

ANEXA I

REZUMATUL CARACTERISTICILOR PRODUSULUI

Produsul medicinal nu mai este autorizat

Ceguv" o gfkce o gpv"nceg"qdkgevw"wpqk" o qpkvqtk | tk"uwrnk o gpvctg0"Ceguv"nwetw"xc"rgt o kyg"
kfgpvkhkectgc"trkf "fg"pqk"kpht o c kk"tghgkvqctg"nc"uki wtcp 0"Rtqhgukqpk vkk"fkp"fq o gpkwn"u p v kk"uwpv"
twic k"u "trqvtg|g"qtkeg"tgce kk"cfxgtug"uwurgevcv0"Xg|k"rev0 60: "rgpvtw" o qfwn"fg"trqvtctg"c"tgce kknqt"
cfxgtug0

1. FGPWOKTGC"EQOGTEKCN "C"OGFKECOGPVWNWK

NYXTHRACIS 100 o il o n"eqpepvtcv"rgpvtw"uqnw kg"rgthw|cdkn

2. EQORQ\K KC"ECNKVCVKX " K"ECPVKVCVKX

Wp" o n"fg"eqpepvtcv"eqp kpg"qdknvqzczk o cd"322 o i0"
Un flacon de 6 o n"eqp kpg"qdknvqzczk o cd"822 o i0

Qdknvqzczk o cdwn"guvg"rtqfwu",p"egnwn" o wtkpg" I U-PU2"fg" o kgnq o "rtkp"vgj p q n i k c"CFP"tgeq o dkpcpv0

Gzkrkpgv"ew"ghgev"ewpquewv

Un ml dg"eqpepvtcv"eqp kpg"uqtdkvqn"58 o i0

Rgpvtw"nkuc"vwwvtqt"gzkrkpg knqt."xg|k"rev0 8030

3. HQTOC"HCTOCEGWVKE

Eqpepvtcv"rgpvtw"uqnw kg"rgthw|cdkn "*eqpepvtcv"invtkn+0"
NYXTHRACIS guvg"q"uqnw kg"fg"nc"nk o rfg"nc"qrcnguegpv ."fg"nc"kp eqnqt "nc"i ndwkg"ucw"w qt" o ctqpkw-
i ndwkg"ectg"rqcvg"eqp kpg"q"ugtkg"fg"rctvkewng"rtqvgkeg"ew"curgev"fg"nc"vtcpurctgpv"nc"cmd"*ectg"xqt"hk"
,p"fg"rtcvg"rtkp"hnvtctgc"nc"pkxgnwn"nkpkk"fg"rgthw|kg+"ew"xcnqctgc"r J"fg"7.7" k"xcnqctgc"qu o qncnkv kk"
,pvtg"499" k"52: o Qu o lmi0

4. DATE CLINICE

4.1 Kpfkcc kk"vgtcr gwvkeg

NYXTHRACIS guvg"kp fkecv",p"eq o dkpc kg"ew"cpvk o ketqdkgpg"cf gexcvg"rgpvtw"vtcv o gpvwn"cpvtczwnwk"
fg"kpjcnc kg"ecw|cv"fg" *Bacillus anthracis* nc"vqcvg"ecvg iqtckng"fg"x-tuv "*xg|k"rev0 703+0

NYXTHRACIS guvg"kp fkecv"rgpvtw"c"cu ki wtc"rtqhknczck"rqv-gzrwpgtg", o rqtxc"cpvtczwnwk"fg"
kpjcnc kg"nc"vqcvg"ecvg iqtckng"fg"x-tuv .",p"ec|wn",p"ectg"pw"gzkuv "cnvg"qr kwpk"vgtcr gwvkeg"ucw"pw"uwpv"
cf gexcvg"*xg|k"rev0 703+0

4.2 Fq|g" k" o qf"fg"cf o kpkvttctg

NYXTHRACIS vtgdwkg"cf o kpkvttcv"k o gfkcv"eg"uvctgc"enkpke "q"ko rwpq0

Tratamentul farmaceutic" k" o qpkvqtk|ctgc"cf gexcvg"vtgdwkg"u "hkg",pvqvf gcvpc"fkurqpkdkng",p"ec|wn",p"
ectg."fwr "cf o kpkvttctg"fg"NYXTHRACIS uwtxkpg"wp"gxgpk o gpv"fg"vkr"cpchkcnczk0

Fq|g

Fq|c"tgeq o cpfcv "fg"NYXTHRACIS nc"rcekpg k"cfwn k"ew"itgwvcgc"fg" o kpk o w o "62 mi"guvg de
16 o il mknqitc o "itgwvcg"eqtrqtcn "cf o kpkvttcv",p"rgthw|kg"kpvtcxgpqcu "wpke 0" Fq|c"tgeq o cpfcv "fg"

NYXTHRACIS nc"rcekgp k"cfwn k"ew" i tgvvcvgc"uwd"62 mi" guvg"fg"46 o ilmi"cf o kpkuvtcv ",p"rgthw|kg" kpvtxgppcu "wpke 0"

Maينة de administrarea de NYXTHRACIS ug"tgeq o cpf "rtg o g fkec kg"ew"wp"cpkj kuvc o kpke"*xg|k" rev0 606" k"60: +0"

Rgpvtw"clwuv tk"cng"fq|gk"fkp"ecw|c"tgce kknqt"cuqekcvg"cf o kpkuvt tkk",p"rgthw|kg"*TCR+"xg|k"vedgnwn 30

Vcdgnwn 3<"Clwuv tk"cng"fq|gk"fg"qdknvqzczk o cd"fkp"ecw|c"tgce kknqt"cuqekcvg"cf o kpkuvt tkk",p"rgthw|kg

Ugxtkvcvgc"TCR"	Clwuvctgc"fq gk
Tgce kg"cuqekcv cf o kpkuvt tkk",p"rgthw kg"fg"itcf" 1-5	Ug"qrtg vg"rgthw kc"ew"qdknvqzczk o cd" k"ug"cf o kpkuvtgc "vtvc o gpv"fg"uwu kpgtg0 "p"ec wn"rtk o gk"crctk kk"c"wpwk"gxgpk o gpv"fg"itcf"5"fg"vkr"tgu"ktc kg" wkgv vqctg." dtqj qurcu o "ucw"wtvkectkg"i gpgtcnk cv ".qdknvqzczk o cdwn"ug"qrtg vg"fg"ghkpkvxx0 "p"ec wn"tgekfxgk"wpwk"gxgpk o gpv"fg"itcf"4"fg"vkr"tgu"ktc kg" wkgv vqctg"ucw" wtvkectkg"ucw"cn"tgekfxgk"qtke tq"uk o rvq o g"fg"itcf"5".qdknvqzczk o cdwn"ug" qrtg vg"fg"ghkpkvxx0" "p"egngncvg"ukvwc kk."fwr "tg o kukwpgc"eq o rngv "e"uk o rvq o gnat."rgthw kc"ug"rqcvg" rgnwc"ew"q"xkvg "ew"72 " o ck" o ke "fge"v xkvg c"vvknk cv ",pckpv"fg"qrtktgc" rgthw kgk0"p"cdugp c"wpqt"uk o rvq o g"cuqekcv"cf o kpkuvt tkk",p"rgthw kg."xkvg c"fg" cf o kpkuvtctg"c"rgthw kgk"guvg"fguetku",p"vedgnwn 50" Ug"xc"cf o kpkuvtc"rtg o g fkec kg0
Tgce kg"cuqekcv cf o kpkuvt tkk",p"rgthw kg"fg"itcf" 4	Ug"qrtg vg"ko g fkec"rgthw kc"ew"qdknvqzczk o cd0 Ug"cf o kpkuvtgc "vtvc o gpv"fg"uwu kpgtg0 Qdknvqzczk o cdwn"ug"qrtg vg"fg"ghkpkvxx0"

I twrg"urgekng"fg"rcekgp k

Vstnici

Pw"guvg"pgeguct "clwuvctgc"fq|gk"nc"rcekgp kk"ew"x-tuvc"× 87 fg"cpk"*xg|k"rev0 704+0

Eqrkk" k"cfqnguegp k

Fq|c"tgeq o cpf cv "ne eqrkk" k"cfqnguegp k"ug"uvcdkng vg",p"hwpe kg"fg"itgvvcvg."c c"ew o "ug"ctcv ",p" tabelul 4"fg" o ck"lqu0

Vcdgnwn 4<"Fq|g"tgeq o cpf cv"fg"qdknvqzczk o cd"nc"eqrkk" k"cfqnguegp k"*fq|g"uvcdkng"p"hwpe kg"fg" itgvvcvg"eqtrqtcn +

I tgvvcvg"eqtrqtcn "*mi+	Fq "o ilmi" itgvvcvg"eqtrqtcn +
> 40	16
> 37"r-p "nc"62	46
Ö37	54

Mod de administrare

Qdknvqzczk o cdwn"ug"cf o kpkuvtgc| ",p"rgthw|kg"kpvtcxgppcu "ew"fwtcvc"fg";2"fg" o kpwvg0

Rtgecw kk"ectg"vtgdwkg"nwcvg",pckpv"fg" o cprwnc"tg"ucw"cf o kpkuvtctgc"ogfkec o gpvwmwk

Pw"ug"ci kv "hnceqpw n0" Qdknvqzczk o cdwn"ug" fknwgc| ",p"uqnw kg"fg"enqtw "fg"uqfkw"; o ilon"2.; ' +"
 rgpvtw"rtgrctcvg" kplgevc dknng", pckpv g"fg"cf o kpkvctctg", p"rgthw|kg"kpvtcxgpqcu "xg|k"rev0 808+0"

Qdknvqzczk o cdwn" fknwcv" rgpvtw"cf o kpkvctctg", p"rgthw|kg"kpvtcxgpqcu "ug"cf o kpkvctctg| ",p"rgthw|kg"ew"
 fwtcv"fg"; 2 fg"okpwwg."nc"xkvg|c"fg"rgthw|ctg"fguetku ",p"vcdgnwn 5."hqnuqkpf"q"rwp i "fg"rgthw|kg"ucw"q"
 ugtpi "rgpvtw"rgthw|kg" k"wp"hnvtw", peqtrqtcv"ew"fk o gpukwpgc"fg"2.44 o ketqpk0"

Rcekp k"vtgdwkg" o qpkvqtk|c k"cvgpv" rgpvtw" c"ug" fgrkuvc"ug o pngn" k"uk o rvq o gng"tgce kknqt"fg"
 jkrgtugpukdknkv cvg"rg"vqcv "fwtcv"rgthw|kgk" k"vk o r"fg"okpko w o"q"qt "fwr "cf o kpkvctctg"xg|k"rev0 606+0"
 "p"ec|wn"crctk kgk"tgce kknqt"cuqekcv g"cf o kpkvct tkk",p"rgthw|kg"ug"rtqegfgc| "eqphqt o"kpfkcc kknqt"fkp"
 tabelul 30

Nkpkc"kpvtcxgpqcu "ug"xc"ur nc"ew"uqnw kg"fg"enqtw "fg"uqfkw"fg"; o ilon"2.; ' +"
 rgpvtw"rtgrctcvg" kplgevc dknng" fwr ",pejgkgtg"rgthw|kgk"kpvtcxgpqcu g0)

**Vcdgnwn 3: Doza, xqno w n"rgthw|cdkn"vqvcn" k"xkvg|c"cf o kpkvct tkk",p"rgthw|kg"fg"qdknvqzczk o cdwn"
 p"hwpe kg"fg"itgwvcvg"eqtrqtcn**

I tgwvcvg"eqtrqtcn "mi+ *fg g"uvcdknkv g",p"hwpe kg"fg"itgwvcvg" eqtrqtcn +	Xqno "rgthw cdkn"vqvcn" *on+ *rwp i "ucw"ugtkpi" rgpvtw"rgthw kg"	Xkvg c"cf o kpkvct tkk",p" rgthw kg *onlqt +
> 40 mi"ucw"cfwnv"38 o ilmi+		
> 40	472	389
> 15 mi" k"62 mi"46 o ilmi+		
53"- 40	472	389
16 - 52	100	89
037 mi"54 o ilmi"itgwvcvg"eqtrqtcn +		
11 - 37	100	89
7"- 10	72	55.5
5.3"- 6.;	47	39
4.3"- 5	42	3505
3.3"- 4	37	10
03	9	6.9

, Rgpvtw"kpvtwe kwpk"rtkxkf" fknwctgc" o gfkcc o gpvwnwk" k"vknk|ctgc"rwp i k"ucw"ugtkp i k"rgpvtw"rgthw|kg"
 ,pckpv g"fg"cf o kpkvctctg."xg|k"rev0 8080

4.3 Eqpvtckpfkcc k

Jkrgtugpukdknkv cvg"nc"uwdvcp c"cevx "ucw"nc"qtkectg"fkpvtg"gzekrkp k"gpw o gtc k"nc"rev0 8030

4.4 Cvgp kqp tk" k"rtgecw k"urgekng"rgpvtw"vknk|ctg

Trasabilitate

Rgpvtw" c"cxgc"uwd"eqpvtq"vtcu dknkv cvg" o gfkcc o gpvngq"dkqnq i keg."pw o gng" k"pw o tw n"nqvw nwk"
 o gfkcc o gpvwnwk"cf o kpkvctcv"vtgdwkg",ptg i kvctcv g"ew"cvgp kg0)

Tgce k"cuqekcv g"cf o kpkvct tkk",p"rgthw|kg."tgce k"fg"jkrgtugpukdknkv cvg" k"cpchknczkg

