# €• ‚ƒ „…†‡•ˆ ‰Š‹Œ‚†‚ ‚Š•†Š ‡•Ž•ˆ

φσšαλƒτφιφšκσηκλσšφτφωφšφσφτš

Ιλκιλιλι ι ƒƒκτλ

ʊtsʟɢ dzjʢʊtɢɦlsəjdz ʧtɢtsнƶʢls ʧtsнdzjкɢ dzʊ нtsʧʲdzdzɢlsjdzdzts dzʊвdzʷнjdzɢj. ʊtsəʊ ʰj ʧtsʟətsdzɢ вʲtɢʟtslsts ƶɦlsʊdztsəʷəʊdzj dzʊ dztsəʊ ɢdzʷtstɢdzʒʊцɢʷ tslsdztsɦdzts вjʟtsʧʊɦdztsɦlslsʊ. ʃls dzjнɢцɢdzɦʢɢlsj ɦʧjцɢʊdzɢɦlsɢ ɦj ɢʟɢɦʢəʊ нʊ ɦʲtsв ʰ ʊəʊls əɦʷʢʊ ʧtsнtsʟɢtɢʊdzʊ dzjкjdzʊdzʊ tɢjʊʢцɢʷ. ıʊ dzʊцɢdzʊ dzʊ ɦʲtsв ʰ ʊəʊdzj dzʊ dzjкjdzʊdzɢ tɢjʊʢцɢɢ əɢкlsj lstsцʢʊ 4.8.

## 1. ʀʃɾıφʃɾʂφʧʜʊʃɾıʀʃ ʧʃʃɾʊʂʊ

NYXTHRACIS 100 mg/ml ʢtsdzцjdzlstɢʊls ʟʊ ɢdzʷƶʟɢtsdzjdz tɢʊʟlsətstɢ

## 2. ʂφʏɾʜʊʃɾıʀʂʃʃʀʏɾʜʊʃɾıʜʒʜʊφʃ

Iɦjʢɢ ml ʢtsdzцjdzlstɢʊls ɦʲнʲtɢкʊ 100 mg tsвɢdzlstsʢɦʊʢɦɢdzʒʊв (obiltoxaximab).
ɾнɢdz ʷdzʊʢtsdz tsls 6 ml ɦʲнʲtɢкʊ 600 mg tsвɢdzlstsʢɦʊʢɦɢdzʒʊв.

ʃвɢdzlstsʢɦʊʢɦɢdzʒʊв ɦj ʧtɢtsɢʟəjкнʊ ə dzɢʰ ɢ dzɢjdztsdzdzɢ ʢdzjlsʢɢ (GS-NS0) цtɢjʟ tɢjʢtsdzвɢdzʊdzlsdzʊ ɾ ı ʂ lsjƊdztsdztsɢʷ.

ı tsdzts ʰ dzts əj ʰ jɦlsəts ɦ ɢʟəjɦlsdzts нjƷɦlsəɢj

Iɦjʢɢ ml ʢtsdzцjdzlstɢʊls ɦʲнʲtɢкʊ 36 mg ɦtstɢвɢlstsdz.

ıʊ ʧʲdzdzɢʷ ɦʧɢɦʲʢ dzʊ ʧtsdzts ʰ dzɢlsj əj ʰ jɦlsəʊ, əɢкlsj lstsцʢʊ 6.1.

## 3. ʃɾʂφʧʜʊʃɾıφʌʃʧʃφ

ʂtsdzцjdzlstɢʊls ʟʊ ɢdzʷƶʟɢtsdzjdz tɢʊʟlsətstɢ (ɦlsjtɢɢdzjdzʢtsdzцjdzlstɢʊls)
NYXTHRACIS j вɢɦlsʲtɢ нts tsʧʊdzjɦцjdzlsjdz, вjʟцəjlsjdz нts вdzjнtsкʲdzls нts вdzjнtsʢʊʷjdzɢʢʊətsкʲdzls tɢʊʟlsətstɢ, ʢtsƷlsts dztsкj нʊ ɦʲнʲtɢкʊ dzʊdzʢtsʧtsdzƶʧtɢtsʟtɢʊцdzɢ нts вjdzɢ ʧtɢtslsjɢdztsəɢ цʊɦlsɢцɢ (ʢtsɢlsts ʰj вʲнʊls tslsɦlstɢʊdzjdzɢ цtɢjʟ ʧtɢjdzɢdzʊəʊdzj ʧtɢjʟəɢtɢʊнjdz ʷɢdzlsʲtɢ) ɦ tɢl 5,5 ɢ tsɦdztsdzʊdzɢlsjls 277 – 308 mOsm/kg.

