkgrq fcp{gdqkqvqumucmu{ ocdw"qdugt yqycpg"w" |ftqy {ej"fqqtuf{ej"ostf

Mncu{hkmccl"wmfcf»y" k"pct f»y" OgfFTC	E uvq"	Pkg d{v"e uvq"
\cdwt gpkc"wmfcf" w" k o wpqniqike pgiq		Tgcmele"cpchknemv{e pc" Pcfytc nkyq
\cdwt gpkc"wmfcf" w" pgt yqygiq	D»n"i"eqy {	\cytqv{"i"eqy { Zcytqv{"i"eqy { rqfe cu" okcp{" rq {elk"ekfc Pkgfqc wnec
\cdwt gpkc"qmc		ykcvcqyuvt v
\cdwt gpkc"wejc" k"d" fpkmc		We wekg"f {umq o hqtvw"y" uszcej
\cdwt gpkc"pce {pkqyg		\crgngpk" {f
\cdwt gpkc"wmfcf" w" qffgej yqygiq." mncvmk" rkgtuky gl k" t»frkgtukc	Mcu gn	Rqftc pkgpk"ictfc" Ejt{ rmc" Pkgftq pq " cvqm" Fwu pq ek
\cdwt gpkc" q" fmc" k" lgnkv		D»n"ycti
\cdwt gpkc"um»t {"k" vmcpmk" r qfum»tpgl	y k f."rqmt { ymc. y u{ rmc	Cngtike pg" crgngpk"um»t {" Y {u{ rmc" wqi»npkqpc" /wu e gpk"uk "um»t {"
\cdwt gpkc"ok" pkqyq-u mkgngvqyg i vmcpmk" f e pgl		D»n"mq e {p" Mwte g"ok pk" Dr gpk ok pk" D»n"u e mk"
\cdwt gpkc"qi»npg" k uvcp{ "y" okgluew" r qfcpk	D»n"y" okgluew" r qfcpk" infuzji	D»n" We wekg"f {umq o hqtvw"y" mncveg" rkgtuky gl" Dreszcze \ o e gpk" Qdt m"y" okgluew" r qfcpk" infuzji Rq cugteqy {"d»n"y" mncveg" rkgtuky gl" Vmnyq " D»n"y" okgluew" pcmfwec" {f{

Orku"y {dtepc{ej" f|kcfc "pkgrq fcp{ej

Pcfytc nkyq "k"cpchknemulc

Do d|kcfc pkgrq fcp{ej |iequ|qp{ej w": "qu»d."w"mv»t{ej" kphw|l qdqnvmucmu{ ocdw"rt|gtycpg"ze y|in fw pc"rqfglt|gpk"pcfytc nkyq ek."pcng cef{<"rqmt| { ymc."y {u{ rmc."mku|gn." yk f." |cytqv{" i"eqy {"r qftc pkgpk"ictfc."ejt{ rmc."fwu|pq k" f {umq o hqtvw"y" mncveg" rkgtuky gl" W" r q|quvcf{ej" qu»d |" pcfytc nkyq ek "y {uv rkef{ rt|gyc pkg"qdley {"um»tpg."vemkg"lcm" yk f" k"y {u{ rmc."c"8"qu»d |iequk"eq" mku|gn"0" Tgcmele"cpchknemv{e|pc"rt|gdkgicfc" |"tq|ncp .uy f| e "y {u{ rm "rqmt| {ymqy "pc"yk mu|q ek"

rkykgt|ejpk"ekfc."y"v{o"pc"u|{k."mncveg"rktukqygl."rnceej."dt|wejw"mq e|{pcej."c"vcm g"}"
fwu|pq ekc o k"m"m"cu|ng o 0

Pkg"uvykgft|ppq."cd{"tgemelg"pcf ytc nkyq ek"y"y{u{rmk"d{f{"y"yqf{ycpg"rt|g|"wyqnpkpgpkge{vqmkp-
pkg"}|cqdugt yqycpq" cfp{ej"kuvqvp{ej"mnpkpe|pkg"}|okcp"uv gpkc"cytokin0

K o owpqi gppq

Yu|{uvmkej"we|guvpmk»y."mv»t|{"qvt|{o cnk"rqlgf{pe|g"rk"rqfy»lpg"fcymk"qdknvmucmu{o cdw"y"v|gej"
dcfcpkcej"mnpkpe|p{ej."dcfcpg"rqf"m vgo"rqlykpkc"uk "rt|gekyekc"rt|gekymq"qdknvmucmu{o cdqyk0"
W": "qu»d"*4.7 " " :1542++."mv»tg"qvt|{ocf{"eq"pcl"opkgl"lfgp"fcym"fq {np"qdknvmucmu{o cdw."fqu|f"q"
y"vtcmekg"nge|gpkc"fq"y"y{mu|vcfegpkc"rt|gekyekc"rt|gekymq"rtqfwmvqyk"nge|pke|gow"*cpi0"cpk-
vjgtergwke"cpvkdqf{"CVC+0"Okpc"knq ekqyg"d{f{"pkumkg."y"|cmtgukg qf"3<42"fq"3<5420"pkg"y{mc|cpq"
|okcp"htc o cmqmkpgv"mk"cpk"rtqhkwn"vqmu{e|pq ek"w"qu»d |"CVC0

\i fcu|cpkg"rqfgl|gycp{ej" f|kfc "pkgrq fcp{ej

Rq"fqrwu|e|gpkw"rtqfwmv"nge|pke|giq"fq"qdtqvw"kuvqvp"lguv"|i fcu|cpkg"rqfgl|gycp{ej" f|kfc "
niepo fcp{ej0"woq nkyk"vq"pkgrt|gt ycpq"o qpkvqtqycpk"uvquwpmw"mqt|y"ek"fq"t|{mc"uvquycpk"
rtqfwmv"nge|pke|giq0"Quqd{"pcng eg"fq"hejyqygiq"rgtuappnw"ogf{e|pgiq"rqykpp{"|i fcu|c "
yu|gnmkg"rqfgl|gycp" f|kfcpkc"pkgrq fcpq"|"c"rq tgfpkv ygo"mtelqygiq"u{uvgo"|"i fcu|cpk"
y|okgpkqpgiq"y" |cf e|pkmw"X0

4.9 Rt|gfeymqycpk

Y"rt|{rcfmw"rt|gfeymqycpk"pcng {"o qpkvqtqyc "rcelgp»y"rqf"m vgo"rqfokqvqy{ej" k"
rt|gfokqvqy{ej"qdlcy»y" f|kfc "pkgrq fcp{ej0

5. Y / C EKYQ EK"HCTOCMQNQIKE \ PG

5.1 Yfc ekq ek"htc o cmqf{pc o ke|pg

I twrc"htc o cmqvgtergw{e|pc<"uwtqykeg"qf"rtpq ekqyg" k"ko o wpqinqdwnk{"."ko o wpqinqdwnk{"
urge{hke|pg."mqf" CVE<"L28DD44

Ogejcpk|o" f|kfcpkc

Qdknvmucmu{o cd"lguv"rt|gekyekc"fg o" o qpmnqpcnp{o."mv»tg"yk g"cpv{igp"qejtapp{"*RC+"dcmvgtkk"
B. anthracis0"Qdknvmucmu{o cd"jc o wlg"yk |cpkg"RC"fq"lgiq"tgegrvqt»y"mq o »tmqy{ej."f|k mk"e|go"w"
|crqdkgie"rt|gpkmpk ekw"fq"mq o »tmk"e|{ppkmc"ngvcnpgiq"e|{ppkmc"qdt| mw"- gp|{ocv{e|p{ej"
umfcfpm»y"vqmu{p{"y"y{v yct|cpgl"rt|g|"ncuge|m "y inkmc"qf r qykgf|kcp{ej"|"c|gl"rcvqigppg"
f|kfcpk0

F|kfcpk"htc o cmqf{pc o ke|pg

Qdknvmucmu{o cd"yk g"yqnp{"RC"|"rqykpqycevygo"qf r qykfcfcl e{o"t»yppyciqygl"uvfcgl"
f{uqelcelk" *Mf+"y{pqu| egl"2.55 pO0

Y"yctwpccej" in vitro qdknvmucmu{o cd"yk g"uk " |"RC"u|e|gr»y"Co gu."Xqnnw o" k"Uvgtpg" dcmvgtkk"
B. anthracis0"Grkvqr"e| uvge|mk"RC."fq"mv»tgiq"rt|f e|c"uk "qdknvmucmu{o cd."pkg"y{mc|wlg"
|o"lppq ek"y" |pcp{ej"u|e|grcej B. anthracis0

Dcfpkc" in vitro y" o qfgnw"mq o »tmqy{ o"|"y{mqt|{uvcpkgo" o {ukej" o cmtqhci»y"uwigtwl ." g"
qdknvmucmu{o cd"pgwvtnk|wlg"vqmu{e|pg" f|kfcpk"vqmu{p{"ngvcnpgl"- rqf e|gpkc"RC" k"e|{ppkmc"
ngvcnpgiq0

Dcfpkc"umwve|pq ek" in vivo pc"mt»nkcej"tcu{"dkfcgl"pqyq|gnepf|mkg l"*cpi0" Pgy" \ gncpf" Y jkgv.
P \ Y+"k" o cmccej"lcyclumcej" |cmc qp{ej"ftqi "y|kgyp "rt|gvt ycnpkmc o k" B. anthracis u|e|grw"Co gu"

y {mc|cē{"|cng pe qf"fc ymk"| yk mu|gpkg rt|g { ycnpq ek"rq"nge|gpkw"qdknvqmucmu{ ocdgo"0"Gmurq|{elc"
pc"rt|gvt ycnpkmk"B. anthracis rgyqfqcēc"| yk mu|gpkg uv gpkc RC"y"uwtq yke{"mt»nkm»y"tcu{"NZW i
o cmcm»y"lcy clumkej"0"Rq"leczeniu qdknvqmucmu{ ocdgo uv gpkg"RC"| o pklglu|cēq"uk w"yk mu|q ek"
| ykgt| v."mv»tg"rt|g {ē{"0"Uv gpkg"RC"w"| ykgt| v"qvt|{ owl e{ej rncegdo | yk mu|cēq"uk c "fq"kej"
okgtek0