Tgce kknng"cuqekcv g"cf o kpkvct tkk",p"rgthw|kg|fg"jkrgtugpukdknkv cvg"cw"huq"qdugtxcvg"htgexgpv",p"uvw fknng"
 enkpeg"ghgevcvg"ew"qdknvqzczk o cdwn"ug"cf o kpkvctctg| ",p"wpkv k" o qpkvqtk|cv g"fg"rgtuqpcn"kpvtwkv."cx-pf"nc"
 fkurq|k kg"fqv tkng"pgeguctg"rgpvtw" c"i guvkqpc"cpchknczkc0"Rcekp k"vtgdwkg" o qpkvqtk|c k"cvgpv"rg"vqcv "
 fwtcv"cf o kpkvct tkk"rgthw|kgk" k"vk o r"fg"okpko w o"q"qt "fwr "cf o kpkvctctg0)

Cx-pf",p"xfgtg"e "uvwfkng"enkpeg"cw"quv"ghgevcvg"nc"xqnpvctk"u p vq k."rgthw|kng"ew"qdknvqzczk o cd" cw"quv"qrtkv",p"o qo gpvwn"crctk kgk"qtke twk"vkr"fg"tgec kg0"Rg"dc|c"gzrgtkgp gk"cuqekcvg"vwnk| tkk"cnvt" cpvkeqtrk"o qpqenqpcnk",p"vtvc o gpvwn"wpqt"chge kwpk"ugxgtg.",p"i gpgtcn"cf o kpkuvtctgc"rgthw|kng"r qcvg"hk" hkpcnk|cv ",p"ec|wn",p"ectg"ug"rtqegfgc| "eqtgurwp| vqt0"p"ec|wn"crctk kgk"tgec kknqt"cuqekcvg" cf o kpkuvt tkk",p"rgthw|kg"ug"rtqegfgc| "eqphqt o "kpfkcc kknqt"fkp"vcdgnwn 30"

Maite de administrarea de ob knvqzczk o cd"ug"tgeq o cpf "rtg o gfkec kg"ew"wp"cpvk jkuvc o kpkc."ew o este fkhgpkj kftc o kp "xg|k"rev0 604+0"p"uvwfkng"enkpeg"ghgevcvg"ew"qdknvqzczk o cd."fkhgpkj kftc o kpc"e"quv" cf o kpkuvtcv "ew"52 fg"o kpwvg",pckpvg"fg"cf o kpkuvtctgc"qdknvqzczk o cdwnwk0"Rtg o gfkec kc cu un cpvk jkuvc o kpkc"pw"ctg"ghge"fg"rtxgp kg"cpchkcnczkg" k"r qcvg"cuwepfg"ucw"co-pc"fgdwwn"uk o rvq o gnt" tgec kknqt"fg"jkr gtugpukdkncvcvg0

Ogpkpikvc"fkp"cpvtcz

Qdknvqzczk o cdwn"pw"vtcxgtugc| "dctkgtc"jg o cvqgpeghcnke "k"pw"r qcvg"hk"vwnk|cv",p"rtgxgpkgtc"ucw",p" vtcv o gpvwn"o gpkpikvkg"ectg"crctg"ec"q"eq o rnkcc kg"c"cpvtczwnwk0"

Eqrkk" k"cfqnguegp k

Nu s-cw"ghgevcv"uvwfk"rtxkpf"rtqhkwn"fg"uk i wtcp "ucw"htc o ceqfkpe o ke "cn"qdknvqzczk o cdwnwk"nc"eqrkk" k"cfqnguegp k"xg|k"rev0 704+0

Kpvtce kwpk"ew"tg|ultatele testelor de laborator

Gzrwpgtgc"nc"NYXTHRACIS r qcvg"kpvtgthgc"ew"vguvng"ugtnq i keg"eqtgncvg"ew"cpvtczwn0

Sorbitol

Un ml de NYXTHRACIS eqp kpg"58 o i"fg"uqtdkvn"xg|k"rev0 4" k"803+0" Vwnk|ctgc"o gfkec o gpvngt"ectg"eqp kp"uqtdkvn"r qcvg"hk"letan ",p"ec|wn"cf o kpkuvt tkk"rg"ecng" kpvtcxgpqcu "nc"uwdkge k"ew"kpvtgtpc "gtgfkvtc"nc"htwevq| "KGH+0"Qdknvqzczk o cd"pw"ug"cf o kpkuvtgc| "nc"rcekp k"ew"KGH"ew"gzegr kc"ukvwc kknqt",p"ectg"guvg"cdunwv"pgeguct"fkp"ecw|c"ukvwc kgk"enkpeg" k"pw" gzkuv "cnvg cnvtpcvkxg0"Ug"xc"hecg"q"cpce pg| "fgvncv "c"uk o rvq o gnt"KGH"nc"hkgectg"rcekp",pckpvg"fg" cf o kpkuvtctgc"ceguvwk"o gfkec o gpv0

Uwictkk" k"eqrkk"fg"x-tuv "hctvg"o ke "ew"x-tuvc"uwd"4"cpk+"cw"wp"tkue"crctvg."fgqctgeg"guvg"rqukdkn"u " pw"hk"quv",pe "fkci pquvkec k"ew"KGH0"

Sodiu

Ceguv"o gfkec o gpv"eqp kpg"sodiu o ck"rw kp"fg"3 o o qn"45 o i+"rgt hnccq"fg"8"o n."cfke r tceve""nu eqp kpg"uqfkw"0

4.5 Kpvtce kwpk"ew"cnvg" o gfkec o gpvg" k"cnvg"htq o g"fg"kpvtce kwpg

Ekr tqhnqzcep

Tr -wp"uvwfk"rtxkpf"kpvtce kwpkng"o gfkec o gpvcug."62"fg"uwdkge k"cw"rtk o kv"q"fq| "wpe "fg" qdknvqzczk o cd."cf o kpkuvtcv ",p"o qpvtgtrkg"ucw"eqpeq o kvgpv"ew"ekrtqhnqzcep 0" Fqw |gek"fg"uwdkge k" cw"rtk o kv"qdknvqzczk o cd"cf o kpkuvtcv",p"o qpvtgtrkg."kct"42"fg"uwdkge k"cw"rtk o kv"qdknvqzczk o cd"cuqekc" ew"ekrtqhnqzcep "vk o r"fg";" |kng0"cf o kpkuvtctgc"fg"qdknvqzczk o cd"38 o i lmi",p"rgthw|kg"kpvtcxgpqcu " ,pckpvg"fg"cf o kpkuvtctgc"rgthw|kgk"kpvtcxgpqcu"ew"ekrtqhnqzcep "ucw"fg"cf o kpkuvtctgc"qtcn ."fg"fqw " qtk"rg"|k."fg"ekrtqhnqzcep "eq o rtk o cvg"pw"c"kpvnwgp cv"rtqhkwn"htc o ceqekpgvke"cn"qdknvqzczk o cdwnwk0"p" mod similar."qdknvqzczk o cdwn"pw"c"kpvnwgp cv"rtqhkwn"htc o ceqekpgvke"cn"ekrtqhnqzcep"kgk"cf o kpkuvtcv"rg" ecng"qtcn "ucw"kpvtcxgpqcu 0

Nu s-cw"ghgevcv"cnvg"uvw fkk"rtkxkf"kpvgtce kwpkng0"fgqctgeg"qdknvqzczk o cdwn"guvg"wp"cpvkeqtr"
o qpqenqpcn."tkuewn"fg"kpvgtce kwpk"guvg"tgfwu0

608 Hgtvknkvcvgc."uctekpc" k"cn rvctgc

Sarcina

Fcvng"rtqxpkyg"fkp"vknk|ctgc"qdknvqzczk o cdwnwk"nc"hg o gkng"i tckxfg"uwpv"kpzkuvgpvvg."pu "ug"kg hcrvwn"
e "Ki I"wo cp "vtcxgtugc| "rncegpvc0

Uvwfknkng"nc"cpk o cng"pw"cw"gxkfgp kcv"ghgevg"vqzkeg" f wp vqctg"fttgevg"ucw"kpfttgevg"cuwrte"hwpe kgk"fg"
tgrtqfwegtg"xg|k"rev0 705+0

Ec"o uwt "fg"rtgecw kg."guvg"fg"rtghgtcv"u "ug"gxkvg"vknk|ctgc"NYXTHRACIS ,p"vk o rwn"uctekpkk0

Cn rvctgc

Pw"ug"ewpqc vg"fce "qdknvqzczk o cdwn"ug"gzetgv "p"ncrvngng"wo cp0"Ug"ewpqc vg"e "Ki I"wo cp "ug"gzetgv "
p"ncrvngng"wo cp"p"rtk o gng"|kng"fwr "pc vgtg" k"uecfg"r-p "nc"eqpegpvtc kk"okek"ko gfkcv"fwr "cegucv0"p"
eqpugekp .pw"ug"rqcvg"zgenwfg"wp"tkue"rgpvtw"pqw-p uew kk"cn rvc k"rg"fwtcvc"cegucv"uewtv"kpvgtxcn"fg"
vk o r0"Wvngtqkt."vknk|ctgc"qdknvqzczk o cdwnwk"rqcvg"hk"cxwv "p"xgfgtg",p"vk o rwn"cn rv tkk"pw o ck"fce "
uvctgc"enkpkc "k o rwpg"vtcvc o gpvwn0

Hgtvknkvcvgc

Nu s-au ghgevcv"uvw fkk"rtkxkf"hgtnknkvcvgc"ew"qdknvqzczk o cd0

4.7 Ghgevg"cuwrte"ecrcekv kk"fg"c"eqpfweg"xgjkewng" k"fg"c"hnqquk"vknkclg

Qdknvqzczk o cdwn"rqcvg"cxgc"q"kpnhwgp "oke "cuwrte"ecrcekv kk"fg"c"eqpfweg"xgjkewng"ucw"fg"c"hnqquk"
vknkclg"fgqctgeg."fwr "cf o knistrarea de NYXTHRACIS."ct"rwwgc"uwtxgpk"eghcngg."c o g gnk."qdqugen " k"
x tu vwtk"xg|k"rev0 60:+0

4.8 Tgce kk"cfxgtug

Tg|w o cvwn"rtqhkwnwk"fg"ukiwtecp

Ukiwtecp c"cf o kpkuvt tkk"fg"qdknvqzczk o cd"chquv"uvwfkev "pw o ck"nc"uwdkge k"cfwn"ku p vq k0

Ukiwtecp c"qdknvqzczk o cdwnwk"chquv"gxcnwcv "nc"542 fg"uwdkge k"u p vq k"*ew"x-tuvc",pvtg"3:" k"9;"fg"cpk+
vtcvc k"ew"wpc"ucw"fqw "fq|g"fg"38 o ilmi"cf o kpkuvtcvg"kpvtcxgppqu",p"vtgk"uvwfkk"enkpkcg0

Rgt"vqvcn."472"fkp"egk"542 fg"uwdkge k"cw"rtk o kv"q"fq| "wpke "fg"38 o ilmi"fg"qdknvqzczk o cd0"Tgce kk"
cfxgtug"cuqekcvg"ew"jkrgtugpukdknkvcvgc"*kpenwukx"gtwr kk"ewvcpcv"vtcp|kvqtkt+"cw"cr twv"nc"; "441472+
fkp"ceg vk"uwdkge k" k"u-c",ptgi kvtcv"wp"ec|"fg"cpchknkczkg",p"vk o rwn"rgthw|kgk0"cf o kpkuvtctgc"rgthw|kgk"c"
hquv",pvtgtwrv "nc"5' '*:1472+"fkp"ecw|c"tgce kknqt"fg"jkrgtugpukdknkvcvg"ucw"cpchknkczkg0

Egng"o ck"htgexgpvg"tgce kk"cfxgtug"tcrqtvcvg"cw"hquv"eghcngg"*6 ' .";1472+."rtwtkv"*6 ' .";1472+ k"wtvkectkg"
*4 ' .".81472+0

Egng"o ck"htgexgpvg"tgce kk"cfxgtug"qdugtxcvg"rg"fwtcvc"rtk o gnqt"vtgk"qtg"fwr "kpk kgtgc"cf o kpkuvt tkk"
rgthw|kgk"cw"hquv"rtwtkv"*p?9="4.: ' +."wtvkectkg"*p?8="4.6 ' +."eghcngg"*p?6="3.8 ' +."gtwr kg"ewvcpcv "
vtcp|kvqtkg"*p?5="3.4 ' +."vwug"*p?5="3.4 ' +."c o g gnk"*p?5="3.4 ' +"*kpenwfg"co g gcn " k"co g gcn "
rquvwtcn +0)

Wt o vqctng"tgce kk"cfxgtug"ugxgtg"cw"cr twv"rg"fwtcvc"rtk o gnqt"vtgk"qtg"fwr "cf o kpkuvtctgc"rgthw|kgk"
wtvkectkg"*p?3."2.6 ' +."rtwtkv"*p?3."2.6 ' + k"fqtcunig"*p?3."2.6 ' +0

Tgce kc"cfxgtu "qdugtxcv "egn"o ck"htgexgpv",p"kpvgtxcnwn"ewrtkpu",pvtg"5" k"46 fg"qtg"fwr "kpk kgtgc"
cf o kpkuvt tkk"rgthw|kgk"chquv"eghcngg"*p?5="3.4 ' +0