## 4. ʂʃʀıʀʏıʀ ɾφııʀ

### 4.1 ʊjtɢʊʧjəlsɢцdzɢ ʧtsʢʊʟʊdzɢʷ

NYXTHRACIS j ʧtsʢʊʟʊdz ə ʢtsdzвɢdzʊцɢʷ ɦ ʧtsнƊtsнʷʰ ɢ ʊdzlsɢвʊʢlsjtɢɢʊdzdzɢ dzjʢʊtɢɦlsəʊ ʧtɢɢ əɦɢцʢɢ əʲʟtɢʊɦlstsəɢ ɢtɢƶʧɢ ʟʊ dzjцjdzɢjdz dzʊ ɢdzƊʊdzʊцɢtsdzjdz ʊdzlstɢʊʢɦ, нʲdzкʊʰ ɦjdz dzʊ *Bacillus anthracis* (əк. lstsцʢʊ 5.1).

NYXTHRACIS j ʧtsʢʊʟʊdz ʧtɢɢ əɦɢцʢɢ əʲʟtɢʊɦlstsəɢ ɢtɢƶʧɢ ʟʊ ʧtsɦlsjʢɦʧtsʟɢцɢtsdzdzʊ ʧtɢtsʷɢdzʊʢlsɢʢʊ dzʊ ɢdzƊʊdzʊцɢtsdzjdz ʊdzlstɢʊʢɦ, ʢtsɢʊlsts ʊdzlsjtɢdzʊlsɢədzɢlsj lsjtɢʊʧɢɢ dzj ɦʊ ʧtsнƊtsнʷʰ ɢ ɢdzɢ dzj ɦʊ dzʊdzɢцdzɢ (əк. lstsцʢʊ 5.1).

### 4.2 ɾtsʟɢtɢtsəʢʊ ɢ dzʊцɢdz dzʊ ʧtɢɢdztsкjdzɢj

NYXTHRACIS lstɢʷвəʊ нʊ ɦj ʧtɢɢdzʊɢʊ əjнdzʊɢʊ ʰtsdʒ lstsəʊ j ʢdzɢdzɢцdzts ʧtsʢʊʟʊdzts.

Iɢdzʊɢʊɢ lstɢʷвəʊ нʊ ɢdʒʊ dzʊ tɢʊʟʧtsdztskjdzɢj ʧtsнƊtsнʷʰ ts dʒjнɢʢʊdʒjdzlstsʟdzts dzjцjdzɢj ɢ dzʊвdzʸнjdzɢj ə ɦdzƶцʊƷ dzʊ ʊdzʊʷɢdzʊʢlsɢцdzts ɦʲвɢlsɢj ɦdzjн ʧtɢɢdztskjdzɢjlsts dzʊ NYXTHRACIS.

## Ꞓtslɑʗtsəʢθ

ʅtɛjʃtstɛʲɥɑʃlsjɑɑɑθlsθ нtsLθ NYXTHRACIS ʃtɛɑʃ əʲLtɛθɦlsɑɑɑʃ ʃθɥɑʃjɑɑlsɑʃ ɦ lsjɡɑɑts ɑɑθʔ-ɑʒθɑɑʢts 40 kg j jнɑʃɑɑʃɥɑɑθ ɑʃɑɑlstɛθəjɑɑtsLɑɑθ ɑʃɑɑʷɑɑLɑʃʷ 16 mg/kg lsjɑɑjɦɑɑts lsjɡɑɑts (ls.ls.). ʅtɛjʃtstɛʲɥɑʃlsjɑɑɑθlsθ нtsLθ NYXTHRACIS ʃtɛɑʃ əʲLtɛθɦlsɑɑɑʃ ʃθɥɑʃjɑɑlsɑʃ ɦ lsjɡɑɑts ʃtsн 40 kg j jнɑʃɑɑʃɥɑɑθ ɑʃɑɑlstɛθəjɑɑtsLɑɑθ ɑʃɑɑʷɑɑLɑʃʷ 24 mg/kg lsjɑɑjɦɑɑts lsjɡɑɑts.

ʅtɛjнɑʃ ʃtɛɑʃɑɑtsɥjɑɑɑʃjlsts ɑɑθ NYXTHRACIS ɦj ʃtɛjʃtstɛʲɥəθ ʃtɛjɑʒjнɑʃʢθɥɑʃʷ ɦ θɑɑlsɑʃ⊐ɑʃɦlsθɑʒɑʃɑɑɑʃ (əɥ. lstsɥʢɑʃ 4.4 ɑʃ 4.8).