Umwvge|pq "

\ "wycik"pc"pkg y {mqpcnpq "k"pkggv{e|pq "rt|grtqycf|gpkc"mqpvtnqycp{ej"dcfc "mnpke|p{ej}pcf"
y inkmk o"y |kgyp{o"|"wf|kcēg o"nwf|k"qegpc"umwvge|pq ek"qdknvqmucmu{ ocdw"rqfycpgiq"y"
o qpqvgtcrkk"y"rqt»y pcpkw"| rncegdq"y"nge|gpkw"y inkmc"y |kgypgiq"qrkgtc"uk "pc"dcfcpkc"ej"
umwvge|pq ek"rtqycf|qp{ej"pc"mt»nkmcej"tcu{"P \ Y"k"o cmcmcej"lcy clumkej"0"

Rqfe|cu"v{ej"dcfc " | ykgt| vc"|cmc cpq"cgq|qng o"|"rt|gvt ycnpkmc ok"B. anthracis"u|e|gr"Co gu+"y"
fcyeg"qmqēq"422zNF50."c"pcuv rpkq rqcycp"ko"qdknvqmucmu{ ocd"y"t» p{ej"rwpmncej"e|cuqy {ej"
Y"dcfcpkc"ej"fqv{e| e{ej leczenie y inkmc"y |kgypgiq| ykgt| vqo"rqfycp"nge|gpkg"rq"
y {uv rkgpkw mnpke|p{ej"rqf o kqvqy {ej"nwd"rt|gf o kqvqy {ej"qdlcy»y"|cmc gpkc"qi»npqwuvtlqygiq"
Y"dcfcpkc"ej"rtqhkncmv{mk"rqgmurq|{e{lpgl" | ykgt| vc"nge|qpq"rq"gmurq|{elk"pc"B. anthracis."cng"rt|gf"
y {uv rkgpkgo qdlcy»y"0"Ocmcmq o"lcy clumk o"rqfycp"nge|gpkg"y"o qogpek"gw|{umcpkc"
rq|{v{ypgiq"y {pkmw"dcfcpkc"ngmvtqej go knw o kpguegpe{lpgiq"GEN+uwtq yke{"pc"qdgepq RC"B.
anthracis." tgfpkq"qmqēq"62"iqf|kp"qf"|cmc gpkc"B. anthracis"0"Y"dcfcpkc"ej"pc"mt»nkmcej"tcu{"NZW
| ykgt| vqo"rqfycp"nge|gpkg"rq"w|{umcpkw"rq|{v{ypgiq"y {pkmw"dcfcpkc"GEN"pc"qdgepq "RC"nwd"
y"rt|{rcfmw"vwt|{owl eg iq"uk "rqfy { u|gpkc"vgo rgtcvwt{"ekcfc"rqy { gl"yctvq ek"y {l ekqygl."
tgfpkq"qmqēq"52"iqf|kp"qf"|cmc gpkc"0"Rt|g {ekg"qegpkcpq"rq"4:"fpkcej"qf"|cmc gpkc"B. anthracis y"
dcfcpkc"ej"rt|gfuvykpq{ej"rpk gl0

Umwvge|pq "rqlgf|pe|gl"fc ymk"fq {npgl"qdknvqmucmu{ ocdw"y"o qpqvgtcrkk"y"nge|gpkw"y inkmc"
y |kgypgiq"qegpkcpq"y"lgfp{o"dcfcpkw"pc"mt»nkmcej"tcu{"P \ Y"k"vt|gej"dcfcpkc"ej"pc"o cmcmcej"
lcy clumkej"*CR424."CR426"k"CR523+0" Yu|{ uvmkg"v"dcfcpkc"d{ē{"tcpfqok|qyepg."mqpvtnqycpg"
rncegdq"k" | iqfpg"|"|cucfc ok"FRN0"dcfcpkc"CT255."CR424"qtc|CR523"rtqycf|qpq"y"yctwpmcej"
ngrgl"rt»d{."c"dcfcpkg"CR426"- |"c ngrkpkgo"y|in fgo"itwr{0"

Produkt leczniczy bez wałnego opakowania

Vcdgnc"70" Yumc pkmk"rt|g {ekc"y"dcfcpkcej"umwvge|pq ek"qdknvqmucmu{ o cdw"y"o qpqvgtcrkk"
 *38 o ilmi o e0+

Qfugvym"rt g {ekc"pc"mqpkge"dcfcpkc * ' "] {y{ejlp_+		Yctvq "r ² ;7 ' "EK ³	
Rncegdq	Qdknvqmucmu{ o cd" 38 o ilmi o e0		
Nge gpkg"– mt»nkmk"tcu{"NZW			
Dcfcpkg"CT255 ¹	2"*2135+	83.7 ' "":135+	2.2235, *2.4.2."2.:83+
Nge gpkg"– o cmcmk"lcy clumkg			
Dcfcpkg"CR426 ¹	8 ' "*3138+	68.9 ' "":9137+	2.228:, *2.2.:;."2.8:3+
Dcfcpkg"CR424 ¹	2"*2139+	53.5 ' "":7138+	2.22:7, *2.29;."2.7:9+"
Rtqhkncmv{mc"rqgmurq {e{lpc"– o cmcmk"lcy clumkg			
Dcfcpkg" CR523 ⁶	3:"j po ekspozycji	2"*218+	322 ' "":818+
	46"j po ekspozycji	--	:5 ' "":718+
	58"j po ekspozycji	--	72 ' "":518+
			2.2234, *2.693."3.222+
			2.2264, *2.452."2.;;8+
			2.2567 *-2.259."2.:;4+

EK<"rt|gf|kc"whpq ek

¹ Rt|g {ekg"qegpkcpq"4:"fpk"rq"|cmc gpkw"rt|gvt ycnpkmc ok="rt|gf"nge|gpkgo"w"yu|{uvmkej"
 |tcpfqok|qycp{ej"}|ykg| v"uvykgf|qpq"dcmvgtk ok="nge|gpkgtq|rqe|{pcpq"rq|pce| e{o"y|tq ekg"
 vg o rgtcvwt{"ekcfc"*dcfcpkg"CT255+"nwd"rq"|"w|{umcpkw"rq|{v{ypgiq"y{pkmw"dcfcpkc"

gngmvtqejg oknw okpuguege{lpqi"pc"qdgepq "apw{i"gpw"qejtppgiq"*dcfcpkc"CR426"CR424+0

⁴ Yctvq "r"pc"rqfuvcykg"lfpquvtppgiq"vguw"Duejnnq"*|o qf{hkmcel "y i"Dgtigtc-Dqque"rt|{"
 yumc pkmw"ico oc"?2.223+"y"rt»ypcpkw"rncegdq0

⁵ Fqmfcfp{"rt|gf|kc"whpq ek";7 ' "fnc"t» pke{"yg"yumc pkmcej"rt|g {ekc0

⁶ Rt|g {ekg"qegpkcpq"4:"fpk"rq"|cmc gpkw"rt|gvt ycnpkmc ok0"

*Q|pce|c"kuvqypq "uvcv{uv{e|p "pc"rq|kq okg"2.2470

F|kgek"ko eqf|kg

Gwtqrglumc"Cigpelc"Ngm»y"y uvt|{ o cfc"qdqyk |gm"fqe e|cpkc"y{pkm»y"dcfc "rtqfwmvw"nge|pke|giq"

P [ZVJTCEKU y"lfgpl"nwd"mknmw"rqf itwrciej"rqrwncelk" f|kgek"ko eqf|kg {"y"nge|gpkw"|cmc g "
 ncuge|mc ok"y inkmc"uvquycpkw"wf|kgek"ko eqf|kg {"rcvt|"rwpmw"604+0

Vgp"rtqfwmvw"nge|pke|{"|quvcf"fqrwu|e|qp{"fq"qdtqw"|"i qfpkg"|"rtqegfwt "fqrwu|e|gpkc"y"
 y{1 vmqy{ej"qmknke|pq ekcej0"Q|pce|c"vq." g|g"y|in fw"pc"t|cfmkgy{uv rquycpkgejqtqd{"k"|" "
 rqyqf»y"gy{e|p{ej"pkg"d{eq"o q nk y g"|"w|{umcpkg"rgfpl"khqt o celk"fqv{e| egl"vgiq"rtqfwmvw"
 nge|pke|giq0

Gwtqrglumc"Cigpelc"Ngm»y"fqmqpc"tc|"fq"tqmw"rt|gin fw"yu|gnmkej"pqy{ej"khqt o celk"y"tc|kg"
 mqpkge|pq ek."EjRN"|quvcpkw"|cmvwcnk|qycpc0