Nkuvctgce kknqt"cfxgtug uwd"htq o "fg"vcdgn

Vcdgnwn"6"rtg|kp "tgce kknq"cfxgtug"qdugtxcvg",p"cuqekgtg"ew"qdknvqzczk o cd"nc"egk"472"fg"uwdkge k" u p vq k"ectg"cw"rtk o kv"q"fq| "kpvtcxgpqcu "wpke "fg"38 o ilmi"qdknvqzczk o cd."itwrcvg"rg"crctcvg." ukuv o g" k"qti cpg" k",p"hwpe kg"fg"htgexgp 0

Htgexgp c"tgce kknqt"cfxgtug"guvg" fghkpv "fwr "ewo"wt o gc| <"hqctvg"htgexgpvg"*x 3132+."htgexgpvg" *x 31322" k"> 3132+ "k" o ck"rw kp"htgexgpvg"*x 313 222" k"> 31322+0"p"ecftwn"hkge tgg"ecvgiqtkt"fg" htgexgp ."tgce kknq"cfxgtug"uwpv"rtg|gpvcvg",p"qt fkgpc"fguetgue vqctg"cu"ugxgtkv kk0

Vcdgnwn 6<"Tgce kknq"cfxgtug"trctvcvg"nc"uwdkge k"cfwn k"u p vq k

Encukhkectg"OgfFTC"rg"crctcvg." ukuv o g" k"qti cpg	Htgexgpvg"	Ock"rw kp"htgexgpvg
Vwndwt tk"cnq"ukuv o wnw"ko wpkvet		Tgce kk"cpchkcctkg Jkrgtugpukdknvcvg
Vwndwt tk"cnq"ukuv o wnw"pgtxqu	Cefalee	C o g gc C o g gc "rquwten Jkrqgug kg
Vwndwt tk"qewnctg		Hqvhqdkg
Vwndwt tk"cewuvkeg" k"xguvkdwnctg		Fkueqphqtv"nc"pkxgnwn"wtge jkk
Vwndwt tk"xcuewnctg		Hngdkv
Vwndwt tk"tguurktcvqtkk."vqtcekeg k" o gfkcuvkpcng	Tuse	Ktkvc kg"htkpi kcp " Fkuhqpkg" Eqp i guvkg"ukpwucn " Fkurpgg
Vwndwt tk"i cuvtqkpvguvkpcng		Fwtgtg"nc"pkxgnwn"dw gnqt
Chge kwpk"ewwpcvg" k"cnq" guwvwnwk" subcutanat	Rtwtkv."wtvkectkg. gtwr kg"ewwpcv " tranzitorie	Fgt o cvkv "cngtike " Gtwr kg"ewwpcv "vtcp kvqtkg" i gpgtenk cv " Gzhqnkgtg"rkgnk
Vwndwt tk"o wuewnq-ue jngvkeg k"cnq" guwvwnwk"eqplwpevx		Fwtgtg"nc"pkxgnwn"gzvtg o kv knqt" Urcu o g" o wuewnctg" Eqpvtce kk" o wuewnctg"kpqnuwpvctg" Fwtgtg"nc"pkxgnwn" o czkctgnqt"
Vwndwt tk"i gpgtcng" k"nc"pkxgnwn" locului de administrare	Fwtgtg"nc"nqewn" cf o kpkvut tkk"rgthw kgk	Fwtgtg" Fkueqphqtv"vqtceke" Htkuqcpvg" Qdqgcn " Gfg o "nc"nqewn"cf o kpkvut tkk" rgthw kgk" Cpikp "rgevqtcn "fg"cnv "ecw ." fkhgtkv "fg"egc"ectfke " Sensibilitate Fwtgtg"nc"pkxgnwn"nqewnwk"fg" ,p grctg",p"xgp

Fguetgtgce"tgce kknqt"cfxgtug"ugnge kqpcvg

Jkrgtugpukdknvcvg" k"cpchkcctkg

Tgce kknq"cfxgtug" trctvcvg"nc"egk" : " uwdkge k"nc"ectg" cf o kpkvutctg" rgthw|kgk" ew" qdknvqzczk o cd" c" hquv" pvtgtrwv " fkp"ecw|c" wpqt" rqukdng" tgce kk" fg" jkrgtugpukdknvcvg" cw" kpenwu" wtvkectkg. " gtwr kk" ewwpcvg" vtcp|kvqtkg."vwug."rtwtkv."c o g gnk."ktkvc kg"htkpi kcp ."fkuhqpkg."fkurpgg" k"fkueqphqtv"nc"pkxgn"vqtceke0" Tguvwn" uwdkge knqt"ew"tgce kk"fg" jkrgtugpukdknvcvg"cw"rtg|gpvcv"ew"rtge fgtg"uk o rvq o g"ewwpcvg"ew o "sunt rtwtkv" k" gtwr kk" ewwpcvg" vtcp|kvqtkg."ket" 8" uwdkge k" cw" trctvcv" vwug0" Gxgpk o gpvwn" fg" vkr" cpchkcctkg" c" hquv" ectcevgtk|cv" fg" gtwr kg" ewwpcv " vtcp|kvqtkg" ew" curgev" fg" wtvkectkg" fkhw| ." rtwtkikpqcw ." crtqerg" i gpgtenk|cv ." kpenwux" nc" pkxgnwn" eghgk." vqtcegnwk." urcvgnwk." cdfq o gpvwnk." o g o dtgnqt" uwrgtkqctg" k" kphgtkqctg."fkurpgg" k"vwug0

Pw"cw"gzkuvcv"fqxg|k"e "tgce kknq"fg"jkrqtugpukdnkvcvg" k"gtwr kknq"ewwpcvvg"vtcp|kvqtkk"cw"hqvu"rtqxqecvg" fg"gnkdgtctgc"fg"ekvqmkpg="pw"u-cw"qdugtxcv"o qfkhke tk'tgnxcpvg"fkp"rwpev"fg"xfgtg"enkpkc"cnq"ceguvqtc" fkp"wt o 0

Kowpqi gpkvcvg

Hqt o ctgc"fg"cpvkeqtrk"anti-qdknvqzcck o cd" c"hqvu" gxcnvcv "nc"vq k"uwdkge kk"ectg"cw" rtk o kv" wpc"uow"fqw" fq|g"fg"qdknvqzcck o cd",p"vtgk"uvwfkk"enkpkcg0"Qrv"uwdkge k"]4.7 ' '*:1542+_ectg"cw" rtk o kv"egn"rw"kp"q"fq| " kpvtxgpqcu " fg" qdknvqzcck o cd" cw" rtg|gpvcv" t urwpu" rtkp" cpvkeqtrk" cpti-vtcvc o gpv" *CCV+ euqekcv" vtcvc o gpvwnwk"rq|kvx0" Fkp"rwpev"fg"xfgtg"ecpvkvcvx."vkvwtknq"cw"hqvu"tgfwug."xctkpf",pvtg"3<42" k"3<5420" Pw"cw"gzkuvcv"fqxg|k"cnq"o qfkhke tkk"rtqhknnwk"ht o ceqekpgvke"ucw"rtqhknnwk"fg"vqzkevcvg"nc"uwdkge kk"ew" t urwpu"fg"vkr"CCV0

Tcrqtvtgc"tgce kknq"cfxgtug"uwurgevcvg

Tcrqtvtgc"tgce kknq"cfxgtug"uwurgevcvg" fwr "cwvqtk|ctgc"o gfkco gpvwnwk"guvg"ko rqtvcv 0" Ceguv"nwtw" rgt o kvg"o qpkvqtk|ctgc"eqpvkpw "c"tcrqtvwnw"dgphkekwltkue"cn"o gfkco gpvwnwk0"Rtqhgukqpk vkk"fkp" domenkn"u p v kk"uwpv"twic k'u "tcrqtvg|g"qtkg"tgce kg"cfxgtu "uwurgevcvg" rtkp"kpvtg o g fkn" **sistemului pc kqpcn"fg"tcrqtvtgc."cuvhgn"ew o "guvg"o gp kqpcv",p" [Cpgzc X0](#)**

4.9 Uwrctfq|cl

'p"ec|"fg"uwrctfq|cl."rcekgp kk"vtgdwkg"o qpkvqtk|c k"rgpvtw"cu"ug"fg"rkuvc"ug o pgnq"ucw"uk o rvq o gng" gxgpk o gpvgnq"cfxgtug)

5. RTQRTKGV K"HCTOCEQNQ I KEG

5.1 Rtqrktgv k"ht o ceqfkc o keg

I twrc"ht o ceqvtcrgwvke <"Ugtwk"ko wpg" k"ko wpgqinqdwnkpg."ko wpgqinqdwnkpg"urgekheg."eqfwn"CVe<" L28DD44

Ogecpku o "fg"ce kwpg

Qdknvqzcck o cdwn"guvg"wp"cpvkeqtr"o qpqenqpcn"ectg"ngci "cpvki gpw"rtqvgevt*"CR+"cn"*B. anthracis*0" Qdknvqzcck o cdwn"kpjkd "ngictgc"CR"fg"tgegrvqtkk"fg"nc"pkxgnwn"egnwngnqt.",o rkgfke-pf"r vtwpfgtgc",p" egnwn "c"hecvqtwnw"ngvcn"cn"cpvtczwnwk" k" c"hecvqtwnw"gfgo cvqu."egng"fqw "gp|k o g"fkp"eq o rqpqp "c" vqzkgk"urgekheg"cpvtczwnwk"ew"tqn",p"o gfkgtgc"ghgevgnqt"rcvqi gpg"cnq"ceguvgkcl)

Efecte farmacodinamice

Xcnqctgc"eqpucvpgk"fg"fkueqktg*"Mf+"rgpvtw"chkpkvcvgc"fg"ngictg" c"qdknvqzcck o cdwnwk"fg"CR"nkdt"guvg" fg"2.55 pO0"

In vitro."qdknvqzcck o cdwn"ug"ngci "fg"CR"fg"nc"pkxgnwn"vwnrkpnqt"C o gu."Xqnnw o "k"Uvgtpg"fg"*B. anthracis*0"Grkvqrwn"fg"rg"CR"nc"pkxgnwn"e twkc"ug"ngci "qdknvqzcck o cdwn"guvg",pv-npkv",p"ec|wn"vwnrkpnqt" de *B. anthracis* rgpvtw"ectg"gzkuv "tcrqtv tk0

Studiile efectuate *in vitro* ,p"ecftwn"wpwk"vguv"egnwnt."ectg"vwnk|gc| "o cetqhc ig"o wtkpg."uwi gtc| "e " qdknvqzcck o cdwn"pgwvtenk|gc| "ghgevgng"vqzkeg"cnq"vqzkgk"ngvcng."q"eq o dkpc kg"fg"CR" k"hecvqtw"ngvcn0"

Studiile efectuate *in vivo* rgpvtw" gxcnwctgc"ghkecekv kk"nc"kg rwtk" Pgy" \ gcnpcf" Y jkyg" P \ Y+ " k"o cecek" e{pq o qniwu"uwrw k"wpwk"vguv"fg"rtqxqectg"rg"ecng"kpjcncvqtkg"ew"urqtk"fg"vwnrkp "C o gu"fg"*B. anthracis* cw"fg o qpwtcv"q"etg vgtg"fgrgpfgpv "fg"fq| "c"uwrctxkg wtkk" fwr "vtcvc o gpvwn"ew"qdknvqzcck o cd0" Gzrwpgtgc"nc"urqtk"fg"*B. anthracis* c"fwu"nc"etg vgtgc"eqpegpvtc kknq"ugtkeg"fg"CR"nc"kg rwtk" P \ Y " k"nc" o ck o w gng"e{pq o qniwu0" Fwr "vtcvc o gpvwn"ew"qdknvqzcck o cd."u-c",ptgi kuvtcv"q"ue fggtg" c"eqpegpvtc kknq"

fg"CR"nc" o clqtkvcvgc"cpk o cngnqt"uwr txcxg wkvqctg0"Eqpepvtc kkn"fg"CR"nc"cpk o cngng"nc"ectg"u-a folosit rncegdq"cw"etgucw"r-p "nc" fgeguwn"ceguvqctc0