ɹθ ʃtɛtsɑʒʷɑɑθ ɑɑθ нtsLθlsθ ə ɦɑɑlɑɑɥθʔ ɑɑθ tɛjθʢɥɑʃɑʃ, ɦəʲtɛLθɑɑʃ ɦ ɑʃɑɑʷɑɑLɑʃʷlsθ (IRR), əɑʃɥlsj lsθвɑɑʃɑɥθ 1.

**ʊθвɑɑʃɥθ 1: ʅtɛtsɑʒjɑɑʃ ɑɑθ нtsLθlsθ tsвɑʃɑɑlstsʢɦθʢɦɑʃɑʒθв ʃtɛɑʃ tɛjθʢɥɑʃ, ɦəʲtɛLθɑɑʃ ɦ ɑʃɑɑʷɑɑLɑʃʷlsθ**

| ʊjɥjɦls ɑɑθ IRR | ʃ tsнɑʃʷɑʃʢθɥɑʃʷ ɑɑθ нtsLθlsθ |
|---|---|
| ʈjθʢɥɑʃʷ, ɦəʲtɛLθɑɑθ ɦ ɑʃɑɑʷɑɑLɑʃʷlsθ, ɦlsjʃʃjɑɑ 1–3 | ʁɑɑʷɑɑLɑʃʷlsθ ɑɑθ tsвɑʃɑɑlstsʢɦθʢɦɑʃɑʒθв lstɛʷвəθ нθ ɦj ʃtɛjʢʲɦɑɑj ɑʃ нθ ɦj tsɦɑʃɑʒɑɑtɛɑʃ ʃtsнʰʲtɛɥθʰ ts ɑɑjɥjɑɑɑʃj.<br>ʅtɛɑʃ ʃʲtɛəθlsθ ʃtsʷəθ ɑɑθ ⊐tɛɑʃʃtsəj, вtɛtsɑɑ⊐tsɦʃθʟʲɑɑʒ ɑʃɑɑʃ ɡjɑɑjtɛθɑɑɑʃLɑʃtɛθɑɑθ ɑɑtɛlsɑʃʢθtɛɑʃʷ ɦlsjʃʃjɑɑ 3, ʃtɛɑʃɑɑtsɥjɑɑɑʃjlsts ɑɑθ tsвɑʃɑɑlstsʢɦθʢɦɑʃɑʒθв lstɛʷвəθ нθ вʲнj tsʢtsɑɑɥθlsjɑɑɑts ʃtɛjɑɑɦlsθɑɑtsəjɑɑts.<br>ʅtɛɑʃ ʃtsəlsθtɛʷʰ ɑʃ ɦj ⊐tɛɑʃʃtsəj ɑʃɑɑʃ ɑɑtɛlsɑʃʢθtɛɑʃʷ ɦlsjʃʃjɑɑ 2 ɑʃɑɑʃ ʃtɛɑʃ ʃtsəlsθtɛʷʰ ɑʃ ɦj ɦɑʃɑʒʃʃlstsɑʒɑʃ tslɑ ɦlsjʃʃjɑɑ 3, ʃtɛɑʃɑɑtsɥjɑɑɑʃjlsts ɑɑθ tsвɑʃɑɑlstsʢɦθʢɦɑʃɑʒθв lstɛʷвəθ нθ вʲнj tsʢtsɑɑɥθlsjɑɑɑts ʃtɛjɑɑɦlsθɑɑtsəjɑɑts.<br>I ʃtɛtslsɑʃəjɑɑ ɦɑɑlɑɑɥθʔ, ɦɑɑjн ʃʲɑɑɑts tslsLəɑɑɥθəθɑɑj ɑɑθ ɦɑʃɑʒʃʃlstsɑʒɑʃlsj, ɑʃɑɑʷɑɑLɑʃʷlsθ ɑʒtsɥjj нθ вʲнj əʲLtsвɑɑtsəjɑɑθ ʃtɛɑʃ 50% tsls ɦʢtstɛtsɦlslsθ, ʃtsɦlsɑʃɡɑɑθlsθ ʃtɛjнɑʃ ʃtɛjʢʲɦəθɑɑjlsts. ʅtɛɑʃ ɑɑʃʃɦθ ɑɑθ ɦɑʃɑʒʃʃlstsɑʒɑʃ, ɦəʲtɛLθɑɑʃ ɦ ɑʃɑɑʷɑɑLɑʃʷlsθ, ɦʢtstɛtsɦlslsθ ɑɑθ ɑʃɑɑʷɑɑLɑʃʷlsθ j tsʃɑʃɦθɑɑθ əlsθвɑɑʃɥθ 3.<br>ʊtɛʷвəθ нθ ɦj ʃtɛɑʃɑɑtsɥjɑʃ ʃtɛjɑʒjнɑʃʢθɥɑʃʷ. | ʁɑɑʷɑɑLɑʃʷlsθ ɑɑθ tsвɑʃɑɑlstsʢɦθʢɦɑʃɑʒθв lstɛʷвəθ ɑɑjLθвθəɑɑts нθ ɦj ɦʃʃtɛj.<br>ʊtɛʷвəθ нθ ɦj tsɦɑʃɑɑtɛɑʃ ʃtsнʰʲtɛɥθʰ ts ɑɑjɥjɑɑɑʃj.<br>ʅtɛɑʃɑɑtsɥjɑɑɑʃjlsts ɑɑθ tsвɑʃɑɑlstsʢɦθʢɦɑʃɑʒθв lstɛʷвəθ нθ вʲнj tsʢtsɑɑɥθlsjɑɑɑtsʃtɛjɑɑɦlsθɑɑtsəjɑɑts. |
| ʈjθʢɥɑʃʷ, ɦəʲtɛLθɑɑθ ɦ ɑʃɑɑʷɑɑLɑʃʷlsθ, ɦlsjʃʃjɑɑ 4 | |