5.2 Yfc ekyc ek"het o cmqmkpgv{e|pg

Yejeckpkckg

Het o cmqmkpgv{mc"qdknvqmucmu{ o cdw"lguv"nkpky c"y"|"cmtgukg"fcygm"qf"6 o ilmi o e0 *2.47-mtqypq "
 pcl o pkglu|gl"cngecpgl"fcymk+"fq"38 o ilmi o e0 rq"rqlgf{pe|{o"rqfcpkw"fq {np{o"|"ftqy{o"
 qejqvpkmq o0"Rq"rqlgf{pe|{o"rqfcpkw"fq {np{o"qdknvqmucmu{ o cdw"y"fcyeg"38 o ilmi o e0 |ftqy{o"

o e{| |pq o "k"mqdkgvqo tgfpgk"yctvq ek"E_{ocz} k"CWE_{inf} y {pquif{"qfrqykgfpgk"622 ± ;3.4 ilon"qtc|" 7392 ± 3582 i fqd lonl"Qmtgu"r>fvtycpkc"qdknvqmucmu{ ocdw"y {pqukē"qmāq"42"fpk"* tgfpgk+0

F{uvt{dwelc

tgfpgk"qdl vq "f{uvt{dwelc"qdknvqmucmu{ ocdw"y"uvcpgk"uvcelpqptp{ o"y {pqukē"9;.9 ± 3;.4 onlmi"k" d{ēc"yk mu|c"pk qdl vq "quqē|c."eq"uwigtwlg"rgyp "f{uvt{dwel "y"qdt dkg"vmcpgm0

Ogvcdqnk| o

Pkg"rt|grtqycf|ppq"htq o cnp{ej"dcfc " o gvcdqnk| o u qdknvqmucmu{ ocdw0
Lgfpcm rt|gekycēc"o qppmqpcnpg"|cucfpike|q"wgicl "f{uvt{dwelk"rq|c"rt|guvt|g " ygyv vt|pce|{pkqy .|"rvgpelcnp{ o"y {ejy {vgo"fq"vmcpgm."k"u "mvcvcdqnk|qycpg|"w|kēc"o"rtqvc| fq"o cē{ej"rgrv{ f>y"k"co k p q m y cu>y."mv>tg"pcuv rpkg"yejqf| "y"umēcf"gpfi gppg| rwnk"nwd"u " y {fcncpg0

Gnk o k pcelc

tgfpgk"yctvq ek"mktgpuw"qdknvqmucmu{ ocdw"y {pqukē{"5.57 ± 2.;54 onlflmi"kd{ē{|pce|pkg"o pkglu|g pk "yur>ēe|{ppkm"rt|gu e|cpkc"mē dwu|m q y g i q."eq"y umc|wlg." g r t c m v { e | p k g " p k g " o c k l i r e n s u p g t m q y g i q q d k n v q m u c m u { o c d w 0

Urgelcnpq"itwr{ rcelgp>>y

Yrē{y"rēk."ykgmw"k"tcu{
Hct o cmqmkpgv{m "qdknvqmucmu{ ocdw"qegpkcpq"pc"rqfuvcykg"rqrwnce{lpgl"cpnk| {"hct o cmqmkpgv{e|pgl" |"y {mqt|{uvcpgk"o"rt>dgm"uwtqyke{"rqejqf| e{ej"q"592"|ftqy {ej"qu>d."mv>te qvt| {o cē{ rqlgf|pe| fcym "fq {np "y"tcocej"e|vgtgej"dcfc "mnpke|p{e|0"pc"rqfuvcykg"vgl"cpnk| {"uvykgtf|ppq." g"rēg " * g umc"y"rt>y pcpkw|" o um +."tcuc"*kppc"pk "dkēc"y"rt>y pcpkw|"dkēc + "cpk"ykgm"*rqfgu|ē{"y" rqt>y pcpkw|" oēqf{ o+"pkg"o cl |pce| egiq"yrē{y w"pc"rctc o gvt {"hct o cmqmkpgv{e|pg" qdknvqmucmu{ ocdw0"Dcfcpkc"mnpke|pg"qdknvqmucmu{ ocdw"pkg"qdglo qycē{"lgfpcm"y {uvtc|cl egl"nke|d{ qu>d"y"ykgmw"87"ncv"kuvctu| {ej."cd{"qmtg nk .e| { hct o cmqmkpgv{mc y"vgl"i twrkq"ykgmqygl"t> pk"uk "qf" hct o cmqmkpgv{mk"w oēqfu| {ej os>d0"Urq"b" f"542"we|guvpm>y"dcfc "mnpke|p{ej"qdknvqmucmu{ ocdw quqd{"y"ykgmw"87"ncv"kuvctu|g"uvcpgy{ē{|;.6 " "521542+.c"quqd{"y"ykgmw"97"ncv"kuvctu|g- 4 " *81542+0

F/kēcēpkc"/yk |cpg"/"o cu "ekēc
Mktgpu"rt| {"fw gl"o cuk"ekēc"32;"mi+"d{ē"q"qmāq"5: ' "yk mu| {pk "y"rqrwnce|tghgtgpe{lpgl0
Wrt|{refmw"fcymqy cpk" |ng pgiq"qf"o cu {"ekēc"38"o ilmi o e0+"rqqfwlg"vq| yk mu|gpkg CWE_{inf} o 34 ' ."eq"pkg"o c"|pce|gpkc klinicznigiq0

F/kgēk"oēqf/kg
Pkg"dcfcpg"htc o cmqmkpgv{mk"qdknvqmucmu{ ocdw"wf|kgek0\cngēcpg"fcymqy cpgk"rt|gfuvcy kppg" y vcdgnk"4"*rwpm"604+"qrtceqycpq"pc"rqfuvcykg"u{ o wncelk"ogvqfc o k"htc o cmqmkpgv{mk"rqrwnce{lpgl" ygfēwi"qdugtqycp{ej"yctvq ek"gmurq| {elk"pc"qdknvqmucmu{ ocdw"qu>d"fqtuē{ej"rq"rqfcpkw"fcymk" 38 o ilmi o e0

5.3 Rt|gfmnpke|pg"fcpg"q"dg|rkgē|g uvyk

Fcpg"pkgmnpke|pg."y {pkmc| eg|"mqpygpelqpcn{ej"dcfc "hct o cmqmkpgv{p{ej"fqv{e| e{ej" dg|rkgē|g uvyc."dcfc "vqmu{e|pq ek"rq"rqfcpkw"ykgmqmtqvp{ o"qtc|"vqmu{e|pgiq"yrē{y w"pc"tq|t>f"mk" tq|y>l"rqvquouvyc."pkg"wlcy p kcl "u|e|gi>npgiq"|citq gpkc"fic e|ēqykgmcl0

W"rcfē{ej"mt>nkm>y"tcu{"P\ Y"k"o cmcm>y"lcyclumkej"|cmc qp{ej"y inkmko."mv>t{ o"rq" rqqykgtf|gpkw"ejqtqd{"rqfcpq"fq {npkg"qdknvqmucmu{ ocdw"×6 o ilmi+"nwd"rtgrctcv"mqpvtpnp{. " qdugtqycp{| o kcp{"y"q tqfmqy {o"wmēcf|kg"pgtyqy {o"dcmvgtkg."uvcv|cncnp{."mt y qvqm"k"pkgmkgf" o c t v y k e + 0 " O k m t q u m q r q y g " o k c p { " w " r c f ē { e j " | y k g t | v . " m v > t g " q v t | { o c ē { " q d k n v q m u c m u { o c d . " d { ē { "

urqyqfycpg qdgepq ek dcmvgtkk"rq|c"wmfcfg o"pce|{pkqy{ o."c"pkg"f|kcfcpkg o qdknvqmucmu{ ocdw0"\
rwpmw"ykf|gpkc"jkuvqrcvqni kk"o »| iw"pkg"uvykgft|ppq"|cng pq ek"qfrqykgf|k"qf"fcymk0"W"mt»nkm»y"
tcsy P \ Y"*y"fpkw"4:0+"cpk"w"o cmcm»y"lcy clumkej"*fq"fpkc"780+."mv»tg"rt|g {€{"|cmc gpkg"y inkmg o."
pkg"uvykgft|ppq"|yk |cp{ej"}|nge|gpkgo" |okcp"y"o »| iw"rq"rqlgf{pe|{ o"rqfcpkw"qdknvqmucmu{ ocdw"
y"fcymcej"qfrqykgf"pkq"fq"38 o ilmi" k"fq"54 o ilmi lfcym 0"W"o cmcm»y"lcy clumkej."mv»tg"rt|g {€{"
|cmc gpkg"y inkmg o."rq"nge|gpkw"qdknvqmucmu{ ocdg o"pkg"|cqdugyqycpq"|yk |cp{ej"}|v{ o"
rtqfwmvg o"umwvm»y"pgwtqdgjcykqtcnp{ej}0

Rt|grtqycf|ppq"lgfpq"dcfcpg"tq|yqlw"|ctqfmc" k"rëqfw w"|ftqy{ej"ek ctp{ej"mt»nkm»y"tcu{"P \ Y."
mv»t{ o"rqfcpq"fq {npkg"6"fcymk"qdknvqmucmu{ ocdw"y{pqu| eg"fq"54 o ilmi o e0*f ywmtqvpq "fcymk"
uvquycpgl"wnwf|k y"rt|gnke|gpkw"pc"o ilmi o e0+ y"80."320."350" k"390"fpkw"ek {0"Pkg"uvykgft|ppq"
pgicv{ypgiq"y rë{y w"qdknvqmucmu{ ocdw"pc"ek ctp"uc o ke "cpk"pc"rëqf{0"Umw o wngycpe"gmurq|{elc"w"
mt»nkm»y"tcu{"P \ Y"*32 000 iëfqd lon"rt|{"PQCGN"y{pqu| e{ o"54 o ilmi lfcym "p"? "6"fcymk+"
pc"rqfuvcykg"CWE_{0-15 dni}uvcpqykëc"y"rt|{dnk gpkw"fywmtqvpq "tgfpkl"CWE" fnc"o e|{p" k"mqdiet
ë e|pkg"rt|{"mnpke|pgl"fcyeg"fq {npl"38 o ilmi o e0"Yctvq ek"E_{ocz} rq"rqfcpkw"54 o ilmi o e0 lfcym "
y{pqukë{"33:2 iëfqd lon0