Eficacitate

Fgqctgeg"pw"guvg"hg | cdkn"ucw"gvke"u "ug"ghgevwg | g"uvw fkk"enkpkcg"eqpvtqncvg"ew"cpvtcz" fg"kpjcnc kg"nc" uwdkge k"wo cpk."ghkecekvvcvg"qdknvqzczk o cdwnwk"cf o pkuvtcv",p" o qpqvgtcrkg"eq o rctcvkx"ew"rncegdq",p" vtcvc o gpvwn"cpvtczwnwk"fg"kpjcnc kg"ug"dc | gc | "rg"uvw fkk"fg"gxncwctg" c"ghkecekv kk"ghgevwcv"nc"kg"rwtk" P \ Y" k" o cecek"e{pq o qni wu0

p"ceguvg"uvw fkk."u-c"ghgevwcv"vguv"fg"rtqxqectg" c"cpk o cngnqt"ew"urqtk"fg"B. anthracis uwd"htq o "fg" cgtquqk"vwnrkpc"C o gu+"nc" crtqzk o cvkx"422zNF72 e tqtc"wnvgtkqt"nk"u-a administrat tratament cu qdknvqzczk o cd"nc"tgrgtg"vg o rqteng"fkhtkvgl"p"uvw fkkng"rtkxpf"vtcvc o gpvwn"cpvtczwnwk"fg"kpjcnc kg." animalelor li s-a administrat travc o gpv" fwr "fgdwwn"ug o pgnqt"ucw"uk o rvq o gnqt"enkpkcg"fg"cpvtcz" ukuv o kel"p"uvw fkkng"fg"rtqhknczkg"rquv-gzrwpgtg."cpk o cngng"cw"hquv"vtcvcvg" fwr "gzrwpgtgc"nc"B. anthracis." ,pu " ,pckpv"fg"crctk kc"uk o rvq o cvnqi kgk0" O cecek"e {pq o qni wu"cw"hquv"vtcvc k"nc" o q o entul qd kpgtkk"tg | wnvvcnqt"rq | kvkxg"nc"vguwn"ugtk" fg"gngevtqejg o knw o kpguegp "GEN+"rgpvtw"CR"cn"B. anthracis"nc"wp"kpvtxcn" o gfkw"fg" crtqzk o cvkx"62"fg"qtg" fwr "rtqxqectgc"ew"B. anthracis0" p"uvw fkkng" rtkxpf"vtcvc o gpvwn"ghgevwcv"rg"kg"rwtk" P \ Y."cpk o cngng"cw"hquv"vtcvcvg" fwr "wp"vguv"rq | kvkx"rtkp"GEN" rgpvtw"RC"ucw"etg vgtgc"rgtukuvppv "c"vg o rgtcvwtk"eqtrqteng"rguv"pkxgnwn"kp kcn."nc"wp"kpvtxcn" o gfkw" fg" crtqzk o cvkx"52"fg"qtg" fwr "rtqxqectg0"Uwr txcxg wktgc" c"hquv"gxncwcv "nc"4:"fg" | kn" fwr "rtqxqectg" cu B. anthracis ,p"uvw fkkng"fguetkug",p"eqpvkpwctg0

Ghkecekvvcvg"wp"kpvtxcn" o gfkw"fg" crtqzk o cvkx"62"fg"qtg" fwr "rtqxqectgc"ew"B. anthracis0" p"uvw fkkng" rtkxpf"vtcvc o gpvwn"ghgevwcv"rg"kg"rwtk" P \ Y."cpk o cngng"cw"hquv"vtcvcvg" fwr "wp"vguv"rq | kvkx"rtkp"GEN" rgpvtw"RC"ucw"etg vgtgc"rgtukuvppv "c"vg o rgtcvwtk"eqtrqteng"rguv"pkxgnwn"kp kcn."nc"wp"kpvtxcn" o gfkw" fg" crtqzk o cvkx"52"fg"qtg" fwr "rtqxqectg0"Uwr txcxg wktgc" c"hquv"gxncwcv "nc"4:"fg" | kn" fwr "rtqxqectg" cu B. anthracis ,p"uvw fkkng"fguetkug",p"eqpvkpwctg0

Vcdgnwn 7<"Tevg"fg"uwr txcxg wktg",p"uvw fkkng"ghgevwcv"ew" o qpqvgtcrkg"rgpvtw"gxncwctgc" ghkecekv kk"ew"qdknvqzczk o cd"38 o ilmi+

		Rtqrqt kc"uwr txcxg wktk"nc"hkpcnwn"uvw fkwk [% *uwr txcxg wkvqtklp+]	Xcncqctg"r ²	I95 % ³	
		Rncegdq	Qdknvqzczk o cd"38 o ilmi"		
Vtcvc o gpv"- kg"rwtk" P \ Y					
Uvw fkw"CT255 ¹	2" *2135+	83.7 ' " *135+	2.2235,	*2.4; 2"- 2.:83+	
Vtcvc o gpv"- o cecek"e{pq o qni wu					
Uvw fkw"CR426 ¹	6' " *3138+	68.9 ' " *9137+	2.228:,	*2.2; ;"- 2.8:3+	
Uvw fkw"CR424 ¹	2" *2139+	53.5 ' " *7138+	2.22:7,	*2.29; "- 2.7:9+	
Rtqhknczkg"rquv-gzrwpgtg"- o cecek"e{pq o qni wu					
Studiul CR523 ⁴	3"qtg rquv-gzrwpgtg	2" *218+	100 ' " *818+	2.2234,	*2.693"- 3.222+
	46"qtg rquv-gzrwpgtg	--	:5 ' " *718+	2.2264,	*2.452"- 2.; ;8+
	58"qtg rquv-gzrwpgtg	--	72 ' " *518+	2.2567	*-2.259"- 2.: :4+

K'<"kpvtxcn"fg",petgfgtg

¹ Uwr txcxg wktgc"gxncwcv "nc"4:"fg" | kn" fwr "rtqxqectgc"ew"urqtk"kp fke "hcrvwn"e "vqcv"cpk o cngng" tcpfq o k | cvg"cw"hquv"rq | kvkxg"rgpvtw"dcevgtg o kg",pckpv"fg"vtcvc o gpv."kct"vtcvc o gpvwn" c"hquv"kp kcv",p"

wt o c "wpgk" etg vgtk" ug o pkhkecvkxg" c"vg o rgtcvwtkk" eqtrqtng" *uvwfkw" CT255+ "ucw" c"wpwk" tg | wncv" r q | kvkx" cn"
vguwnwk" fg" fg rkvctg" c"cpvk i gpwnwk" rtqvevqt" rtkp" gngvqtqj g o knw o kpguegp " *uvwfkkng" CR426" k" CR424+0
4 Xcnqctgc" r" ug" dc | gc | "rg" vguwn" Dque jnqq" wpkftge kqpcn" *ew" o qfkhkectg" fg" vkr" Dgt i gt-Boos a
i c o c ? 2.223+ "eq o rctcvkx" ew" rncegdq
5 Xcnqctgc" gzcev "c" kpvgtxcnwnwk" fg" , petgfgtg" ; 7 ' " rgpvtw" fkhgtgp c" cuqekcv "tcvgnqt" fg" uwrtcxkg wktg
4 Uwrctcxkg wktgc" gxcnwcw "nc" 4 : "fg" | kn" fg" nc" rtqxqectgc" ew" urqt. "
€ fgpqv "ug o pkhkec kg" uvcvkukve "nc" wp" pkxgn" fg" 2.247

Eqrkk" k" cfqnguegp k

C i gp kc" Gwtqrgcp " rgpvtw" Og fkec o gpvg" c" uwurgpfcv" vg o rqtct" qdnk i c kc" fg" fgrwpere a rezultelor
studiilor efectuate cu NYXTHRACIS nc" wpc" ucw" o ck" o wnv" uwd i twrg" fg" eqrkk" k" cfqnguegp k" ,p"
vtevc o gpvwn" kphge kgk" rtqxqecvg" fg" dcekn" *xg | k" rev0 604" rgpvtw" kphqt o c kk" rtkxkpf" wvknk | ctgc" nc" eqrkk" k"
cfqnguegp k+0

Ceguv" o g fkec o gpv" c" hquv" cwvqt | cv" , p" šeapfk kk" gzegr kqpcngö0" Cegucv" , pugc o p e " fkp" ecw | c" tctkv kk"
dqkk" k" fkp" o qvkxg" gvkeg" pw" c" hquv" rqukdkn "qd kptg" c" kphqt o c knqt" eq o rnv" g" rtkxkpf" ceguv" o g fkec o gpv0
C i gp kc" Gwtqrgcp " rgpvtw" Og fkec o gpvg" xc" tgxk | wk" , p" hkgectg" cp" qtkeg" kphqt o c kk" pqk" fku rqpdkng" k"
ceguv" TER" xc" hk" cevwcnk | cv" . fwr "ew o "xc" hk" pgeguct0

5.2 Rtqrtkgy k" hct o ceqekpgvkeg

Cduqtd kg

Hct o ceqekpgvkec" qdknvqzczo cdwnwk" guvg" hkgpct " rgpvtw" wp" kpvgtxcn" de doze ewrtkpu" , pvtg" 6 o ilmi " *fg"
2.47" qtk" fq | c" okpk o " tgeq o cpfcv + " k" 38 o ilmi" fwr " cfokpkvttctg" wpke " , p" rgtw | kg" kpvtxgpcu " nc"
uwdkge k" u p vq k0" Fwr " cfokpkvttctg" wpke " , p" rgtw | kg" kpvtxgpcu " fg" qdknvqzczo cd" , p" fq | " fg"
16 o ilmi" nc" uwdkge k" u p vq k" fg" c o dgng" ugzg. "xcnqctgc" o g fkg" c" E_{ocz} k" c" CUE_{inf} a fost de
400 ± ; 3.4 o eilon" k. "tgurgevx. "7392 ± 3582 o ei | kl on0" Vko rwn" fg" , plwo v ktg" rncu o cvke " c"
qdknvqzczo cdwnwk" c" hquv" fg" crtqzko cvkx" 42 fg" | kn" * o g fkg+0

Fkuvtkdw kg

Xcnqctgc" o g fkg" c" xqno o wnw" fg" fkuvtkdw kg" c" qdknvqzczo cdwnwk" nc" uvctgc" fg" ge jknkdtw" c" hquv" fg"
9 ; 9 ± 3 ; 4 onlmi" k" c" fgr kv" xcnqctgc" xqno o wnw" rncu o cvke. "eggc" eg" uwigtgc | "wp" cpw o g" i tcf" fg"
fkuvtkdw kg" vkuwnt 0

Metabolizare

Nu s-cw" ghgevcv" uvwfkk" hqt o cng" rtkxkpf" o gvcdqk | ctgc" ew" qdknvqzczo cd0
Ew" vqcv" ceguvgc. " p" i gpgtcn. "fkuvtkdw kc" cpvkeqtrknt" o qpqenqpcnk" k o rnce "fkuvtkdw kg" , p" chctc" urc kului
xcuewnt" , puq kv " fg" rtgnwctg" rqvvp ken "nc" pkxgn" vkuwnt" k" ecvcdqk | ctgc" fg" e vtg" rtqvge | g" , p" rgrvkfg" fg"
fk o gpukwpk" o kek" k" c o kpqcek | k" ectg" uwpv" wnvgtkqt" , peqt rqt c k" , p" tg | gtxqtwn" gpfq i gp" ucw" gzctgvc k0

Elimina

Xcnqctgc" o g fkg" eqtqurwp | vqctg" gnk o kp tkk" qdknvqzczo cdwnwk" cw" hquv" fg" 5.57 ± 2. ; 54 onl | klmi" k" o wnv"
o ck" o kek" fge- v" tvvc" fg" hknvctg" inq o gtwnct . "eggc" eg" kp fke " hcrvwn" e . "rtcevc. " engctcpegul
qdknvqzczo cdwnwk" pw" guvg" o g fkv" tgpnc0

I twrg" urgekng" fg" rcekgp k

Ghgevn" ugzwnwk. "x-twv" k" tcvugk

Rtqhknwn" hct o ceqekpgvke" cn" qdknvqzczo cdwnwk" c" hquv" gxcnwcw" rtkpvt-q" cpcnk | "hct o ceqekpgvke "
rqrwnc kqpcn "ectg" c" wvknk | cv" rtqdg" ugtkeg" rtqxgpkvg" fg" nc" 592" fg" uwdkge k" u p vq k" ectg" cw" rtk o kv" q" fq | "
kpvtxgpcu "wpke " , p" ecftwn" c" 6" uvwfkk" enkpkeg0" Rg" dc | c" ceguvgk" cpcnk | g. "ugzwn" *hg o gk" hc " fg" d tdc k+."
tcuc" *pqp-ecwec | kgpk" hc " fg" ecwec | kgpk+ "ucw" x-tuv" *x-tuvpk" hc " fg" vkpgtk+ "pw" cw" cxwv" ghgevg"

ug o pkhkecvkxg"cuwrte" rctc o gvtknqt" fg" hct o ceqekpgvke "ck" qdknvqzcck o cdwnwk0" Ew" vqcvg" ceguvgc. "uvwfkng" enpkpeg" ghgevcvg" ew" qdknvqzcck o cd" pw" cw" kpenwu" wp" pw o t" uwhkegpv" fg" uwdkge k" ew" x-tuvc" fg" 87" cpk" k" rguvg" rgpvtw" c" uvcdknc" fce "gzkuvg" fkhgtg" g" fg" hct o ceqekpgvke "hc " fg" uwdkge k" fg" x-tuv " o ck" v-p t 0" Fkpvgt" egk" 542" fg" uwdkge k" ,ptqnc k" ,p" uvwfkng" enpkpeg" ghgevcvg" ew" qdknvqzcck o cd. ;.6 ' *52" fkp 542+" cxgcw" x-tuvc" fg" 87" cpk" k" rguvg. "kct" 4 ' *8" fkp 542+" cxgcw" x-tuvc" fg" 97" cpk" k" rguvg0

Ghgevq" eqtgnvcvg" ew" eqpvkvw kc" hk/ke

Clearance-wn" eqtgurwp| vqt" wpqt" xcnqt" o ctk" cng" i tgwv kk" eqtrqteng" *32; mi+" c" hquv" ew" crtqzko cvkx" 5: ' " o ck" o ctg" fge-v" ,p" rqrwnc kc" fg" tghgtk" 0" Wvknk| ctgc" fq| tkk" ,p" hwpe kg" fg" i tgwvcvg" eqtrqteng" *38 o ilmi+" fgvg" okp "etg vgtgc" ew" 34 % a ASC_{inf}. "ectg" pw" guvg" tngxcpv " fkp" rwpev" fg" xgfgtg" enpkel0