## ʁʃjɥɑʃθɑɑɑʃ ʃtsʃɑɑθɥɑʃɑʃ

### *ʁ lsθtɛɥjɦʢθ əʲLtɛθɦls*

ʅj ɦj ʃtɛjʃtstɛʲɥəθ ʢlstɛɑʃɡɑʃtɛθɑɑj ɑɑθ нtsLθlsθ Lθ ʃθɥɑʃjɑɑlsɑʃ ɑɑθ əʲLtɛθɦls Ó 65 ɡtsнɑʃɑɑʃ (əɥ. lstsɥʢθ 5.2).

### *ʅjнɑʃθlstɛɑʃɥɑɑθ ʃtsʃɑɑθɥɑʃʷ*

ʅtɛjʃtstɛʲɥɑʃlsjɑɑɑθlsθ нtsLθ Lθ ʃjнɑʃθlstɛɑʃɥɑɑʃ ʃθɥɑʃjɑɑlsɑʃ ɦj tsɦɑɑtsəθəθ ɑɑθ lsjɡɑɑtslsts, ʢθʢlsts j ʃtsʢθLθɑɑts ə lsθвɑɑʃɥθ 2 ʃtsнtsɑɑb.

**ʊθвɑɑʃɥθ 2: ʅtɛjʃtstɛʲɥɑʃlsjɑɑɑθ ʃjнɑʃθlstɛɑʃɥɑɑθ нtsLθ tsвɑʃɑɑlstsʢɦθʢɦɑʃɑʒθв (нtsLɑʃtɛθɑɑj ɑɑθ вθLθlsθ ɑɑθ lsjɡɑɑtslsts)**

| ʊjɑɑjɦɑɑts lsjɡɑɑts [kg] | ʁtsLθ [mg/kg ls.ls.] |
|---|---|
| > 40 | 16 |
| > 15 нts 40 | 24 |
| 15 ɑʃɑɑʃ ʃtsнtsɑʒθɑɑʢts | 32 |

Ɩ Θцфдє дєΘ тфєсфдєтзкјдєфј

∫вфдєlзтѕҜпΘҜпфдфζΘв lзєʷвэΘ нΘ пјј тфєсфдєΘсΘ цєсјL фдєlзєΘэјдєтѕLдєΘ фдєẘƛLфʷ э тфєтѕнʲдєкјдєфј дєΘ 90 ζфдєƛlѕф.

*ɿєсјнтfΘLдєф ζјјєҜф, Ҝѕфlѕтѕ lзєʷвэΘ нΘ вʲнΘls эLјlѕф тфєсјнф тєΘвтѕlѕΘ пʲп фдєф тфєфдєтѕ кјдєфј дєΘ дјҜΘєпlѕэјдєфʷ тфєтѕнƛҜlѕ*

Λ дєΘҜтѕдєʲls дєј lзєʷвэΘ нΘ пјј тєΘLҜдєʰΘ. ∫вфдєlзтѕҜпΘҜпфдфζΘв lзєʷвэΘ нΘ пјј тєΘLєсјнф п дєΘlзєфјэ Ƨдєтѕєфн 9 mg/ml (0,9%) фдєкјҜцфтѕдєјдє тєΘLlѕэтѕє тфєсјнф тфєфдєтѕкјдєфј ҜΘlѕтѕ фдєlзєΘэјдєтѕLдєΘ фдєẘƛLфʷ (эк. lѕтцҜΘ 6.6).