Pkg"rt|grtqycf|ppq"dcfc "tcmqvy»te|q ek."igpqvqmu{e|ppq ek"cpk"y rë{y w"qdknvqmucmu{ ocdw"pc"
rëqfpq 0

80 FCPG" HCTOCEGWV [E \ PG

803 Y {mc| "uwduvcpel" rq o qepke| {ej

Jkuv{f{pc
Uqtdkvqn"*G642+
Rqnkuqtdcv": 2"*G655+
My cu"solny *G729."fq"fquvquycpkc r J+
Yqfqtqvnpgm"uqfw"*G746."fq"fquvquycpkc r J+
Yqfc"fq"yuvt|{mkyc

804 Pkg| iqfpq ek" hct o cegw{e|pg

Pkg"okgu|c "vgiq"rtqfwmv"nge|pke|giq|"kpp{ok"rtqfwmvcok"nge|pke|{ok."qrt»e|"y{okgpkp{ej"y"
rwpmekg"8080

805 Qmtgu"yc pq ek

Pkgqvyctvc"hkqmc

9ncv

Tq|ekg e|qp{"tq"v y»t"y"yqtmw" kphw|{lp{ o

Rq"tq|ekg e|gpkw"y"yqtmw" kphw|{lp{ o"y{mc|cpq"uvcdknpq "rqf"y|in fgo"ejgoke|p{ o."hk|{e|p{ o" k"
okmtqdkqnqike|p{ o"pr|g|": "iqf|kp"y"vg o rgtcvwt|g"rqmqlygl"*42ÅE"- 47ÅE+"nwd"y"nqf»yeg"*4ÅE"-
: ÅE+0

o kmtqdkqnqike|pgiq"rwpmw"ykf|gpkc."q"knq"ogvqfc"qv ykgtepkc|tgmquv{vvelk|tq|ekg e|cpkc"pkg"
gnk okpwlgt{|{mc"|cpkge|{u|e|gpkc"okmtqdkqnqike|pgiq."rtqfwmv"pcng {pcv{ej okcuv"w { 0

Lg nk"rt|{iqvycp{"rtqfwmv"pkg"|quvcpg"y{mqt|{uvcp{"pcv{ej okcuv."|c"e|cu" k"yctwpmk"lg iq"
rt|gejyq{yepkc"qfrqykcfc" w {vmqypkm0

Tq|ekg e|qp{"tq|vy>t"y"uvt|{mcyeg"fq"kphw|lk"

Rq"tq|ekg e|gpkw"rt|{iqvqycp{"tq|vy>t"rtqfwmvw"nge|pke|giq"P [ZVJTCEKU pcng {pcv{ej okcuv" rqfc k"pkg"pcng {"iq"rt|gejqy{yc 0"Wszelkie nkg y{mqt|{uvcpe resztki produktu pcng {"y{t|wek 0

806 Urgelcpg" tqfmk"quvtq pq ek"rqfe|cu"rt|gejqy{ycpkc

Rt|gejqy{yc "y"nqf»yeg"4ÅE"- :ÅE+0

Pkg"|cotc c 0

Rt|gejqy{yc "y"qt{ikpcnp{ o"qrcmqycpkw"y"egnw"qejtqp{"rt|gf" ykcv€g o 0

Yctwpmk"rt|gejqy{ycpkc"rtqfwmvw"nge|pke|giq"rq"tq|ekg e|gpkw."rcvt|"rwpmv"8050

807 Tqf|cl"|"cyctvq "qrcmqycpkc

822" o il8" on"mqpegpvtcvw"y"hkqneg"*u|n€q"v{rw"K+"|"iwoqy{ o mqtmg o k"rqnrqtq|ngpqy{ o"y|kge|mkg o" |"mcrung o"cnw okpkqy{ o 0

Qrcmqycpkg"cykgtc"3"hkqnm 0

808 Urgelcpg" tqfmk"quvtq pq ek"fqv{e| eg"wuwycpkc"rt|{iqvqycpkc"rtqfwmvw"nge|pke|giq"fq" stosowania

Yc pg"kpvtwmeig"fqv{e| eg"rt|{iqvqycpkc

€ Mqpegpvtcv"fq"urqt| f|cpkc"tq|vyqtw"fq"yuvt|{mkye"rt|gf"rqfcpkg o"pcng {"qdgltg .e|{"pkg" |cykgtc e| uvgm"uv€{ej"czy nie |okgpk€|cdetykpkc0"P [ZVJTCEKU jest przezroczyt{ o lub qrcnk|wl e{ o."dg|dctyp{ o."dncfq »€v{ o nwd"dncfqt |qycyq »€v{ o tq|vyqtwg o."mv»t{"oq g" |cykgtc "pkgykngm "nke|d "rt|g|tqe|{uv{ej"nwd"dkc€{ej"e| uvgm"dkc€mqy{ej"*qfhkvtqy{ycp{ej" y"vtcmekg"rqfycpkc+0

€ Hkqnm "y{t|wek .Ig nk"tq|vy>t" |okgpk€ dety nwd|cykgtc"e| uvmk"qdeg"*rcvt|"rwpmv"5+0

€ Pkg"rqvt| uc "hkqnm 0

Rt|{iqvqycpkc"tq|ekg e|gpkc"y"yqtmw"kphw|{lp{o"

30 Rqvt|gdp "knq "qdknvqmucmu{o cdw"y" o knk itc ocej"qdne|{ ."o pq e|cngcep "fcym "y" o ilmi oe0 rqfcp "y"vcdgnk"4"rcvt|"rwpmv"604+"rt|g|"o cu "ekcfc"fcpgiq"rcelgpc"y"mknqitc ocej0

40 Y{ocicp "qdl vq "qdknvqmucmu{o cdw"y"rqvcek"mqpegpvtcvw"fq"urqt| f|cpkc"tq|vyqtw"fq" kphw|lk"y" o knkvtcej"qtc|nke|d "rqvt|gdp{ej"hkqngm"qdne|{ ."f|kgn e"qdne|qp "fcym qdknvqmucmu{o cdw"y" o knk itc ocej"*mtqm"3+"rt|g|"uv gpkc"322 o ilon0"Rqlgf{pe|c"hkqnmc" fquvte|c"8 on"mqpegpvtcvw qdknvqmucmu{o cdw fq"urqt| f|cpkc"tq|vyqtw"fq"kphw|lk0

50 Y{dte "qfrqykfpk"tq|okct"yqtmc"kphw|{lpgiq|"tq|vyqtwg o"ejnqtmw"uqfw"fq"yuvt|{mkye "q" uv eniu 9 o ilon"2.; '+0"Rqdtc|"yqtmc"kphw|{lpgiq"qdl vq "tq|vyqtw"t»yp "qdl vq ek" qdknvqmucmu{o cdw"y" o knkvtcej"qdne|qpgl"y"tc ocej"mtqm"4"rqy{ gl0"Y{t|wek "tq|vy>t" rqtcp{|"yqtmc"kphw|{lpgiq0

60 Rqdtc "y{ocicp "qdl vq "mqpegpvtcvw qdknvqmucmu{o cdw do spot| f|cpkc"tq|vyqtw"fq"kphw|lk" *qdne|qp "y"mtqm"4+"|hkqnmk"*hkqngm+"rtqfwmvw"nge|pke|giq"P [ZVJTCEKU0"Y{t|wek " pkgy{mqt|{uvcpe"e| "rtqfwmvw"nge|pke|giq"P [ZVJTCEKU rqlquvc€ "y"hkqneg0

70 Rt|gpkc "y{ocicp "qdl vq "mqpegpvtcvw qdknvqmucmu{o cdw fq"urqt| f|cpkc"tq|vyqtw"fq" kphw|lk"fq"y{dtepgiq"yqtmc"kphw|{lpgiq0

80 Fgnkmcvpgk"qdt»ek "yqtm"kphw|{lp{."cd{"y{okgu|c"tq|vy>t0"Pkg"yuvt| uc 0

90 kphw|l rqfcyc "rt|g|";2"okpwv|"u|dmq ek "infuzji ygfw"i"vcdgnk"5"rcvt|"rwpmv"604+."|" |cuquqycpkgo hknvtc"kphw|{lpgiq"2.44 o 0

:0 Rt|{iqvqycp{"tq|vy>t"cejqywlg"uvcdknpq "rt|g|": "iqf|kp"rqfe|cu"rt|gejqy{ycpkc"y" vgo rgtcvwt|g"rqmqlqygl"*42ÅE"do 47ÅE+"nwd"y"nqf»yeg"4ÅE"do :ÅE+0