Eqrkk" k" cfqnguegp k

Rtqhkwn" hct o ceqekpgvke" rgpvtw" qdknvqzcck o cd" pw" c" hquv" gxcnvcv" nc" eqrkk" k" cfqnguegp" k0" Tgeq o cpf tkng" rtkxpf" uvcdkntgc" fq| gnt" fkp" vcdgnwn 4" rev0 604+" uwpv" fgtxcvg" fkp" uk o wn tk" ectg" wvknk| gc| "q" uvtcvkg" fg" hct o ceqekpgvke " rqrwnc kqpcn " eqpegrwv " rgpvtw" c" eqtgurwp" fg" gzrwpgtk" qdugtxcv" nc" cfwn k" nc" qdknvqzcck o cd" cf o kpkuvtcv" ,p" fq| " fg" 38 o ilmi0

5.3 Fcvg" rtgenpkpeg" fg" ukiwtcp

Fcvng" pqp-enpkpeg" pw" cw" gxkfgp kcv" pkekwp" tkue" urgekn" nc" q o " rg" dc| c" uvwfkng" eqpxgp kqpcng" hct o ceqngikeg" rtkxpf" gxcnwtgc" ukiwtcp" gk. "vqzkevcvg" fwr " fq| g" tgrgvcvg. "vqzkevcvg" cuwrte" hwpe k" gk" fg" tgrtqfwegt" k" fg| xqnv tkk0

Ng| kwpkng" nc" pkxgnwn" ukuvg o wnwk" pgtxqu" egpvtcn" *UPE+" *rtg| gp c" dcevgtknqt. "kphnc o c kg." jg o qtcikg" k" qec| kqpcn" pgetq| + "cw" hquv" qdugtxcv" nc" kgrwtk" P \ Y" k' o cecek" e{pq o qni wu" kphgevc k" ew" cpvtcz" ectg" cw" fgegfcv. "e tqtc" nk" u-c" cf o kpkuvtcv" kpvtxgpqu" qdknvqzcck o cd" ,p" fq| " x 4 o ilmi+" ucw" ci gpvwn" eqpvtn" nc" o q o gpvwn" eqphkt o tkk" dqnk0" Oqfkhke tkng" o ketqueqrkeg" nc" cpk o cngng" ectg" cw" fgegfcv" k' e tqtc" ni s-a cf o kpkuvtcv" qdknvqzcck o cd" cw" hquv" rtqxqecvg" fg" rfg| gp c" dcevgtknqt" gzvtxcuewctg" k" pw" fg" ghgevw" qdknvqzcck o cdwnwk0" Pw" u-c" kf gpvkhkecv" q" tgnc kg" fq| -t urwpu" rgpvtw" tg| wncvng" jkuvrcvqngikeg" nc" pkxgn" egtgdtcn0" Pw" u-cw" gxkfgp kcv" ng| kwpk" egtgdtcng" cuqekcv" vtcv o gpvwnwk" nc" kgrwtk" P \ Y" *nc" |kwc" 4: + "ucw" o ck o w gng" e{pq o qni wu" *r-p "nc" |kwc" 78+" kphgevc k" ew" cpvtcz" k" ectg" cw" uwrctxkg wkv" fwr "q" cf o kpkuvtcv" wpke " fg" qdknvqzcck o cd" ,p" fq| g" fg" r-p "nc" 38 o ilmi" k. "tgurgevix. "r-p "nc" 54 o ilmi" fq| 0" Fwr " trevc o gpvwn" ew" qdknvqzcck o cd. "pw" u-cw" qdugtxcv" ghgevq" pgwtq-eq o rqtvc o gpvncg" cuqekcv" ew" qdknvqzcck o cd" nc" o ck o w gng" e{pq o qni wu" kphgevcvg" ew" cpvtcz" k" ectg" cw" uwrctxkg wkv0

S-c" ghgevcv" wp" ukpiwt" uvwfk" rtkxpf" fg| xqnvctgc" g o dtkqpc" k" hgvn "nc" kgrwtqckeg" P \ Y" u p vqvcg" iguvcvpg" e tqtc" nk" u-cw" cf o kpkuvtcv" 6" fq| g" kpvtxgpqvcg" fg" qdknvqzcck o cd" fg" r-p "nc" 54 o ilmi" *fg" 4" qtk" o ck" o ctk" fge-v" fq| c" cf o kpkuvtcv" "nc" q o uvcdkncv "rg" dc| c" i tgwv kk" eqtrqteng" gzrtk o cv " ,p" o ilmi+" ,p" |kngng" 8. "32. "35" k' 39" cng" i guvc" kgk0" Pw" s-cw" qdugtxcv" fqxg| k" cng" wpqt" ghgevq" pqekxg" nc" hg o gngng" i guvcvpg" ucw" ghgevq" pqekxg" hgvcg" fkp" ecw| c" qdknvqzcck o cdwnwk0" Gzrwpgtkng" ew o wncvixg" nc" kgrwtk" P \ Y" *32 000 o eiÉ| kl o n+ "nc" wp" pkxgn" nc" ectg" pw" ug" qdugt " pkekwp" ghgev" cf xgtu" fg" 54 o ilmi" fq| " *p? 6" fq| g+ " rg" dc| c" CUE₀₋₃₇ kng" cw" hquv" fg" crtqzko cvkx" fqw " qtk" o ck" o ctk" fge-v" xcnqtgc" o gfk" c" CUE" ew o wncv" qdugtxcv" nc" q o " rgpvtw" c" dgng" ugzg" eqtgurwp| vqctg" wpgk" fq| g" enpkpeg" kpvtxgpqvcg" fg" 38 o ilmi0" Xcnqtng" E_o fwr "q" fq| " fg" 54 o ilmi" cw" hquv" fg" 33: 2 o eiÉ| kl o n0

Nu s-cw" ghgevcv" uvwfk" ew" qdknvqzcck o cd" rtkxpf" ectekpq i gpkvcvg. " i gpvqzkevcvg" k" hgtvknkvcvg0

80 RTQRTKGV K"HCTOCEGWVKEG

803 Nkuvc" gzevrkpg knqt

J kuvk fkp
Uqtdkvqn" *G642+
Rqnuqtdcv" : 2" *G655+
Cekf" enqtjkf tke" *G729. " rgpvtw" clwuvctgc" r J -wnwk+
Jkftqzkf" fg" uqfkw" *G746. " rgpvtw" clwuvctgc" r J -wnwk+

Cr "rgpvtw"rtgrctevg"kpIgevcdkng

804 Kpeq o rcvdknkv k

Ceguv" o gfkce o gpv"pw" rqcvg"hk" c o guvgecv"ew"cnvg" o gfkce o gpvg."ew"gzegr kc"egnt" o gp kqpcvg"nc" rev0 8080

805 Rgtkqfc" fg"xcncdknkvcvg

Hnceqp"uki kncv

9 ani

Uqnw kg"fkncv "p"rwpic"rgpvtw"rgthw|kg

Fwr "fknwctg",p"rwpic"rgpvtw"rgthw|kg."uvcdknkvcvg"ejkoke ."hk|ke " k" o ketqdkcp "p"vk o rwn"vknk| tkk" c" hquv" fg" o qpvtcv "rgpvtw"wp"kpvgtxcn" fg": qtg"nc"vg o rgtcvwtc"ec o gtgk"42ÅE- 47ÅE+"ucw",p"eqpfk kng" r uvt tkk nc"htkikfgt"4ÅE- :ÅE+0

Fkp"rwpev"fg" xgfgtg" o ketqdknqike."medicamentul vtgdwkg"vknk|cv" k o gfkcy."ew"gzegr kc"ec|wnwk",p"ectg" o gvqfc"fg"rtko "fguejkgfgt|tgeqpukvwktg|fknwctg"gnk o kp "tkuewtkng"fg"eqpvc o kpctg" o ketqdkcp 0

Fce "pw"ug"vknk|gc| "k o gfkcy."vk o rkk" k"eqpfk kng"fg"r uvtctg"fg"fwtcvc"vknk| tkk"uwpv"tgurqpucdknkvcvg" vknk|cvqtwnwk0

Uqnw kg"fkncv "p"ugtkpic"rgpvtw"rgthw|kg

Fwr "rtgi vktgc"uqnw kgk"fkncv"fg"NYXTHRACIS."cegucv"ug"cf o kpkuvtgc| "k o gfkcy" k"pw"ug" fgrq|kygc| 0"Qkeg o gfkce o gpv"pgvknk|cv"vtgdwkg"ctwpecv0

806 Rtgecw kk"urgekng"rgpvtw"r uvtctg

C"ug"r uvtc"nc"htkikfgt"4ÅE- :ÅE+0

C"pw"ug"eqpignc0

C"ug"r uvtc",p" c o dncnlwn"qtkikpcn"rgpvtw" c"hk"rtqvglc"fg"nw o kp 0

Rgpvtw"eqpfk kng"fg"r uvtctg" cug" o gfkce o gpvwnwk" fwr "fknwctg."xg|k" rev0 8050

807 Pcvwtc" k"eqp kpwwnc" o dncnlwnk

600 o il8"on"fg"eqpegpvtcv",p"hnceqp"*uvken "fg"vkr"K+"ew"fq"r"fg"ecwekwe" k"ecrce"fkprqnrtrqkngp "ew" ecru "fg"cnw o kpkw0

Ewkc"eqp kpg"3"hnceqp0

808 Rtgecw kk"urgekng"rgpvtw"gnk o kpctg"tg|kfwwtknt" k"cnvg"kpvtwe kwpk"fg" o cprwncg

Kpvtwe kwpk"ko rqtvepv"tghgtkvqctg"nc"rtgi vktg

€ pckpv"fg"cf o kpkuvtctg."eqpegpvtcvwn"rgpvtw"uqnw kg"rgthw|cdkn "vtgdwkg"kpurvevcv"xk|wcn"rgpvtw" c" fg"vevc"rtg|gp c"wpqt"gxgpwvcng"rctkewng"ucw" o qfkhe tk"fg"ewnqctg0"NYXTHRACIS este o uqnw kg"fg"nc"nk o rgfg"nc"qrcnguegpv ."fg"nc"kpqnt "nc"i ndwkg"ucw" w qt" o ctqpkw-i ndwkg"ectg" rqcvg"eqp kpg"q"ugtkg"fg"rctkewng"rtqvgkeg"ew"curgev"fg"nc"vtcpurctgpn"nc"nd"ectg"xqt"hk" ,pfg" tvcvg"rtkp"hnvtctgc"nc"pkxgnwn"nkpkg"fg"rgthw|kg+0

€ p"ec|wn",p"ectg"uqnw kc"rtg|kpv " o qfkhe tk"fg"ewnqctg"ucw"rctkewng"uvt kpg."hnceqpwn"vtgdwk" gnk o kpcv"*xg|k" rev0 5+0

€ C"pw"ug"ci kvc"hnceqpwn0

Rtgi vktgc" k"fkncv"p"rwpic"rgpvtw"rgthw|kg

- 30 Ug"ecnewngc| "ecpvkvcvge"pgeguct "fg"qdknvqzczo cd"gzrtkocv ",p"onkkitcog",pownkpf"fq|c" tgeqocpfcv "*o ilmi+"fkp"vcdgnwn 4"*xg|k"rev0 604+"ew"xcnqctgc"kpfxkfwcn "c"itgwv kk"eqtrqteng"c" rcekpvnwkw"gzrtkocv ",p"mknqitcog)
- 40 Ug"ecnewngc| "xqnow wn"pgeguct"gzrtkocv",p"onkknvkt"fg"qdknvqzczo cd"eqpegpvtcv"rgpvtw"uqnw kg" rgthw|cdkn "k"pwotwn"fg"hnecqcpge"pgeguct"rgpvtw"fq| "rtkp",ortktgc"fq|gk"ecnewncvg" gzrtkocvg",p"onkkitcog"*gvrc 3+"nc"eqpegpvtc kg."322 oilon0"Hkgectg"hnecqp"rgtorkvg" administrarea a 6 on"fg"qdknvqzczo cd"eqpegpvtcv"rgpvtw"uqnw kg"rgthw|cdkn 0
- 50 Ug"engig"q"rwpi "fg"rgthw|kg"ew"fkogpukwpgc"cfgecxv "fg"uqnw kg"rgpvtw"rtgrctcvg"kp1gevcdkng"fg" enqtw "fg"uqfkw"; oilon*2.; '+0"Ug"gzvtcig"wp"xqnow"fg"uqnw kg"fkp"rwpic"rgpvtw"rgthw|kg"gi cn" ew"xqnow wn"ecnewncv"gzrtkocv",p"onkknvkt"fg"qdknvqzczo cd",p"gvrc"4"fg"ock"uwu0"Ug"gnk okp " uqnw kc"ectg"chquv"gzvtcu "fkp"rwpic"rgpvtw"rgthw|kg)
- 60 Ug"gzvtcig"xqnow wn"pgeguct"fg"qdknvqzczo cd"eqpegpvtcv"rgpvtw"uqnw kg"rgthw|cdkn "*ecnewncv"nc" gvrc"4+"fkp"hnecqpwn"*hnecqcpng+"fg"NYXTHRACIS0"Ecpvkvcvge"pgwvknk|cv"t o cu ",p"hnecqpwn" *hnecqcpng+"fg"NYXTHRACIS vtgdwkg"ctwpecv 0
- 70 Ug"vtcpugt "xqnow wn"pgeguct"fg"qdknvqzczo cd"eqpegpvtcv"rgpvtw"uqnw kg"rgthw|cdkn ",p"rwpia rgpvtw"rgthw|kg"cngecu 0"
- 80 Ug"t uvqetp "w qt"rwpic"rgpvtw"rgthw|kg"rgpvtw"cqoqigpk|c"uqnw kc0" C"pw"ug"ci kvc0
- 90 Rgthw|kc"ug"cfokpkvutgc| "vkor"fg";2 fg"okpwwg"nc"xkvg|c"fg"rgthw|ctg"fguetku ",p"vcdgnwn 5"*xg|k" rev0 604+. "hqnukpf"wp"hnvwtw",peqtrqtcv"ew"fkogpukwpgc"fg"2.44 oketqpk0"
- :0 Uqnw kc"rtgi vkv "guvg"uvcdkn "vkor"fg": "qtg",p"eqpfk kkg"r uvt tkk"nc"vgor gtcvwtc"ecogtgk"*42ÅE"- 47ÅE+"ucw"vkor"fg": "ore ,p"eqpfk kkg"r uvt tkk"nc"htkikfgt"*4ÅE"- :ÅE+0