ţΘLєсјнјдєфʷls тєΘLlѕэтѕє тѕвфдєlзтѕҜпΘҜпфдфζΘв LΘ фдєlзєΘэјдєтѕLдєΘ фдєẘƛLфʷ lзєʷвэΘ нΘ пјј эдєфэΘ э тфєтѕнʲдєкјдєфј дєΘ 90 ζфдєƛlѕф ʲп пҜтѕтєтѕпlѕ дєΘ фдєẘƛLфʷlѕΘ, тѕтfфпΘдєΘ э lѕΘвдєфцΘ 3, ҜΘlѕтѕ пјј фLтfтѕдLэΘ фдєẘƛLфѕдєјдє пΘҜ фдєф пјтфєфдєцѕэҜΘ LΘ фдєẘƛLфѕдєдєΘ тfѕζтfΘ ф эсєΘнјдє ẘфдєлʲє 0,22 ζфҜєтѕдєΘ.

ɿΘцфјдєлфлѕј lзєʷвэΘ нΘ вʲнΘls эдєфζΘлѕјдєдєѕ дΘвдєˣнΘэΘдєф LΘ тфєфLдєΘцф ф пфдζтfлѕтѕζф дєΘ пэєтʲΞцƛэплѕэфлѕјдєдєѕплls тfѕ эєтјζѕј дєΘ фдєẘƛLфʷlѕΘ ф тfѕдєј јнфдє цΘпп пдєјн тфєфдєѕкјдєфјlѕѕ (эк. lѕтцҜΘ 4.4). ţјΘҜцффлѕј, пэʲтєLΘдєф п фдєẘƛLфʷlѕΘ, lзєʷвэΘ нΘ пјј тѕэдєΘнʷэΘls, ҜΘҜlѕѕ ј тfѕпѕтѕцјдєѕ э lѕΘвдєфцΘ 1.

ѡфпlѕјζΘlѕΘ lзєʷвэΘ нΘ пјј тфєтѕζфјј п дΘlзєфјэ Ƨдєтѕєфн 9 mg/ml (0,9%) фдєкјҜцфтѕдєјдє тєΘLlѕэтѕє э ҜтєΘʷ дєΘ фдєlзєΘэјдєтѕLдєΘlѕΘ фдєẘƛLфʷ.

**ѵΘвдєфцΘ 3: ţтѕLΘ тѕвфдєlзтѕҜпΘҜпфдфζΘв, тѕвʰ фдєẘƛLфтѕдєјдє тѕвјдζ ф пҜтѕтєтѕпlѕ дєΘ фдєẘƛLфʷlѕΘ птfтѕтєјн lѕјдєјпдєтѕlѕтѕ lѕјєćдєтѕ**

| **ѵѕјдєјпдєтѕ lѕјєćдєтѕ [kg] (нѕLфтєΘдєј дєΘ вΘLΘlѕΘ дєΘ lѕјєćдєтѕlѕтѕ)** | **∫вʰ тѕвјдζ дєΘ фдєẘƛLфʷlѕΘ [ml] [фдєẘƛLфтѕдєјдє пΘҜ фдєф пјтfтєфдєцѕэҜΘ]*** | **ѡҜѕтєтѕпlѕ дєΘ фдєẘƛLфʷlѕΘ [ml/цΘпј]** |
|---|---|---|
| **> 40 kg фдєф эʲLтєΘпlѕјдє (16 mg/kg lѕ.lѕ.)** | | |
| > 40 | 250 | 167 |
| **> 15 нѕ 40 kg (24 mg/kg lѕ.lѕ.)** | | |
| 31 нѕ 40 | 250 | 167 |
| 16 нѕ 30 | 100 | 67 |
| **15 kg фдєф тfѕ-ζΘдєҜѕ (32 mg/kg lѕ.lѕ.)** | | |
| 11 нѕ 15 | 100 | 67 |
| 5 нѕ 10 | 50 | 33.3 |
| 3,1 нѕ 4,9 | 25 | 17 |
| 2,1 нѕ 3 | 20 | 13,3 |
| 1,1 нѕ 2 | 15 | 10 |
| 1 фдєф тfѕ-ζΘдєҜѕ | 7 | 4.7 |

*ɿΘ фдєпlѕтєƛҜцфф LΘ тєΘLтєјнΘдєј дєΘ дјҜΘєпlѕэјдєфʷ тфєтѕнƛҜlѕ ф ƛтfѕlѕтєјвΘ дєΘ пΘҜΘ фдєф пјтfтєфдєцѕэҜΘlѕΘ тфєјнф тфєфдєтѕкјдєфј, эфкlѕјј lѕтцҜΘ 6.6.