Rt|{iqvqycpkc"tq|ekg e|gpkc"y"uvt|{mcyeg"fq"kphw|lk

30 Rqvt|gdp "knq "qdknvqumucmu{ocdw"y"oknkitecej qdnke|{."opq e"|cngcep "fcym "y"
o ilmi oe0 rqfcp "y"vcdgnk"4"*rcvt|"rwpmv"604+"rt|g|"ocu "ekcfc"fcpgiq"rcelgpc"y"mknqitcecej0
40 Y {ocicp "qdl vq "qdknvqumucmu{ocdw"y"rqvcek"mqpegpvtcvw"fq"urqt| f|cpkc"tq|vyqtw"fq"
kphw|lk"y"oknkvtcej"qtc|"nke|d "rqvt|gdp{ej"hkqngm"qdnke|{."f|kgn e"qdnke|qp "fcym "
qdknvqumucmu{ocdw"y"oknkitecej"*mtqm"3+"rt|g|"uv gpk"322 o ilon0"Rqlgf{pe|c"hkqnmc"
fqvcte|c"8 on"rtqfwmvw"nge|pke|giq"P [ZVJTCEKU y"rqvcek"mqpegpvtcvw"fq"urqt| f|cpkc"
tq|vyqtw"fq"kphw|lk0
50 Y {dte "qfrqykgfpk"tq|okct|uvt|{mcy mk"fq"rqfcpkc"ecfgl"qdl vq ek"infuzji0
60 \c"rqoqe "y {dtepgl"uvt|{mcy mk"khkvtc"kphw|{lpgiq"2.44" o"rqdte "y {ocicp "qdl vq "y"
mqpegpvtcvw qdknvqumucmu{ocdw"fq"urqt| f|cpkc"tq|vyqtw"fq"kphw|lk"*qdnke|qp "y"mtqm"4+0"
Y {t|wek "pkgy {mqt|{uvc "e| rtqfwmvw"nge|pke|giq"P [ZVJTCEKU rq|quvc "y"hkqneg0"
70 Rqdtc "qfrqykgfpk "qdl vq tq|vyqtw"ejnqtmw"uqfw"fq"yuvt|{mkyc "q"uv gpkw"; o ilon"
*2.; '+.cd{"qvt|oc "ecfmqyk"v"qdl vq "infuzji rqfcp "y"vcdgnk"40
80 Fgnkmcvpgk"y {okgu|c "tq|vy>t0"Pkg"yuvt| uc 0
90 Rt|{iqvqcp{"tq|ekg e|qp{"tq|vy>t"qdknvqumucmu{ocdw"pcv{ej okcu rqfcp0"Pkg"rt|gejqy {yc "
tq|vyqtw"y"uvt|{mcy eg0"Pkg"y {mqt|{uvc "rtqfwmvw"y {t|wek 0

Wuwycpk

Y u|gnmk"pkgy {mqt|{uvcpg"tgu|vmk"rtqfwmvw"nge|pke|giq"nwd"lgiq"qfref|pcng {"wuw " |iqfpg"|"
nqmcnp{ok"rt|grkucok0

7. RQF OKQV"QFRQYKGF \KCNP ["RQKCFCL E\ "RQ\ YQNGPKG"PC" DOPUSZCZENIE DO OBROTU

UHN"Rjct o cegwkecnu" Fgwwuejncpf" I od J
Oetkg-Ewtkg-Uvtcuug":
9;75;"N%ttcej
Pkgoe{

8. PWOGT"RQ\ YQNGPKG"PC"FORWU\ E\ GPKG" FQ"QDTQVW"

GW13142136:71223

9. DATA WYDANIA PIERWSZEGO POZWOLENIA NA DOPUSZCZENIE DO OBROTU K"FCVC"RT\GF/W GPKC"RQ\ YQNGPKG

Fcvc"y {fcpc"rkgt yu|giq"rq|yqngpk"pc"fqrwu|e|gpk"fq"qdtqv<3:"nkuvqrcfc"4242"tqmw

10. FCVC"\CVYKGTGTF \GPKC"NWD"E\ EKQYGL"\OKCP ["VGMUVW" CHARAKTERYSTYKI PRODUKTU LECZNICZEGO

U|e|gi>eqy"qkphqtocelg"q"v{ o "rtqfwmekg"nge|pke|{ o "u "fqv rpg"pc"uvtqpk"kpvtgpgvqygl"Gwtqrglumkg"
Cigpelk"Nem>y "jvr<1lyy0goc0gwtqrc0gw >qtc|"pc"uvtqpk"kpvtgpgvqygl"}pc|yc"wt|fw"mtclw"
e|eqmgy umkiq"*nkpm"fq"uvtq{+;@0

ANEKS II

- A. Y [VY ~ TEC"DKQNQ I KE \ PGL"UWDUVCPELK"E \ [PPGL"
ORAZ WYTWÓRCA ODPOWIEDZIALNY ZA
ZWOLNIENIE SERII
- B. Y CTWPMK"NWD"Q I T CPKE \ GPKC"FQV [E \ EG"
ZAOPATRZENIA I STOSOWANIA
- C. KPPG" Y CTWPMK"K" Y [OQTCPKC"FQV [E \ EG"
DOPUSZCZENIA DO OBROTU
- D. Y CTWPMK"NWD"Q I T CPKE \ GPKC"FQV [E \ EG"
BEZPIECZNEGO I SKUTECZNEGO STOSOWANIA
PRODUKTU LECZNICZEGO
- E. U \ E \ G I ~ NPG" \ QDQYK \ CPKC"FQ" Y [MQPCPKC"RQ"
YRTQYCF \ GPKW"FQ"QDTQVW" Y"U [VWCELK." I F ["
RQ \ Y QNGPKG"PC" YRTQYCF \ GPKG"FQ"QDTQVW"LGUV"
UDZIELONE W PROCEDURZE DOPUSZCZENIA W
Y [L VMQY [EJ"QMONE \ PQ EKCEJ

**A. Y [VY ~ TEC"DKQNQ I KE \ PGL"UWDUVCPELK"E \ [PPGL"QTC \ " Y [VY ~ TEC"
ODPOWIEDZIALNY ZA ZWOLNIENIE SERII**

Pc|yc"kcftgu"y{vy>te{"dkqnqike|pgl"uwduvcpele"e}{ppgl

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

Pc|yc"kcftgu"y{vy>te{"qfrqykgf|kcnpgiq"|c"|yqnpkpgk"ugtkk

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

B. YCTWPMK"NWD"QITCPKE \ GPKC"FQV[E \ EG" \ CQRCVT \ GPKC"K"UVQUQYCPKC"

Rtqfwmv"nge|pke|{"y{fcycp{"pc"tgegrv 0

C. KPPG"YCTWPMK"K"Y [OCICPKC"FQV[E \ EG"FORWU \ E \ GPKC"FQ"QDTQVW

€ **Qmtguqyg"trqvt{"q"dg|rke|g uvykg"uvquycpkc"*cpi0"Rgtkqfke"uchgv{"wrfcvg"tgrqtvu."
RUWTu+**

Y{ocicpkc"fq"rt|gfgq gpkc"qmtguqy{ej"trqvt>y"q"dg|rke|g uvykg"uvquycpkc"vgiq"rtqfwmv"
nge|pke|giq"u "qmtg nqpg"y"y{mc|kg"wpklp{ej"fc"tghgtgpe{lp{ej"*y{mc|"GWTf+."q"mv>t{o"
oqyc"y"ctv0"329e"wuv0"9"f{tgmv{y{"42231:51Yg"klg"iq"mqnglp{ej"cmvwnk|celcej"qifcu|cp{ej"pc"
gwtqrglumkg|"uvtqpkg"kpvgtpgvqygl"fqv{e| egl"ngm>y0

**D. YCTWPMK"NWD"QITCPKE \ GPKC"FQV[E \ EG"DG \ RKGE \ PGIQ"K"
SKUTECZNEGO STOSOWANIA PRODUKTU LECZNICZEGO**

€ **Rncp"|ct| f|cpkc"t{|{mkg o"*cpi0"Tkum"Ocpcig o gpv"Rncp."TOR+**

Rqfokqv"qfrqykgf|kcnpg"qfglolg"y{ocicpg"fkfcpc"kpvgtygpelg"|"cmtguw"pcf|qtw"pcf"
dg|rke|g uvygo"htocmqvgtcrkk"y{u|e|gi>npkqpg"y"TOR."rt|gfuvykpq{o"y"oqfwng"30:04"
fqmwogpvcelk"fq"rq|yqngpkc"pc"qfrwu|e|gpkg"fq"qdtqvw."k"y|gnmkej"lg"iq"mqnglp{ej"
cmvwnk|celcej0

Wcmvwnpkqp{"TOR"pcng {"rt|gfuvykc <

€ pc"fcpgk"Gwtqrglumkg|"Cigpelk"Ngm>y=

€ y"tc|kg"okcp{"u{uvgo"ct| f|cpkc"t{|{mkg o."|yfcu|e|c"y"y{pkmw"w}{umcpc"pqy{ej"
kphqto celk."mv>tg"oqi "kuvqypkg"y r{p "pc"uvquwpgm"t{|{mc"fq"mqt|{ ek."nwd"y"y{pkmw"
w|{umcpc"uvqyp{ej"kphqto celk."fqv{e| e{ej"dg|rke|g uvykg"uvquycpkc"rtqfwmv"nge|pke|giq"
nwd"qfpqu| e{ej"uk "fq"okpkocnk|celk"t{|{mc0

E. U\E\GI~NPG"\QDQYK \CPKC"FQ"Y [MQPCPKC"RQ"YRTQYCF\GPKW"FQ" QDTQVW"Y"U [VWCELK."IF ["RQ\ YQNGPKG"PC"YRTQYCF\GPKG"FQ"QDTQVW" LGUV"WF\KGNQPG"Y"RTQEGFWT\G"FQRWU\E\GPKC"Y"Y [L VMQY [EJ" QMQNKE\ PQ EKCEJ

Vq"rq|yqngpkg"pc"fq"rdw|e|gpk"fq"qdtqv"quvcf"wf|kgnqpg"y"rtqegfwt|g"fq"rdw|e|gpk"y" y{lvmqy{ej"qmqnke|pq ekcej"i|qfpgk"|"ctv"36"wu"0": "tq|rqt| f|gpk"*YG+"pt"948|4226"rqfokq qfrqykgf|kcp{"y{mqpc"pcuv rwl eg"e|{ppq ek."|i|qfpgk"|"qmtg nqp{ o"jctoqqpitcogo<