Rtgi vktgc" k"fkncwctgc"p"ugtkpic"rgpvtw"rgthw|kg

- 30 Se canewngc| "ecpvkvcvge"pgeguct "fg"qdknvqzczo cd"gzrtkocv ",p"onkkitcog",pownkpf"fq|c" tgeqocpfcv "*o ilmi+"fkp"vcdgnwn 4"*xg|k"rev0 604+"ew"xcnqctgc"kpfxkfwcn "c"itgwv kk"eqtrqteng"c" rcekpvnwkw"gzrtkocv ",p"mknqitcog)
- 40 Ug"ecnewngc| "xqnow wn"pgeguct"gzrtkocv",p"onkknvkt"fg"qdknvqzczo cd"eqpegpvtcv"rgpvtw"uqnw kg" rgthw|cdkn "k"pwotwn"fg"hnecqcpge"pgeguct"rgpvtw"fq| "rtkp",ortktgc"fq|gk"ecnewncvg" gzrtkocvg",p"onkkitcog"*gvrc 3+"nc"eqpegpvtc kg."322 oilon0"Hkgectg"hnecqp"rgtorkvg" administrarea a 6 ml de NYXTHRACIS eqpegpvtcv"rgpvtw"uqnw kg"rgthw|cdkn 0
- 50 Ug"engig"q"ugtkpi "ew"fkogpukwpgc"cfgecxv "rgpvtw"xqnow wn"vqvcn"cn"rgthw|kgk"ectg"wtogc| "u "hkg" cfokpkvutcv 0
- 60 Hqnukpf"ugtkpic"cngecu "k"q"nkpk"fg"rgthw|kg"ew"hnvwtw",peqtrqtcv"ew"fkogpukwpgc"fg" 2.44 microni."ug"gzvtcig"xqnow wn"pgeguct"fg"qdknvqzczo cd"eqpegpvtcv"rgpvtw"uqnw kg"rgthw|cdkn " *ecnewncv"nc"gvrc"4+0"Ecpvkvcvge"pgwvknk|cv"t o cu ",p"hnecqpwn"*hnecqcpng+"fg"NYXTHRACIS vtgdwkg"ctwpecv 0"
- 70 Ug"gzvtcig"q"ecpvkvcvge"cfgecxv "fg"uqnw kg"rgpvtw"rtgrctcvg"kp1gevcdkng"fg"enqtw "fg"uqfkw" ; oilon*2.; '+rgpvtw"rtgi vktgc"xqnow wn"vqvcn"rgpvtw"rgthw|kg"kpkecv",p"vcdgnwn 40
- 80 Ug"qoqigpk|gc| "ew"itkl "uqnw kc0" C"pw"ug"ci kvc0
- 90 Fwr "rtgi vktgc"uqnw kgk"fkncwctgc"fg"Qdknvqzczo cd."cegcuv"ug"cfokpkvutgc| "kogfkcv0" C"pu se fgrq|kvc"uqnw kc",p"ugtkpi 0" Ogfkccogpwn"t o cu"pgwvknk|cv"vtgdwkg"gnk okpcv0

Eliminare

Qtkeg"ogfkccogp"pgwvknk|cv"ucw"ocvgtken"tg|kfwcn"vtgdwkg"gnk okpcv",p"eqphqtokvcvg"ew"tgingogpvtknng" nqecngl)

7. FG KP VQTWN"CWVQTK\C KGK"FG"RWPGTG"RG"RKC

UHN"Rjctocgwkecnu" Fgwuejncpf" I od J
 Marie-Curie-Uvtcuug":
 9;75;N3/4ttcej
 Igtocpkc

8. PWO TWN*GNG+"CWVQTK\C KGK"FG"RWPGTG"RG"RKC "

GW13142136:71223

9. FCVC"RTKOGK"CWVQTK\ TK"UCW"C"TG'PPQKTKK"CWVQTK\C KGK

Fcvc"rtk o gk'cwvqtk| tk<3:"pqk o dtkg"4242

10. DATA REVIZUIRII TEXTULUI

kphqt o c kk"fgvncvqg"rtkxkpf"ceguv" o gfkco gpv"uwpv"fkurqpkdkng"rg"ukvg-wn"Ci gp kgk"Gwtqrgpg"rgpvtw"
Medicamente [jwr<1lyy0goc0gwtqrc0gw>](#)" k"rg"ukvg-wn"}pw o gng"Ci gp kgk"UO"*nkpm+;@0

Produsul medicinal nu mai este autorizat

ANEXA II

- A. HCDTKECPVWN"UWUVCP GK"DKQNOIKE"CEVKXG" K"
FABRICANTUL RESPONSABIL PENTRU ELIBERAREA
SERIEI
- B. EQPFK KK"UCW"TGUVTKE KK"RTKXKPF"HWTPK\CTGC" K"
UTILIZAREA
- C. CNVG"EQPFK KK" K"EGTKP"G"CNG"CWVQTK\C KKG"FG"
RWPGTG"RG"RKC
- D. EQPFK KK"UCW"TGUVTKE KK"RTKXKPF"WVKNK\CTGC"
UKIWT " K"GHKECEG"C"OGFKECOGPVWNWK
- E. QDNKIC KK"URGEKHKEG"RGPVTW"PFGRNKPKTGC"
O UWTKNQT"RQUV-AUTORIZARE ~~ÎN~~ CAZUL
CWVQTK\TKK"PEQPFK KK"GZEGR KQPCNG

**A. HCDTKECPVWN*HCDTKECP KK+"UWDUVCP GK*NQT+"DKQNQIKE"CEVXG" K"
HCDTKECPVWN*HCDTKECP KK+"TGURQPUCDKN*K+"RGPVTW"GNKDGCTGC"UGTKGK**

Pw o gng" k" c f t g u c " h c d t k e c p v w n k * h c d t k e c p k n q t + " u w d u v c p g k * n q t + " d k q n q i k e " c e v x g

Nqp|c"Dkqng i keu."Kpe0"
101 Kpvgtpevkqpcn" Ftkxg
Rqtvu o qwvj."P J"25:23"
SUA

Pw o gng" k" c f t g u c " h c d t k e c p v w n k * h c d t k e c p k n q t + " t g u r q p u c d k n * k + " r g p v t w " g n k d g t c t g c " u g t k g k

CegtkRjctoc"D0X0
Dquejuvtccv"73
6:33" I E."Breda
Olanda

B. EQPFK KK"UCW"TGUVTKK KK"RTKXKPF"HWTPK \ CTGC" K"WVKNK \ CTGC"

Ogfkec o gpv"gnkdgtcv"rg"dc| "fg"rtguetr kg" o gfkecn

C. CNVG"EQPFK KK" K"EGTKP G"CNG"CWVQTK \ C K GK"FG"RWPGTG"RG"RK C

€ Tcrqctvgng"rgtkqfleg"cevwnk| cvg"rtkxkpf"uki wtep c"*TRCU+

Egtpk gng"rgpvtw"fg"rwpgtg"TRCU"rgpvtw"ceguv" o gfkec o gpv"uwpv"rtg|gpvcv",p"nkuvc"fg"fcvg"fg"
tghgtp " k"htgexgpg"fg"vtcpu o kvgtg"nc"pkxgnwn" Wpkwpk"nkuv"GWTF+." o gp kqpcv "nc"
articolul 329e"cnkpgcwn *9+"fkp" Fktgevkxc 42231:51EG" k"qtkeg"cevwnk| tk"wnvgtkqctg"cnv"ceguvgia
rwdnkecvg"rg"rqtvcnwn"ygd"gwtrgcp"rtkxkpf" o gfkec o gpvng0

**D. EQPFK KK"UCW"TGUVTKK KK"RTKXKPF"WVKNK \ CTGC"UKIWT " K"GHKECEG"C"
MEDICAMENTULUI**

€ Rncpwn"fg" o cpcig o gpv"cn"tkuewnk"*ROT+

Fgkp vqtw"cwvqtk|c k g k " f g " r w p g t g " r g " r k c " * F C R R + " u g " c p i c l g c | " u " g h g e v w g | g " c e v x k v k n g " k "
kpvgtxgp kng"fg"ht o ceqxi kngp "pgeguctg"fgvncv",p"ROT" crtqdcv" k"rtg|gpvcv",p"
modulul 30:04"cn"cwvqtk|c k g k " f g " r w p g t g " r g " r k c " k " q t k e g " c e v w n k | t k " w n v g t k q c t g " c r t q d c v " c n g " R O T 0

Q" x g t u k w p g " c e v w n k | c v " c " R O T " v t g d w k g " f g r w u <

€ la cergtge C igp k g k " G w t q r g p g " r g p v t w " O g f k e c o g p v g =

€ nc" o q f k h k e c t g c " u k u v g o w n k " f g " o c p c i g o g p v " c n " t k u e w n k . " , p " u r g e k c n " e c " w t o c t g " c " r t k o k t k k " f g "
kphqt o c k k " p q k " e c t g " r q v " f w e g " n c " q " u e j k o d c t g " u g o p k h k e c v k x " c " t c r q t v w n w k " d g p g h k e k w l t k u e " u c w " e c "
w t o c t g " c " c v k p i g t k k " w p w k " q d k g e v k x k o r q t v c p v " * f g " h c t o c e q x i k n g p " u c w " f g " t g f w e g t g " n c " o k p k o w o " c "
tkuewnk+0

**E. QDNKIC KK"URGEKHKEG"RGPVTW" PFGRNKPKTGC" O UWTKNQT"RQUV-
CWVQTK \ CTG" P"EC \ WN"CWVQTK \ TTK" P"EQPFK KK"GZEGR KQPCNG**

Cegcuv" h k k p f " q " c w v q t k | c t g " , p " ŝ e a p f k k " g z e g r k q p c n g o " k " , p " e q p h q t o k v c v g " e w " c t v k e q n w n " 3 6 " c n k p g c w n " * : + " f k p "
Tgiwnc o gpvwn" *EG+ " p t 0 " 94814226. " F C R R " v t g d w k g " u " r w p " , p " c r n k e c t g . " , p " k p v g t x c n w n " f g " v k o r " u r g e k h k e c v . "
w t o v q c t g n g " o u w t k <

Fguetkgtgc	Fevc"fg"hkpcnk ctg
<p>Rgpvtw"cxnkcfc"ogvqfc"fg"fgvgtokpctg"crectogvtnkqt"fg" hctoceqekpgvke"cqdknvqzcczkoedwnwk"IEEN-382+,p"ugt"fg" rtqxpkgp"wo cp."FCRR"vtgdwkg"u"fg"rwp"tg wnvcvng"xcnkftkk" vguvwnwk"rgpvtw"wtovqctgng"curgevg",pckpyg"fg"vknk ctgc"vguvwnwk" rgpvtw"cpnk c"rtqdgng"rgpvtw"uvwfkwn"enkpkc" CJ 723<"kpvgtgtp" c" fkp"rctvgc"CR"*85" k":5+."HG."HN" k"cpvkeqtrknt"cpvko gfkecogpv" k" rgthqto cp c"vguvwnwk",p"ugt"ew"kpvgthgtp"cuqekcv"jgoqnk gk" k" nkr go kgk"Ug"xc"ghgevc"q"gxncwctg"rctcngn"ew"rtqdgng"rtqxpkgv"fkp" studiul CJ 723 ew"ogfkec kg"ewpquewv ."rtkxkp"rtcevkec"enkpkc 0</p> <p>Rgpvtw"cxncw"t urwpuwn"enkpkc."ukiwtcp c" k"vqngtcdknkvcvgc."kpenwukx" gxqnw kc"dqnk" k"urrtcxkg wktgc"nc"uwdkge kk"ew"uwurkekwpg." rtqdcdknkvcvg"ucw"eqphktoctg"fg"cpvtcz"fg"kpjnc kg"vtcvc k"ew" qdknvqzcczkoed."FCRR"xc"fgtwnc."ew"tgurgevctgc"rtqvqeqnwnwk" eqpxgpkv." k"xc"fg"rwp"tg wnvcvng"tcrtvwnwk"hkpcn"rgpvtw"uvwfkwn" CJ 723"fg"hc "6."ew"ogfkec kg"ewpquewv ."rtkxkp"rtcevkec"enkpkc" ,p"eqpfk kknng"crctk kgk"wpwk"hgect"fg"cpvtcz",p" tkng",p care qdknvqzcczkoedwn"guvg"cwvqtk cv" k"fkurqpkdkn0</p>	<p>Ug"xc"fg"rwp",ortgwp"ew" tcrtvwn"enkpkc"hkpcn"cn" uvwfkwnwk" CJ 723</p> <p>Terqctvg"cpweng"ectg" vtgdwkg"fg"rwug"</p> <p>Terqvtwn"hkpcn"xc"hk"hwtpk cv" nc"oczko wo"34"nwpk"fwr" ultima administrare de qdknvqzcczkoed"ucw"wnvko c" ,ptgikvttg" c"fcvgnqt",p" ec wn"eqngev tkk" tgvqturgevkg" c"fcvgnqt0</p>