## 4.3 ɿєтѕlѕфэѕтfѕҜΘLΘдєфʷ

ѡэтєʲΞцƛэплѕэфлѕјдєдєѕплls ҜʲζΘ ΘҜlѕфэдєтѕlѕтѕ эјʰ јплѕэѕ фдєф ҜʲζΘ дєʷҜѕјѕ тѕls тfѕζѕѕʰ дєфлѕјѕ эјʰ јплѕэΘ, фLвєтѕјдєф э lѕтцҜΘ 6.1.

## 4.4 ѡтfјцфΘдєдєф тfєјнƛтfєјкнјдєфʷ ф тfєјнтfΘLдєф ζјјєҜф тfєсф ƛтfѕlѕтєјвΘ

ɿєтѕпдєјнфζѕплls

ɿΘ нΘ пјј тfѕнѕвєсф тfєтѕпдєјнфζѕплlѕlѕΘ дєΘ вфѕдєѕєćфцдєфлѕјј дєјҜΘєпlѕэјдєфʷ тфєтѕнƛҜlѕф, фζѕјlѕтѕ ф тfΘєlѕфндєфʷls дєѕдєζјє дєΘ тфєфдєтѕкјдєфʷ тфєтѕнƛҜlѕ lзєʷвэΘ ʷпдєѕ нΘ пјј LΘтfфпэΘls.

## Ţĵθϟцфф, ŋəʲŧєʟθđфф ŋ фđѿѾƀʟфʷѕθ, ŋəŧєʲΠцƀəŋѕəфѕĵđđŧѕŋѕ ф θđѿѾфđθϟŋффʷ

Ţĵθϟцфф, ŋəʲŧєʟθđфф ŋ фđѿѾƀʟфʷѕθ/ŧєĵθϟцфф đθ ŋəŧєʲΠцƀəŋѕəфѕĵđđŧѕŋѕ цĵŋѕŧѕ ŋĵ đθвđѯ ʸ нθəθѕ ŧƒŧѕ əŧєĵđѯĵ đθ ϟđфđđфцđđф фʟŧƒфѕəθđфʷ ŋ тѕвфđѕŧѕϟŋθϟŋфŋфđѯθв ŧƒŧєф ѕнŧєθəф ƀцθŋѕđđфцф. Ɨ тѕŧєθнф ŧєфŋϟθ тѕѕ ѕĵкϟф ŧєĵθϟцфф фđđф θđѿѾфđθϟŋфŋфʷ, тѕвфđѕŧѕϟŋθϟŋфŋфđѯθв ѕŧєʷвəθ нθ ŋĵ ŧƒŧєфđθϟθ ə ϟтѕđѕŧєтѕđđфŧєθđđф ƀŋđđтѕəфʷ тѕѕ ŧƒĵŧєŋтѕđđθđ, тѕвƀцĵđ ф тѕвŧѕŧєƀнəθđđ ʟθ тѕəđθнʷəθđĵ đθ θđѿѾфđθϟŋфʷ. Ɨ θцфĵđđѕфѕĵ ѕŧєʷвəθ нθ вʲнθѕ đθвđѯ ʸ нθəθđđф əđđфđѯθѕĵđđđŧѕ ŧƒŧєĵʟ цĵđđфʷ ŧƒĵŧєфŧѕн đθ фđѿѾƀʟфʷѕθ ф ŧƒŧѕđĵ ĵнфđđ цθŋ ŋđĵн ŧƒŧєфđđŧѕкĵđđфĵѕŧѕ.

ƣʲ ϟθѕŧѕ ϟđфđđфцđđфѕĵ ŧƒŧєŧѕƀцəθđđфʷ ŋθ ŧƒŧєŧѕəĵнĵđđф ŧƒŧєф ѕнŧєθəф нŧѕвŧєŧѕəŧѕđđцф, фđѿѾƀʟфđфѕĵ đθ тѕвфđѕŧѕϟŋθϟŋфŋфđѯθв ŋθ ŋŋŧƒŧєĵđđф ŧƒŧєф ŧƒŧѕʷəθѕθ đθ ϟθϟəθѕŧѕ ф нθ ĵ ŧєĵθϟцфʷ. Ɨ ʲʟ тѕŋđđŧѕəθ đθ ŧƒŧєфŧѕθ ŋ нŧєƀґфŋ đĵŧѕđđŧѕϟđđŧѕđθđđф θđѕфѕĵđθ, фʟŧƒŧѕđʟəθđđф ŧƒŧєф đĵцĵđđфĵѕŧѕ đθ ŋĵŧєфŧѕʟđđф ʟθвŧѕđʷəθđđфʷ, фđѿѾƀʟфđѕĵ тѕвфϟđđŧѕəĵđđŧѕ đĵŧѕґθѕ нθ вʲнθѕ ʟθəʲŧєʰ ĵđđф ŧƒŧєф ŧƒŧѕнΠŧѕнʷʰ ŧѕ ŧƒŧəĵнĵđđфĵ. Ţĵθϟцфф ѕĵ, ŋəʲŧєʟθđфф ŋ фđѿѾƀʟфʷѕθ, ѕŧєʷвəθ нθ ŋĵ ŧəđθнʷəθѕ, ϟθϟѕŧѕ ĵ ŧƒŧѕŋŧѕцĵđŧѕ ə ѕθвđфцθ 1.