Opis	Vgt okp
<p>Y"egnw"y"cnkfcelk"ogvqf{"qmtg ncpk"RM"qdknvqmucmu{ ocdw"*IEN-382+"y"uwtqyke{"nwf mkg "rfokq"qfrqykgf kcp{"rkykpgp" rt gfuvcyk "y{pkmk"y"cnkfcelk"q pce gpk"rf"m vgo"pcuv rwl e{ej" curgm"y"rt gf" "cuvquycpkgo"ogvqf{"fq"cpnk {"rt>dgm"y" tcocj"dcfcpk"mnkpk pgiq"CJ723<"kpvgtgtgpc" "g"uvtq{"RC"*85" k":5+."GH."NH"qtc "CFC."c"vcm g"ghgm"y"pq "q pce gpk"y" uwtqyke{"jgoqkv{e pgl"knrgoke pgl"0"dcfcpk"t»y"pqngiefek" pcng {"rt grtqycf k "pc"rqdtp{ej"rt>dmcej" "rncpqycpgiq" qvctvgiq"dcfcpk"vgtgpqygiq"CJ7230</p>	<p>Rt gfuvcyk "rc go" " mnkpk p{o"terqtvg"o" mq eqy{o" "dcfcpk" CJ7230</p>
<p>Y"egnw"qegp{"qfrqykgf k"mnkpk pgl."dg rkge g uvyc"uvquycpk"kvngtcepk."y"v{o"rt gdkiw"ejqtq{"k"rt g {ek"w"rcelgp»y" " rfglt gpkgo."rteyfqrfqdkg uv"ygo"nwd"rqvykgtf gpkgo"y inkmc" y kgypgiq."nge qp{ej"qdknvqmucmu{ ocdgo."rfokq" qfrqykgf kcp{"rkykpgp"rt grtqycf k "ygfwi" "w i qfpgkpgiq" rtqvqmfw"qvctvg"dcfcpk"vgtgpqy"hc {"KX"CJ723"y"rt {rcfmw" rlcycgpk"uk "y inkmc"y"mtelcej."if kg"qdknvqmucmu{ ocd"lguv" fqrwue qp{"k"fqv rp{."qtc "rt gfuvcyk "y{pkmk"terqtvw" mq eqygiq0</p>	<p>Rt gfuvcyk "tqe pg" urtcyq fcpk0"</p> <p>Terqtvmq eqy{" rt gfuvcyk "pclr»"pkl"34" okguk e{"rq"quvcvko" rfcpkw"qdknvqmucmu{ ocdw" nwd"quvcvko" "gdtepkw" fcp{ej"y"rt {rcfmw" tgvqturgmv{ypgiq" "dkgtcpc" fcp{ej0</p>

Produkt leczniczy bez ważnego pozwolenia na dopuszczenie do obrotu

ANEKS III

Q \ PCMQYCPKG"QRCMQYC "K"WNQVMC"FNC"RCELGPVC

Produkt leczniczy bez ważnego pozwolenia na dopuszczenie do obrotu

Produkt leczniczy bez ważnego pozwolenia na dopuszczenie do obrotu

A. Q\PCMQYCPKG"QRCMQYC

KPHQTOCELG" \ COKGU \ E \ CPG"PC"QRCMQ YCPKCEJ" \ GYP VT \ P [EJ
RWFG/MQ"TEKTUOWE

1. NAZWA PRODUKTU LECZNICZEGO

P [ZVJTCEKU 100 o i l o n " m q p e g p v t c v " l c f q y {
q d k n v q m u c m u { o c d "

2. \ CYCTVQ "UWDUVCPELK"E \ [PPGL

3" o n " 322 o i " q d k n v q m u c m u { o c d w 0

3. Y [MC \ "UWDUVCPELK"RQOQEPKE \ [EJ

Uwduvcpe l g " r q o q e p k e | g " j k u v { f { p c . " u q t d k v q n . " G 6 5 5 . " m y c u " s o l n y . " y q f q t q v n g p g m " u q f w . " y q f c " f q "
y u v t | { m k y c 0

4. RQUVC "HCTOCEGWV [E \ PC"K" \ CYCTVQ "QRCMQ YCPK

Mqpe g p v t c v " f q " u r q t | f | c p k c " t q | v y q t w " f q " k p h w | l k
822" o i l 8" o n
3" h k q m c

5. SPOSOB DROGA PODANIA

P c n g { " | c r q | p c " u k " | " v t g e k " w n q v m k " r t | g f ") c u v q u q y c p k g o " n g m w 0
F q { n p k g " r q " t q | e k g e | g p k w 0
Y { e | p k g " f q " l g f p q t c | q y g i q " w { e k c l
P k g " y u v t | u c 0

F q f c " m q f " S T " - " y y 0 q d k n v q z c z k o c d - u h n 0 g w

**80 QUVT \ G GPKG" FQV [E \ EG"RT \ GEJQY [YCPK"RTQFWMVW" LECZNICZEGO
Y"OKGLUEW"PKGYKFQE \ P [O"K"PKGFQUV RP [O" FNC" F \ KGEK**

7. KPPG"QUVT \ G GPKC"URGELCNP G. LG NK"MQPKGE \ PG

8. VGTOKP"YC PQ EK

EXP

9. WARUNKI PRZECHOWYWANIA

Rt | g e j q y { y c " y " n q f » y e g 0 "

Pkg"|cotc e 0"
Rt|gejqy{yc "y"qt{ikpcnp{ o"qrcmqycpkw"y"egnw"qejtqp{"rt|gf" ykcvfgo0

10. URGELCNPg" TQFMK"QUVTQ PQ EK"FOV[E\ EG"WUWYCPKC"PKG\W [VGIQ"
RTQFWMVW"NGE \PKE\GIQ"NWD"RQEJQF\ E[EJ"\ "PKGIQ"QFRCF~Y."LG NK"
Y/C EKYG

11. PC\YC"K"CFTGU"RQFOKQVW"QFRQYKGF\KCNPGIQ

UHN"Rjctocegwkencu"Fgwvuejncpf" I odJ
Oetkg-Ewtkg-Uvtcuug":
9;75;"N%ttcej
Pkgoe{

12. PWOGT"RQ\YQNGPKC"PC"FOQWU\E\GPKG"FO"QDTQVW

GW13142136:71223

13. PWOGT"UGTKK

Pt"ugtkk"*Nqv+

14. QI~NPC"MCVGIQTK"FOUV RPO/ER

15. KPUVTWMELC"W [EKC

380 KPHQTOCELC"RQFCPCU[UVGOGO"DTCKNNG0C

\ccmegrvqycpq"w|cucfpgpkg"dtcmw"kphqto celk"u{uvgogo"Dtckngoc0

17. PKGRQYVCT\CNP["KFGPV[HKMCVQT"-KOD2D

Qdglowlg"mqf"4F"d,f e{"pq pkmkg o"pkgrqyvct|cnpgiq"kfgpv{hkmcvqtc0

18. PKGRQYVCT\CNP["KFGPV[HKMCVQT"-FCPG"E\[VGNPG"FNC"E\ /QYK GMC

RE"
UP"
M

OKPKOWO "KPHQTOCELK" \ COKGU \ E \ CP [EJ "PC" OC / [EJ "OPAKOWANIACH
DG \ RQ TGFPEJ

GV [MKGVC "PC" HKQNM

1. NAZWA PRODUKTU LECZNICZEGO I DROGA PODANIA

P [ZVJTCEKU 100 o ilon "mqpegpvtcv" lcfqy {
qdknvqmucmu { ocd"
Fq { npkg "rq" tq | ekg e | gpkw0

2. SPOSÓB PODAWANIA

Y { € e | pkg "fq" lgfptc | qygiq "w { ek0

3. VGTOKP "YC PQ EK

EXP

4. PWOGT "UGTKK

Nqv

**5. \ CYCTVQ "QRCMQ YCPKC" \ "ROFCPKGO" OCU [. "QDL VQ EK "NWD "NKE \ D ["
LGFPQUVGM**

822" o il8" on

80 INNE

Produkt leczniczy bez ważnego pozwolenia na dopuszczenie do obrotu

Produkt leczniczy bez ważnego pozwolenia na dopuszczenie do obrotu

B. WNQVMC\FNC\RCELGPVC

Wnqvmc"fq€ e|qpc"fq"qrcmqycpkc<kphqt o celc" fnc" rcelgpvc

NYXTHRACIS 322" o il o n"mqpegyvtcv"fq"urqt| f|cpkc"tq|vyqtw"fq"kphw|lk
qdknvqmucmu{ o cd

Pkpkglu|{"rtqfwmv"nge|pke|{"d f|kg"fqfcmqyq"o qpkvqtqycp{0"W o q nkyk"vq"u|{dmkg"
|kfgpv{hkmqycpkg"pqy {ej"qphqt o celc"q"dg|rkge|g uv ykg0"W {vmqypkm"ngmw"vg "o q g"y"v{ o"rqo»e"
|iƒcu|cl e"yu|gnmkg"f|kcƒcpkc"pkgrq fcpg."mv»tg"y {uv rkƒ{"rq"|cuvquycpkw"ngmw0"Cd{"fqykgf|kg "uk ."
lcm"|iƒcu|c "f|kcƒcpkc"pkgrq fcpg"—rcvt|"rwpmv"60

**Peng {"wyc pkg"|crq|pc "uk "|vtg ek "wnqvmk"rt|gf"|cuvquycpk o "ngmw."rqpky c "|cykgtc"qpc"
kphqt o celg y c pg" fnc" rcelgpvc0**