Produsul medicinal nu mai este autorizat

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ANEXA III

GVKEJGVCTGC" K"RTOURGEVWN

Produsul medicinal nu mai este autorizat

A. ETICHETAREA

KPHQTOC KK"ECTG"VTGDWKG"U "CRCT "RG"CODCNCLWN"UGEWPFCT
EWWKG"FG"CODCNCL

1. FGPWOKTGC"EQOGTEKCN "C"OGFKECOGPVWNWK

NYXTHRACIS 100 o i l o n"eqpegvtcv"uvgtkn
qdknvqzczk ocd"

2. FGENCTCTGC"UWDUVCP GK*UWDUVCP GNQT+"CEVKXG

1 o n"qdknvqzczk ocd"322 o i l

3. NKUVC"GZEKRGKGP KNQT

Gze kr kgp k" jkuvkfkp . "uqtdkvqn."G655."cekf"enqtjkftke."jkftqz kf"fg"uqfkv."er "rgpvtw"rtgrctcvg"
kplgevc dkn g l

4. HQTOC"HCTOCEGWVKE " K"EQP KPWWVN

Eqpegvtcv"rgpvtw"uqnv kg"rgthw|cdkn
600 o i l 8 ml
1 flacon

5. OQFWN" K"ECNGC*E KNG+"FG"CFOKPKUVTCTG

C"ug"ekvk"rtqur gevwn",pckpv g"fg"vvknk|ctg l
KX"fwr "fknwctg l
Pw o ck"rgpvtw"q"ukpi wt "vvknk|ctg l
C"pw"ug"cikvc l

Eqf"ST"eg"wt o gc| "c"hk"kpvtq f wu" - "y y y l qdknvqzczk ocd-uhn l gw

**80 CVGP KQPCTG"URGEKCN "RTKXKPF"HCRVWN"E "OGFKECOGPVWN"PW"VTGDWKG"
R UVTCV"NC"XGFGTGC" K" PFGOŽPC"EQRKKNQT**

7. CNV *G+"CVGP KQPCTG* TK+"URGEKCN *G+"FCE "GUVG*UWPV+"PGEUCT *G+

8. DATA DE EXPIRARE

GZR

9. EQPFK KK"URGEKCN"FG"R UVTCTG

C"ug"r uvte"nc"htkikfg l

C"pw"ug"eqpignc0"
C"ug"r uvte",p"co dncnlwn"qtkikpcn"rgpvtw"c"hk"rtqvglev"fg"nw okp 0

**10. RTGECW KK"URGEKCNG"PRIVIND ELIMINAREA MEDICAMENTELOR
NEUTILIZATE SAU A MATERIALELOR REZIDUALE PROVENITE DIN ASTFEL
FG"OGFKECOGPVG."FCE "GUVG"EC\ WN**

11. PWOONG" K"CFTGUC"FG KP VQTWNWK"CWVQTK\C KGK"FG"RWPGTG"RG"RKC

UHN"Rjcto cegwvkecu" Fgwvuejncpf" I od J
Marie-Curie-Uvtcuug":
9;75;"N3/4ttcej
Igt ocpk

12. PWO TWN*GNG+"CWVQTK\C KGK"FG"RWPGTG"RG"RKC

GW13142136:71223

13. UGTKC"FG"HCDTKEC KG

Lot

14. ENCUKHKECTG" IGPGTCN "RTKXKPF"OQFWN"FG"GNKDGTCTG

15. KPUVTWE KWPK"FG"WVKNK\ CTG

380 KPHQTOC KK" P"DTCKNNG

Lwuvkhkectg"ceegrvcv "rgpvtw"pgkpenwfgtgc"kphqtoc kgk",p"Dtcknng0

17. IDENTIFICATOR UNIC – COD DE BARE BIDIMENSIONAL

eqf"fg"dctg"dkfko gpukqpcn"ectg"eqp kpg"kgpvhkecvqtw"wpke0

18. IDENTIFICATOR UNIC – DATE LIZIBILE PENTRU PERSOANE

RE"
SN
NN

OKPKOWO"FG"KPHQTOC KK"ECTG"VTGDWKG"U "CRCT "RG"CODCNCLGNG"RTKOCTG"
MICI

GVKE JGV "HNCEQP

**1. FGPWOKTGC"EQOGTEKCN "C"OGFKECOGPVWNWK" K"ECNGC*E KNG+"FG"
ADMINISTRARE**

NYXTHRACIS 100 o ilon"eqpegv"vgtkn
qdknvqzck ocd"
KX" fwr "fknwctg()

2. MODUL DE ADMINISTRARE

Pwock"rgpvtw"q"ukpiwt "wvknk|ctg()

3. DATA DE EXPIRARE

GZR

4. UGTKC"FG"HCDTKEC KG

Lot

5. EQP KPWVWN"RG"OCU .XQNWO"UCW"WPKVCVGC"FG"FQ

600 o i18 ml

80 CNVG"KPHQTOC KK

Produsul medicinal nu mai este autorizat

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B. PROSPECTUL

Rtqurgev<"kphqt o c kk"rgpvtw"rcekpvp

NYXTHRACIS 100 o il o n"eqpegpvtcv"rgpvtw"uqmw kg"rgthw|cdkn qdknvqzczk o cd

Ceguv" o g fkec o gpv" hceg" qdkgevn" wpgk" o qpkvqt | tk" uwrnk o gpvctg" Ceguv" nwetw" xc" rgt o kyg"
kfgpvkhkectgc" tcrkf " fg" pdk" kphqt o c kk" tghgtkvqctg" nc" uki wtcp " 0" Rwwg k" u " hk k" fg" clwvqt" tcrqtvp" pf" qtkg"
tgce kk" cfxgtug" rg" ectg" ng" rwwg k" cxgc" 0" Xg| k" wvnc o c" rctvg" fg" nc" rev" 6" rgpvtw" o qfwn" fg" tcrqtvtg" o"
tgce kknqt" cfxgtug)

**Ekvk k" ew" cvgp kg" k" ,p" ,pvtgik o g" ceguv" rtqurgev" ,pckpvg" fg" c" ,pegrg" u " wvknk | c k" ceguv" o g fkec o gpv"
fgqctgeg" eqp kpg" kphqt o c kk" k" o rqtvcpg" rgpvtw" fw o pgcxqcvt " 0**

- R uvtc k" ceguv" rtqurgev" 0" U-ct" rwwg" u " hkg" pgeguet" u -n" tgek k" 0"
- Fce "cxg k" qtkeg" ,pvtgd tk" uwrnk o gpvctg" .cftguc k-x " o gfkewnw" fw o pgcxqcvt . "hct o cekuvwnw" ucw"
cukuvpvg" o g fkecng)
- Fce " o cphguc k" qtkeg" tgce kk" cfxgtug" .cftguc k-x " o gfkewnw" fw o pgcxqcvt . "hct o cekuvwnw" ucw"
cukuvpvg" o g fkecng) Ceguv" g" kpenw" f" qtkeg" rqukdng" tgce kk" cfxgtug" pg" o g" kqpcvg" ,p" ceguv" rtqurgev" 0"
Xg| k" rev" 6)

Eg" i uk k" ,p" ceguv" rtqurgev

- 30 Ce este NYXTHRACIS k" rgpvtw" eg" ug" wvknk | gc | "
- 40 Ce ttgdwkg" u " vk k" ,pckpvg" u " xk" ug" cf o kpkvgtg | g" NYXTHRACIS
- 50 Ew o "ug" cf o kpkvgtg | " NYXTHRACIS
- 60 Tgce kk" cfxgtug" rqukdng"
- 70 Ew o "ug" r uvtc | " NYXTHRACIS
- 80 Eqp kpvwn" c o dncclwnk" k" cnvg" kphqt o c kk

1. Eg" guvg" NYXTHRACIS k" rgpvtw" eg" ug" wvknk | gc |

NYXTHRACIS eqp kpg" uwduvcp c" cevkx " qdknvqzczk o cd" 0" Qdknvqzczk o cdwn" guvg" wp" cpvkeqtr"
o qpqenqpcn. "wp" vkr" fg" rtqvgkp " ectg" ug" ngci " fg" vqzkgpg" rtqfwug" fg" dcevgtkc" ectg" rtqxqce " cpvtczwn" k"
fgvgt o kp " kpcvkvxctgc" nqt)

NYXTHRACIS euvg" wvknk | cv" ,p" cuqekgtg" ew" o g fkec o gpvg" cpvkdqvkcg" rgpvtw" c" vtcvc" c fwn k" k" eqrkk" ectg"
uwght " fg" cpvtcz" rtqxqce" fg" r vtwp fgtgc" dcevgtkg" rg" ecng" tgurktcvqtkg" *cpvtcz" fg" kpj cnc kg+0"

NYXTHRACIS rqcvg" hk" wvknk | cv" k" fce " guvg" rqukdng" ec" fw o pgcxqcvt " u " hk" kpvctv" ,p" eqpvcev" ew" dcevgtkc"
ucw" urqtkk" dcevgtkg" ectg" rtqxqce " cpvtczwn. " ,pu " pw" cxg k" uk o rvq o g" cng" dqnk. " rtgew o " k" ,p" ec | wn" ,p" ectg"
pw" gzkuv " cnv" vtcvc o gpv" fkurqpkdn" k" rqvtkxkv)

2. Eg" vtgdwkg" u " vk k" ,pckpvg" u " xk" ug" cf o kpkvgtg | g" NYXTHRACIS

Pw" vtgdwkg" u " xk" ug" cf o kpkvgtg | g" NYXTHRACIS

- fce " uwpvg k" cngt i ke" nc" qdknvqzczk o cd" ucw" nc" qtkectg" fkpvtg" egngncnv" eq o rqpvg" cng" ceguvwk"
o g fkec o gpv" *gpw o gtcvg" nc" rev" 8+0)

Cvgp kqp tk" k" rtgcew kk"

"pckpvg" u " xk" ug" cf o kpkvgtg | g" NYXTHRACIS. "cftguc k-x " o gfkewnw" fw o pgcxqcvt . "hct o cekuvwnw" ucw"
cukuvpvg" o g fkecng<

- fce "cxg k" *ucw" eqrknw" fw o pgcxqcvt " ctg+" q" kpvqngtcp " gtgfkvt " nc" htwevq | " *KGH+." q" vwndwtctg"
igpgvke " tct . " ucw" fce " eqrknw" fw o pgcxqcvt " pw" o ck" rqcvg" eqpuw o c" cnk o gpvg" ucw" d wvwtk" fwnek"
fgqctgeg" k" ug" hceg" i tgc . " ctg" x tu vwtk" ucw" ,k" rtqxqce " ghgevg" pgrn ewvg" ew o " ct" hk" dcnqpcg ."
etc o rg" cdfq o kpcng" ucw" fktgg)

Wpgqtk."tgce kknng"cngtikeg"ectg"rqv"cr tgc"fwr "vtatamentul cu NYXTHRACIS rqv"hk" i tecxg0"Guvg"rqukdkn ec." ,pckpvg"fg"cf o kpkvutctgc"fg"NYXTHRACIS u "xk"ug"cf o kpkvutg | g"wp"cpvkjkuvc o kpkle."rgpvtw" c" tgfweg"tkuewn"fg"tgce kk"cngtikeg0

NYXTHRACIS , o rgtwp "ew"cnvg" o gfkec o gpvg

Urwpg k" o gfkewnwk"fw o pgcxqcvt "ucw"htc o cekuvwnwk" fce "wvknk | c k."c k" wvknk | cv"tgegpv"ucw"u-ct" rwwgc"u " wvknk | c k"qtkeg"cnvg" o gfkec o gpvg0

Guvg"rqukdkn"u "xk"ug"cf o kpkvutg | g"cpvkdkvkeg"*ew o "este ekr tqhmqzcekp + "rgpvtw" c"clwvc"nc"vtcvc o gpvwn" cpvtczwnwk"fg"kpjcnc kg0

Uctekpc" k"cn rvctgc

Fce "uwpvg k" i tecxk" ucw"cn rvc k."etgfg k"e "c k"rwwgc"hk" i tecxk" ucw"kpvgp kqpc k"u "t o -pg k" i tecxk" . cftguc k-x " o gfkewnwk"rgpvtw"tgeq o cpf tk" ,pckpvg"fg" c"xk"ug"cf o kpkvutc"ceguy" o gfkec o gpv0

Pw"ug" vkg" fce "NYXTHRACIS rqcvg" f wpc" h vwnwk0

Nw"ug" vkg" fce "NYXTHRACIS vtgeg", p"ncrvng" o cvgtp0" Fw o pgcxqcvt " k" o gfkewn"fw o pgcxqcvt " xg k" fgekfg" fce " o ck"rwwg" k"cn rvc" fwr "eg"xk"ug"cf o kpkvutg | "NYXTHRACIS0