Ɨ єĵđĵĵнфϟθцфʷ ŋ θđѕфΠфŋѕθđĵđđ, đθŧƒŧє. нфѾĵđΠфнєθđĵđđ, ŋĵ ŧƒєĵŧƒŧѕєʲцəθ ŧƒєĵнф ŧƒŧєфđŧѕкĵđđфĵ đθ тѕвфđѕŧѕϟŋθϟŋфŋфđѯθв (əк. ѕŧѕцϟθ 4.2). Ţ фѾĵđΠфнєθđĵđđ ĵ ŧƒŧєфđθϟθđđ 30 đĵфđđƀѕфŧƒŧєĵнф đĵцĵđđфĵ ŋ тѕвфđѕŧѕϟŋθϟŋфŋфđѯθв ə ϟđфđđфцđđф фʟŧƒфѕəθđфʷ, ŧƒŧєтѕəĵнĵđđф ŋ тѕвфđѕŧѕϟŋθϟŋфŋфđѯθв. Ɨ єĵđĵĵнфϟθцфʷѕθ ŋ θđѕфΠфŋѕθđĵđđ đĵ ŧƒŧєĵнтѕѕəтєθѕʷəθ θđθѾфđθϟŋфʷѕθ ф đĵтѕкĵ нθ đĵθŋϟфŧєθ фđđф ʟθвθəф ŧƒŧѕʷəθѕθ đθ ŋфđĵŧƒѕтѕđĵф đθ ŋəŧєʲΠцƀəŋѕəфѕĵđđŧѕŋѕ.

### Фđѕŧєθϟŋĵđđ đĵĵđđфđđґфѕ

Ţ вфđѕŧѕϟŋθϟŋфŋфđѯθв đĵ ŧƒŧєĵđĵфđđəθ ϟтєʲəđŧѕ-đĵтѕʟʲцđθѕθ вθтєфĵŧєθ ф đĵ ŧƒŧєĵнтѕѕəтєθѕʷəθ фđđф đĵϟƀəθ θđѕŧєθϟŋĵđđ đĵĵđđфđđґфѕ.

### Ɨ ĵнфθѕŧєфцđθ ŧƒѕŧƒƀđθцфʷ

ѕ ĵ ŋθ ŧƒŧєŧѕəĵкнθđđф ŧƒŧєŧѕƀцəθđđфʷ ʟθ вĵʟѕŧƒθŋđŧѕŋѕ фđđф Ѿθтєđĵθϟŧѕϟфđĵѕфцđđф (PK) ŧƒŧєŧѕƀцəθđđфʷ đθ тѕвфđѕŧѕϟŋθϟŋфŋфđѯθв ŧƒŧєф ŧƒĵнфθѕŧєфцđθѕθ ŧƒѕŧƒƀđθцфʷ (əк. ѕŧѕцϟθ 5.2).

### Ɨʟθфđĵтѕнĵƣŋѕəфʷ ŋ đθвѕŧєθѕŧѕŧєđđф ѕĵŋѕŧѕəĵ

Ţϟŋŧƒŧѕʟфцфʷѕθ đθ NYXTHRACIS đĵтѕкĵ нθ ŧƒŧəđđфʷĵ đθ ŋĵŧєтѕđŧѕґфцđđфѕĵ ѕĵŋѕŧѕəĵ ʟθ θđѕŧєθϟŋ.