- Peng {"cejqyc "v "wnqvm ."cd{"y"tc|kg"rqvt|gd{"o»e"l "rqpqypkg"rt|ge|{vc 0
- Y"tc|kg"lcmkejmqnykgm"y vrnkyq ek"peng {"y t»ek "uk "fq"ngmct|c."hct o cegwv" nwd"rkgn ipkctm0
- Lg nk"w"rcelgpvc"y {uv rk "lcmkqmnykgm"qdlcy {"pkgrq fcpg. y"v{ o yu|gnmkg"qdlcy {"
pkgrq fcpg"pkgy {okgpqpg"y"vgl"wnqveg."peng {"rqykgf|kg "q"v{ o "ngmct|qyk."hct o cegwv"nwd"
rkgn ipkcteg0"Rcvt|"rwpmv"60

Urku"vtg ek"wnqvmk

- 30 Eq"vq"Iguv"ngm" P [ZV J TCEKU k" y"lcmk o "egnw"uk "i q"uvquwlg"
- 40 kphqt o celg" y c pg"rt|gf"qvt|{ o cpkg o "ngmw"N [ZV J TCEKU
- 50 Lcm"rqfclg"uk "ngm" P [ZV J TCEKU
- 60 Oq nkyg"f|kcƒcpkc"pkgrq fcpg"
- 70 Lcm"rt|gejqy {yc "ngm" P [ZV J TCEKU
- 80 \cyctvq "qrcmqycpkc" k" kppg" kphqt o celg

1. Eq"vq"Iguv"ngm"NYXTHRACIS k" y"lcmk o "egnw"uk "i q"uvquwlg

Ngm" P [ZV J TCEKU |cykgtc"uwduvcpel "e|{pp"qdknvqmucmu{ o cd0"Qdknvqmucmu{ o cd"jest
rt|gek yekƒg o o qpqmnapcpn{ o – tqf|clg o dkcƒmc."mv»tg"rt|{€ e|c"uk "fq"vqmu{p"y {vyct|cp{ej przez
dcmvgtk "y {yqƒwl e "y inkmc k"lg"fg|cm|y wlg0

Ngm" P [ZV J TCEKU uvquwlg"uk "tc|g o "|cpv{dkqv{mc ok y leczeniu os»d" fqtquƒ{ej i dzieci z
y inkmkg o"y {yqƒcp{ o"rt|g|"dcmvgtk."mv»tg"fqvcƒ{"uk "fq"qticpk|ow"rt|g|wmƒcf"qffgejqy {"*y inkm"
y|kgy p{+0

Ngm" P [ZV J TCEKU o q g" d{ "vcm g"uvquycp{"lg nk"rcelgpv"o»iƒ"okg mqpvcmv|"ncuge|m "y inkmc"
nwd"lgl"rt|gvt y cnpkmc ok" cpg pkg" o c"qdlcy»y"ejqtqd{"k" c fpg" kppg"nge|gpkg"pkg"lguv"fqv rpg"cpk"
qfrqykgfpg0

2. Kphqt o celg" y c pg"rt|gf"qvt|{ o cpkg o "ngmw"NYXTHRACIS

Pkg"peng {"rt|{loqyc "ngmw"NYXTHRACIS

- lg nk"rcelgpv" o c"we|wngpkg"pc"qdknvqmucmu{ o cd"nwd"mv»t{mqnykgm|"rq|quvcƒ{ej"umƒcfpkm»y"vgiq"
ngmw"*y {okgpqpg{ej"y"rwpmekg 8+0

Qvt|g gpkc" k" tqfmk"qvtq pq ek"

Rt|gf"qvt|{ o cpkg o "ngmw" P [ZV J TCEKU peng {"rqtq| o cyk " |ngmct|g o."hct o cegwv "nwd"
rkgn ipkctm <

- lg nk"rcelgpv fqtquƒ{ *nwd" f|kgemq+ o c f|kgf|ke|p "pkgvngtcpel "htwmvq|{"– t|cfm "ejqtqd "
igpgv{e|p "– nwd"lg nk" f|kgemq"pkg" o q g"lw "lg "ufqf mkej"rqmct o»y cpk"rk "ufqf|qp{ej"
pcrq|»y."rqpky c "o c"pwfpq ek."y {okqv{ nwd" kppg"pkgrt|{lg o pg"qdlcy {"vcmkg"lcm"y |f ekc."
skurcze qƒ fmc"nwd"dkg i wpmc0

Tgcmelg"cngtike|pg."mv>tg"oqi "y{uv rk "rq"rqfcpkw"ngmw"P [ZVJTCEKU."oqi "e|cucok"d{ ek mkg0"
Rt|gf"rqfcpkg"o"ngmw"P [ZVJTCEKU rcelgpv"oq g"qvt|{ oc "ngm"rt|geky jkuvcokpqy{."cd{ "
| opkglu|{ "t{|{mq"tgcmelk"cngtike|p{ej0

Lek NYXTHRACIS a inne leki

Pcng {"rqykgf|kg "ngmct|qyk"nwd"het o cegwekg"q"yu|{uvmkej"ngmcej"uvquycp{ej"rt|g|"rcelgpvc"
qdgepkg"nwd"quvcvpkq."c"vcn g"q"ngmcej."mv>tg"rcelgpv"rncpwlg"uvquyc 0
Rcelgpv"oq g"qvt|{ oc "cpv{dkqv{mk"*pr0"e{rtqhnqmuce{p "+"y"tc ocej"nge|gpkc"y inknc"y |kgy pgiq0

Ek c"mct okgpkgrktuk

Lg nk"rcelgpvmc"lguv"y"ek {"nwd"mctok"rktuk ."rt|{rwu|e|c." g"oq g"d{ "y"ek {"nwd"if{|rncpwlg"okg "
f|kgemq."rqykppc"rqtcf|k "uk "ngmct|c"rt|gf"qvt|{ ocpkg o"vgiq"ngmw0

Pkg"ykcfaqoq."e|{"ngm"P [ZVJTCEKU oq g|cu|mqf|k "pkgpctqf|qpgow"fkgemw0

Pkg"ykcfaqoq."e|{"ngm"P [ZVJTCEKU rt|gpkmc"fq"o ngmc"nwf|mkgiq0"Rcelgpvmc"n"ngmct|"rqykppk"
yur>npkg"|fge{fqyc ."e|{"pcng {"mctok "rktuk "rq"qvt|{ ocpkw"ngmw"P [ZVJTCEKU0

Rtqycf|gpkgrqlc|f>y"qduewikycpk"o cu|{p

Ngm"P [ZVJTCEKU oq g"rqyqfqc" f|kfcpcpkgrq fcpq."vcmk"lcm"d>n"ifqy{."|cytqv{"ifqy{."
| o e|gpkg"ky{okqv{0"Oqi "qpg"yr{yc "pc"|fqnpq "rtqycf|gpkgrqlc|f>y"nwd"qduewikycpk"
o cu|{p0

Lek NYXTHRACIS |cykgtc"uqtdkvq" *G642+

Uqtdkvq"lguv" t>f{eg o"htwmvq|{"*mv>tc"lguv"tqf|clg o"ewmtw+0"lg nk"rcelgpv fqtquf{ *nwd"fkgemq+"oc
f|kgf|ke|p "pkgvqngtpep "htwmvq|{"-t|cfm "ejqtqd "igpgv{e|p "-ngmct|"oq g"wp"pc ." g"rcelgpvqyk
fqtquf{eg o w *nwd"fkgemw+"pkg"yqnpq"rt|{loqyc "vgiq"ngmw0"Qticpk|o "rcelgpv">y"|f|kgf|ke|p "
pkgvqngtpep "htwmvq|{ pkg"tq|mfcfc"htwmvq|{."eq"oq g"urqyqfqc"ek mkg f|kfcpcpkgrq fcp0
Rt|gf"qvt|{ ocpkg o"vgiq"ngmw"pcng {"rqkphqto"qyc "ngmct|c."lg nk"rcelgpv fqtquf{ *nwd"fkgemq+"oc
f|kgf|ke|p "pkgvqngtpep "htwmvq|{ nwd"lg nk"fkgemq"pkg"oq g"lw "lg "ufqfmkej"rqmct o>y"cpk"rk "
ufqf|qp{ej"pcrql">y."rpkgy c "oc"pwfpq"ek."y{okqv{ nwd"kppg"pkgrt|{lgo pg"fqnginkyq ek."vcmk"lcm"
y|f ekc."smwte|g" qe fmc"nwd"dkgiwpmc0

Lek NYXTHRACIS |cykgtc"u>f

Vgp"ngm|cykgtc"o pkl"pk "3"o oq"uqfw"45"o i+"pc"lqfp "hkqnm "ngmw"P [ZVJTCEKU o obj vq ek 8 o n."
vq|pce|{"ngm"wpclg"uk " |c"šyqnp"qf"uqfw00

3. Lcm"rqfclg"uk "ngm"NYXTHRACIS

Ngm"P [ZVJTCEKU lguv"rqfeycp{"rt|g|"ngmct|c"nwd"rkgn ipkctm 0"Ngmct|"nwd"rkgn ipkctmc"qdnke| "
fcym "pc"rqfucykg"o cu{"ekfc"rcelgpvc fqtquf{iq *nwd"fkgemc+0"

Ngmct|. "rkgn ipkctmc"nwd"het o cegwvc"rt|{iqvwl "ngm"fq"infuzji0"