Eqpfwegtgc" xgjkewngnqt" k" hqnqktgc" wvknclgnqt

NYXTHRACIS rqcvg"rtqxqec"tgce kk"cfxgtug"ew o "uwpv"eghcnng" c o g gnk."qdugcn " k"x tu vwtk0" Ceguy" nwtw" rqcvg"chgevc"ecrcekvcgc" fg" c"eqpfweg" xgjkewng"ucw" fg" c" hqnqktgc" wvknclg0

NYXTHRACIS eqp kpg"uqtdkvqn"*G642+

Uqtdkvqnwn" guvg"q"uwu "fg"htwevq | "*wp"vkr"fg" | c j t+0" Fce "cxg k"*ucw"eqrknwn"fw o pgcxqcvt "ctg+"q" kpvqngtcp "gtgfkvct "nc"htwevq | "*KGH+"q"vwdwtctg"igpgvke "tct ." o gfkewn"fw o pgcxqcvt " rqcvg" fgekfg" e "ceguy" o gfkec o gpv" guvg"eqpvtckpfkecv"rgpvtw"fw o pgcxqcvt "ucw"eqrknwn"fw o pgcxqcvt 0"Qt i cpku o wn" rcekp knqt"ew"KGH"pw" rqcvg"fgueq o rwpg"htwevq | c. eggc"eg" rqcvg"rtqxqec"tgce kk"cfxgtug" i tecxg0 "pckpvg"fg" c" rtk o k"ceguy" o gfkec o gpv."vtgdwkg"u "urwpg k" o gfkewnwk"fw o pgcxqcvt " fce "cxg k"*ucw" eqrknwn"fw o pgcxqcvt "ctg+"KGH"ucw" fce "eqrknwn"fw o pgcxqcvt "pw" o ck" rqcvg"eqpuw o c"cnk o gpvg"ucw" d wwtk"fwnek"fgqctgeg" k"ug" hceg" i tgc .ctg/x tu vwtk"ucw", k"rtqxqce "ghgevg"pgrn ewvg"ew o "ct"hk" dcnqptg."etc o rg"cdfq o kpcng"ucw"fkctgg0

NYXTHRACIS eqp kpg"uqflw

Ceguy" o gfkec o gpv"eqp kpg"sodiu" o ck"rw kp"fg"3 o o qn"*45 o i+"rgt flacon de 6 ml de NYXTHRACIS." adie rtceve""pw"eqp kpg"uqflw"0

3. Ew o "ug"cf o kpkvutg | "NYXTHRACIS

NYXTHRACIS x "xc"hk"cf o kpkvutcv"fg"e vtg"wp" o g fke"ucw"q" cukuvgpv " o g fkecn 0"Og fkewn"ucw" cukuvgpvc" o g fkecn "xc"ecne"mc"fq | c"rg"dc | c" i tgvw kk"fw o pgcxqcvt "*ucw" c"eqrknwnwk"fw o pgcxqcvt +0"

Og fkewn"fw o pgcxqcvt ."htc o cekuvwn"ucw" cukuvgpvc" o g fkecn "xc"rtgi vk" o g fkec o gpvwn"rgpvtw"rgthw | kg0" Uqnv kc"fg"NYXTHRACIS xc"hk"cf o kpkvutcv "rtkp"rgthw | kg"kpvtcxgpqcu "*rkwetctg", p"xgp + "ew"fwtevc"fg" ; 2 fg" o kpvvg." fg"qdkegk"fg"nc"pkxgnwn"dtc wnwk0" Xg k"hk"uwrtcxgi jgcv"rg"fwtevc"cf o kpkvut tkk"rgthw | kgk"ew" NYXTHRACIS k."fg" cug o gpvc."vk o r"fg"egn"rw kp"q"qt "fwr " ,pejgktgc"ceguygk0" "pckpvg"fg" c"xk"ug"cf o kpkvutc"NYXTHRACIS."xk"ug"xqt"cf o kpkvutc"fg"qdkegk" o g fkec o gpvg"rgpvtw" c" "ftgxgpk"ucw"tgfweg"tkuewn"crctk kgk"fg"tgce kk"cngtikeg0

Fce "cxg k"qtkeg", pvtgd tk"uwrnk o gpvctg"ew"rtkxktg"nc"ceguy" o g fkec o gpv."cftguc k-x " o gfkewnwk" fw o pgcxqcvt ."htc o cekuvwnwk"ucw" cukuvgpvgk" o g fkecng0

4. Tgce kk"cfxgtug"rqukdkng

Ec"vqcvg" o gfkcc o gpvng."ceguv" o gfkcc o gpv" rqcvg"rtqxqec"tgce kk"cfxgtug."ew"vqcvge" "pw"crct"nc"vqcvg" rgtuqcpngl)

Urwpk k"o gfkcv" o gfkewnk" fw o pgcxqcvu "ucw"rgtuqcpk"ectg"x "cf o kpkvtgc| "rgthw|kc",p"ec|wn" .p"ectg"qdugtxc k"qtkectg"fkpvtg"wt o vqctng"tgce kk"cfxgtug<"

O-pe tk o g."gtwr kg"rg"rkngg."dihkewnv k"fg"tgurktc kg ucw"tgurktc kg" wkgv vqctg"- ceguvgc"ct"rwwgc"hk" ug o pg"fg"crctk kg" c"wpk"tgce kk"cngtikeg"*fg"jkrgtugpukdknkvcvg+0

Cnvgtgce kk"cfxgtug"cnv"NYXTHRACIS kpenwf<

Htgexgpvg *rqv"chgevc"r-p "nc"3 rgtuqcp "fkp"32+

- Fwtgk"fg"ecr
- Tuse
- Fwtgtg"nc"nqewn"cf o kpkvt tkk"rgthw|kgk
- O-pe tk o g."gtwr kg"rg"rkngg."kpenwukx"gtwr kg"ectg"guvg"xk|kdkn "rg"rkngg" k"guvg",puq kv "fg" o-pe tk o k"*wtvkectkg+

Ock"rw kp"htgexgpvg *rqv"chgevc"r-p "nc"3 rgtuqcp "fkp"322+

- Tgce kk"cngtikeg
- C o g gc
- Ugp|c kg"fg"coqt gc
- Ugpukdknkvcvgc"qejknt"nc"nw o kp "hqvqhdkg+
- Fkueqphqtv"nc"pkxgnwn"wtgejkk
- Ktkvc kg",p"i-v
- T i w gc
- Eqpiguvkg"ukpwucn
- Fkhkewnv k"fg"tgurktc kg
- Fwtgk"nc"pkxgnwn"dw|gnqt
- Ge|go ."gzhqkgtg"rkgnk
- Eqpvtce kk"cnv"o w ejknt."urcuog"cnv"o w ejknt
- Qdqucn
- Htkuqcpg"*ugp|c kg"fg"htki+
- Fkueqphqtv"vqteke"
- Ugp|c kg"fg"fwgtg"igpctn "k"fwgtg"fg"o-kpk" k"rkekqctg."rkgrv."oczknct."o w ejk."nkicogpvg." tendoane sau oase
- W o hntg"nc"nqewn"cf o kpkvt tkk"rgthw|kgk."fwgtg"nc"nqewn"cf o kpkvt tkk"rgthw|kgk"ucw"hgdkv " *kphnc o c kc"xgpgnt+

Terqtvtctg"tgce knt"cfxgtug

Fce "o cphguvc k"qtkeg"tgce kk"cfxgtug."cftguc k-x "o gfkewnk"fw o pgcxqcvu ".hct o cekuvwnk"ucw" cukuvpvgk" o gfkccngl) Ceguvgc"kpenwf"qtkeg"rqukdkng"tgce kk"cfxgtug"pg o gp kqpcvg",p"ceguv"rtqurgev"0" Fg" cug o gpgc."rwwg k"terqtvt"tgce kng"cfxgtug"fkgtg"rtkp"kpvtg o gfkwn"ukuvg o wnw"pc kqpen"fg"terqtvtctg."c c" ew o "guvg" o gp kqpcv",p" **Cpgzc"X**"0"Terqvtv-pf"tgce kng"cfxgtug."rwwg k"eqpvtkdw"nc"hwtpk|ctgc"fg" kphqt o c kk"uwrnk o gpvctg"rtkxpf"uki wtcp c"ceguvwk" o gfkcc o gpv0

5. Ew o "ug"r uvtgc| "NYXTHRACIS

Pw"n uc k"ceguv" o gfkcc o gpv"nc"xgfgtgc" k",pfg o -pc"eqrknqt0

Pw"wnk|c k"ceguv" o gfkcc o gpv"fwr "fcvc"fg"gzrktctg",puetku "rg"ewwk" k"rg"gykejgv "fwr "GZR0"Fcvc"fg" gzrktctg"ug"tghgt "nc"wnv o c"|k" c"nwpk"tgurgevkg0

C"ug"r uvtc"nc"htkikfgt"*4ÅE"- :ÅE+0"

C"pw"ug"eqpignc0

C"ug"r uvtc",p" c o dncnwn"qtkikpcn"rgpvtw" c"hk"rtqvglcw"fg"nw o kp 0

Fwr "fknwctg",p"rwpic"rgpvtw"rgthw|kg."uvcdknkvcygc"ejkoke ."hk|ke " k"o ketqdkcp ",p"vk o rwn"vwnk| tkk" c" hquv" fg o qpvtcv "rgpvtw"wp"kpvgtxcn" fg": qtg"nc"vg o rgtcvwtc"ec o gtgk"*42ÅE"- 47ÅE+"ucw",p"eqpfk kknng" r uvt tkk"nc"htkikfgt"*4ÅE"- :ÅE+0

Fwr "fknwctgc"NYXTHRACIS ,pvt-q"ugtkpi "rgpvtw"rgthw|kg."cegcuvc"ug"cf o kpkvutgc| "k o gfkcv" k"pw"ug" fgrq|kygc| 0"Qkteg" o gfkcc o gpv"pgwvknk|cv"vtgdwkg"ctwpecv0

80 **Eqp kpwwn" c o dncnlwnk" k"cnvg" kphqt o c k**

Eg"eqp kpg"NYXTHRACIS

- Uwdvcp c"cevxx "guyg"qdknvqzczk o cdwn0"Wp" o n"fg"eqpegpvtcv"eqp kpg"qdknvqzczk o cd"322 o i0"Wp" flacon de 6 o n"eqp kpg"qdknvqzczk o cd"822 o i0
- Egnncnvg"eq o rpgpv"uwpv"jkuvkfkp ."uqtdkvn"*G642+."rqnuqtdcv":2"*G655+.cekf"enqtkf"tkc" *G729+ k"jkftqzkf"fg"uqfkw"*G746+0"Xg|k" k"rev0 4"§NYXTHRACIS eqp kpg"uqtdkvnö0

Ew o"ctev "NYXTHRACIS k"eqp kpwwn" c o dncnlwnk

NYXTHRACIS guvg"wp"eqpegpvtcv"rgpvtw"uqnv kg"fg"nc"nk o rgfg"nc"qrcnguegpv ."fg"nc"kpeqnt"nc"i ndwk" ucw"w qt"o ctqpkw-i ndwk0
NYXTHRACIS guvg" c o dncv",p"ewkk"ew"3"hnceqp0

Fg kp vqtw"cwvqtk|c kgl"fg"rwpgtg"rg"rk

UHN"Rjct o cegwkecnu" Fgwwuejncpf" I o d J
Marie-Curie-Uvtcuug":
9;75; "N¼ttcej
Igt o cplc

Hcdtkcpvwn"

Cegtvrjct o c"D0X0
Dquejuvtccv"73
6:33" I E."Breda
Olanda

Ceguv"rtqurgev" c" hquv"tgxk|wk",p

Ceguv" o gfkcc o gpv" c" hquv"cwvqtk|cv",p"šeqpfk kk"gzegr kqpcngö0"Cegcuvc",pugc o p "e "fkp"ecw|c"tctkv kk" dqnk" k"fkp" o qvxxg"gvkeg"pw" c" hquv" rqukdkn "qd kpgtgc" kphqt o c kknqt"eq o rnvvg" rtkxkpf" ceguv" o gfkcc o gpv0
C i gp kc"Gwtqrgcp "rgpvtw" O gfkcc o gpv"xc"tgxk|wk",p"hgectg"cp"qtkeg" kphqt o c k"pqk" fkurqpkdkng" fgurgt" ceguv" o gfkcc o gpv" k" ceguv"rtqurgev"xc"hk"cevwcnk|cv."fwr "ew o"xc"hk"pgeguct0

Cnvg"uwtug" fg" kphqt o c k

Kphqt o c k"fgvckevg" rtkxkpf" ceguv" o gfkcc o gpv"uwpv" fkurqpkdkng" rg"ukvg-wn" C i gp kgl"Gwtqrgpg"rgpvtw" O gfkcc o gpv" < [jvr<ll y y 0g o c0gwtqrc0gw0](#) Gzkuv ."fg"cuvg o gpgc."nkpmtk"e vtg"cnvg"ukvg-wtk" fgurgt" dqnk" tctg" k"vtevc o gpv0

Ceguv"rtqurgev" guvg" fkurqpkdkn",p"vqcvg"nk o dkng" WGIUGG"rg"ukvg-wn" C i gp kgl"Gwtqrgpg"rgpvtw" O gfkcc o gpv0

Kphqt o c k"uwrnk o gpvctg" < [y y 0qdknvqzczk o cd-uh0gw](#) Cod QR cg"wt o gc| "c"hk"kpvtqfwu"