Tq|vy>t"ngmw"P [ZVJTCEKU rqfclg"uk "rt|g|";2"okpwv"yg"yngykg"*mtqrn>yeg+"fq" {€{."|y{mng"fq"
{€{"y"teokgpkw"Rcelgpv"d f|kg"o qpkvqtqycp{"rqfe|cu"rqfeycpk"ngmw"P [ZVJTCEKU i przez co
pelopkl"iqf|kp "rq"|cmq e|gpkw"yngyw0"

Rt|gf"rqfcpkg"o"ngmw"P [ZVJTCEKU rcelgpv"y|{mng"qvt|{ owl"ngmk"|crqdkgiel eg"tgcmelqo "
cngtike|p{ o"nwd"fcicqf| eg"kej"rt|gdkgi0"

Y"tc|kg"lcmkejmqnykgm"fcnu|{ej"y vrnkyq ek"|yk |cp{ej|"g"uvquycpkgo"vgiq"ngmw"pcng {"|yt>ek "uk "
fq"ngmct|c."het o cegwv{"nwd"rkgn ipkctmk0

4. Oq nkygf|kfcpcpkgrq fcpq

Lcm"mc f{"ngm."vgp"ngm"oq g"rqyqfqc "f|kfcpc"pkgrq fcpg."ejqekc "pkg"w"mc fgiq"qpg"y{uv rk 0

Pcng {"pcv{ej okcu"rqkphqt oqyc "ngmct|c"nwd"quqd "rqfcl e "yngy."lg nk"rcelgpv"|cwyc {"mv>tgmqnykgm"}|rqpk u{|ej" f|kfc "pkgrq fcp{ej<

Uy f|gpgk."y{u{rnc."fwu|pq ek"nwd" yku|e| e{"qffgej"- oqi "vq"d{ "qdlcy{ tgcmlk"cngtike|pgl" *pcfyt nkyq ek+0

Fq"pp{ej" f|kfc "pkgrq fcp{ej"ngmw"NYXTHRACIS pcng <

E| uvo *oqi "y{uv rk "w"o cmu{ o cnpkg"3"pc"32"qu>d+

- D»n"iŕqy {
- Mcu|gn
- D»n"y"okgluew"rqfcpk"yngyw
- Uy f|gpgk."y{u{rnc"um>tpc."y"v{ o"uy f| ec"wpkgukqpc"y{u{rnc"*rqmt|y mc+

Pkg|d{v"e| uvo *oqi "y{uv rk "w"o cmu{ o cnpkg"3"pc"322"qu>d+

- Tgcmlg"cngtike|pg
- \cytqv{"iŕqy {
- Ft vykgpgk
- Ytc nkyq "pct| fw"y|tqmw"pc" ykcvŕq"* ykcvŕqyuv v+
- We|wekg"f{umq o hqtvw"y"uszcej
- Rqftc pkgpgk"ictfŕc
- Ejt{rnc
- Pkgftq pq "|cvqm
- Fwu|pq
- D»n"ycti
- Y{rt{um."ŕwu|e|gpgk"uk "um>t{
- Dr gpgk ok pk."mwte|g"ok pk
- \o e|gpgk
- Ftgu|e|g"*we|wekg"|kopc+
- We|wekg"f{umq o hqtvw"y"mncveg"rktukqygl"
- D»n"wqi>npkp{."d»n"mq e|{p."mncmk"rktukqygl."u|e| mk."ok pk."yk |cfgŕ." ek ikgp"nwd"mq ek"
- Qdt| m."d»n"nwd"|c rncpgk" {"y"okgluew"rqfcpk"yngyw

\iŕcu|cpkg"f|kfc "pkgrq fcp{ej

Lg nk"w"rcelgpv"y{uv rk "lcmkmgnykgm"qdlcy{"pkgrq fcpg."y"v{ o"yu|gmmk"qdlcy{"pkgrq fcpg" pkgy{ okgpqpg"y"vgl"wnqveg"pcng {"rqykgf|kg "q"v{ o"ngmct|qyk."hct o cegwekg"nwd"rkgn ipkcteg0" F|kfcpc"pkgrq fcpg"oq"pc"|iŕcu|c "dg|rq tgfpkq"fq"šmtclqygiq"u{uvgow"}iŕcu|cpk"ö" y{okgpqpgiq"y"|cŕ e|p"mw"X0" F|k mk"|iŕcu|cpkw" f|kfc "pkgrq fcp{ej"oq pc"d f|kg"|itqocf|k " yk egl"kphqt o celk"pc"vg o cv"dg|rkge|g uvyc"uvquycpkc"ngmw0

5. Lcm"rt|gejqy{yc "ngm"NYXTHRACIS

Ngm"pcng {"ŕt|gejqy{yc "y"okgluew"pkgykfqc|p{o" k"pkgfquv rp{o" fnc" f|kgek0

Pkg"uvquqyc "vgiq"ngmw"rq"wrŕ{ykg"vgtokpw"yc pq ek"|cokgu|e|qpgiq"pc"rwfgŕmw"kv{mkgekq"rq"GZR0" Vgtokp"yc pq ek"q|pce|c"quvcpk" f|kg "rqfcpgiq"okguk ec0

Rt|gejqy{yc "y"nqf>yeg"*4ÅE"- :ÅE+0"

Pkg"|cotc c 0

Rt|gejqy{yc "y"qt{ ikpcnp{o" qrcmqycpkw"y"egnw"qejtq{ "rt|gf" ykcvŕg o 0

Rq"tq|ekg e|gpkw"y"yqtmw"kphw|lp{o"y{mc|cpq": -iqf|kpp "uvcdknpq "rqf"y|in fg o"ejgokc|p{o." hk|e|p{o" k"okmtqdkqaike|p{o"y"vg o rgtcvwt|g"rqmqlyygl"*42ÅE"- 47ÅE+"nwd"y"nqf>yeg"*4ÅE"- :ÅE+0

Rq"tq|ekg e|gpkw"rt|{iqvqycp{"tq|vy»t"rtqfwmvw"nge|pke|giq"P [ZVJTCEKU y"uvt|{mcyeg"fq" kphw|lk"rqykpkgp"d{ "pcv{ej okcuv"rqfcp{"- pkg"pcng {"iq"rt|gejqy {yc 0"Wszelkie ngy {mqt|{uvcpe resztki produktu pcng {"y {t|wek 0

80 \ cyctvq "qrcmqy cpkc" k" kppg" kphqt o celg

Eq" | cykgtc" ngm" NYXTHRACIS

- Uwdvcpel "e|{pp "ngmw"lguv"qdknvqumucmu { ocd0"3" on"mqpegpvtcvw" | cykgtc"322" o i" qdknvqumucmu { ocdw0" Lg fpc" hkqmc" q" qdl vq ek"8" on" | cykgtc"822" o i" qdknvqumucmu { ocdw0
- Rq|quvcfg"umfc fpmk"vq<"jkuv { f {pc."uqtdkvqn"*G642+."rqnuqtdcv":2"*G655+."m ycu"solny *G729+"k" yqfqtqvnpgpm"uqfw"*G746+0"Rcvt|"vcn g"rwpmv"4"šNgm"P [ZVJTCEKU |cykgtc"uqtdkvqn"*G642+0

Lcm" y {in fc" ngm" NYXTHRACIS k" eq" | cykgtc" qrcmqy cpkc

P [ZVJTCEKU oc" rquvc "rt|g|tqe|{uvgiq"nwd"qrcnk|wl eg iq."dgl dctypgiq."dnfcq »évgiq"nwd" dnfcqdt |qycyq »évgiq"mqpegpvtcvw"fq"urqt| f|cpkc"tq|vyqtw0
P [ZVJTCEKU lguv"fqv rp{"y"qrcmqycpkcej"|cykgtcl e{ej"3"hkqnm 0

Rqf okv" qf r qy kgf | kncp {

UHN"Rjct o cegwkecnu" Fgwwuejncpf" I od J
Ockg-Eurie-Uvtcuug":
9;75;"N3/4ttcej
Pkgoe{

Y {vy»tec"

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Fvc" quvcvpgl" cmvwnk | cell" wnqvmk<

Vgp"ngm" | quvcf" fqrwu | e|qp {"fq" qdtqvw" y" y {l vmqy {ej"qmank|pq ekcej0"Q|pce|c"vq." g" |g" y | in fw"pc" t|cfmkg" y {uv r qycpk"ejqtqd {"k" | "rqyqf»y"gv {e|p {ej"pkg"d {éq" o q nkyg" w | {umcpgk" r gfpgl" kphqt o celk" fq {e| egl"vgiq"ngmw0
Gwtqrglumc" C igpelc" Ngm»y" f qm qpc" eq" tqmw" rt|gin fw"yu | {umkej"pqy {ej" kphqt o celk" q" ngmw" k" y" tc |kg" mqpkge|pq ek"vtg "vgl"wnqvmk" | quvcvpgl" | cmvwnk | qycpc0

Kppg" t» ffc" kphqt o celk

U|e|gi»éqyg" kphqt o celg" q" v { o "ngmw" | pclfwl "uk "pc" uvtqpk" kpvgtpgvqy gl" Gwtqrglumkgl" C igpelc" Ngm»y" [jvvr<ll y y y 0g o c 0gwtqrc0gw0](#) \ pclfwl "vc o" t» y pkg "nkpmk" fq" uvtqpk" kpvgtpgvqy {ej"q t|cfmkej" ejqtqdcej" k" urquqdcej" nge|gpkc0

Vc"wnqvmc"lguv"fqv r pc"yg"yu | {umkej"1 | {mcej" WGIGQ I "pc" uvtqpk" kpvgtpgvqy gl" Gwtqrglumkgl" C igpelc" Ngm»y0

Yk egl" kphqt o celk" < [y y y 0qdknvqzczk o cd-uhn0gw](#) Fqfc "mqf" ST"