### Ʉтѕŧєвфѕŧѕđ

Ɨŋĵϟфʲнĵŧєкθ 36 mg ŋѕŧєвфѕŧѕđ (əк. ѕŧѕцϟфʲ 2 ф 6.1).
Ţĵϟθŧєŋѕəĵđđфѕĵ ŧƒŧєŧѕнƀϟѕфʲ, ŋʲнĵŧєкθʰ ф ŋѕŧєвфѕŧѕđ, đĵтѕґθѕ нθ нтəĵнθѕ нтѕ ŋđĵŧєѕ, θϟтѕ ŋĵ ŧƒŧєфđθґθѕ фđѕŧєθəĵđŧѕʟđŧѕ đθ đĵфцθ ŋ đθŋđĵнŋѕəĵđđ đĵŧƒѕđŧѕŋфđĵтѕŋѕ ϟʲđĵ Ѿŧєƀϟѕŧѕʟθ (ʟ ʟ ʌ). Ţ вфđѕŧѕϟŋθϟŋфŋфđѯθв đĵ ѕŧєʷвəθ нθ ŋĵ фʟŧƒѕđʟəθ ŧƒŧєф ŧƒθцфĵđѕфʲ ŋ ʟ ʟ ʌ, тѕŋəĵđ θϟтѕ đʷđѯθ đĵŧƒŧєĵтѕнтѕđфđѯθ ϟđфđđфцđđθ đĵŧѕвΠŧѕнфđѯтѕŋѕ фđĵŋθđđθđфцđđф θđѕĵŧєđθѕфəđđф ѕĵŧєθŧƒфđ. ƣŧєʷвəθ нθ ŋĵ ŋđĵđѯĵ ŧƒѕнŧєтѕвđđθ θđθđѯđĵʟθ ŧƒŧѕ тѕѕđŧѕ ʰ ĵđđфĵ đθ ŋфđѯŧƒѕтѕđѯфѕĵ đθ ʟ ʟ ʌ тѕѕ əŋĵϟфĵ ŧƒθцфĵđѕ, ŧƒŧєĵнф нθ đѯƀ ŋĵ нθнĵ ѕтѕʟф đĵϟθŧєŋѕəĵđ ŧƒŧєтѕнƀϟѕ.

Ş ʲŧєđѯθцĵѕθѕθ фđθđϟфѕĵ нĵцθ (ŧƒŧѕн 2-ґŧѕнфʰ đθ əʲʟŧєθŋѕ) ŋθ фʟđŧѕкĵđđф đθ тѕŋтѕвĵđ ŧєфŋϟ, ѕʲƣ ϟθѕŧѕ đĵтѕкĵ əŋĵ тѕʰĵ нθ đĵ ŋθ нфθґđŧѕŋѕфцŧєθđфʟθ ʟ ʟ ʌ.

### Ʌθѕŧєфƣ

Ѳтəθ đĵϟθŧєŋѕəтѕ ŋʲнĵŧєкθ ŧƒѕ-đĵθđϟѕ тѕѕ 1 mmol đθѕŧєфƣ (23 mg) đθ əŋĵϟфʲ 6 ml, ѕ.ĵ. đĵтѕкĵ нθ ŋĵ ϟθкĵ, цĵ ŧƒŧєθϟѕфцĵŋϟфʲ đĵ ŋʲнĵŧєкθ đθѕŧєфƣ.

### 4.5 Ɪʟʊɖʤtsʜʝƿɦlsəɖʝ ɦ ʜtɛƛɡɖ ɖʝʢʊtɛɦlsəʝɖɛɖ ʧtɛtsʜƛʢlsɖ ɖ ʜtɛƛɡɖ ʷtstɛʤɖ ɖƶʊ əʟʊɖʤtsʜʝƿɦlsəɖʝ

ʎɖʧtɛtsʷɖtsʢɦʊɥɖɖ

Ɪ ʧtɛtsƛɥəʊɖʝ ʟʊ əʟʊɖʤtsʜʝƿɦlsəɖʷlsʊ ʝʜɖɛɖɥɖƶʊ ʜtsʟʊ tsʙɖʤlstsʢɦʊʢɦɖʤʊʙ ʝ ʧtɛɖɛɖʊɡɖƶʊ ɦʊʤtsɦlstsʷlsʝɖɛɖts, ɖƶɖ ʝʜɖtsətɛʝʤʝɖɛɖts ɦ ɥɖʧtɛtsʷɖtsʢɦʊɥɖɖ ʧtɛɖ 40 ʧʊɥɖʝɖɛlsɖ. Ɪ əʊʜʝɦʝls ʧʊɥɖʝɖɛlsɖ ɦʊ ʧtsɖƛɥəʊəʊɖɖ ɦʊʤtsʷ tsʙɖʤlstsʢɦʊʢɦɖʤʊʙ, ʊ 20 ʧʊɥɖʝɖɛlsɖ ɦʊ ʧtsɖƛɥəʊəʊɖɖ tsʙɖʤlstsʢɦʊʢɦɖʤʊʙ ʧɖ ˣ ɦ ɥɖʧtɛtsʷɖtsʢɦʊɥɖɖ ə ʧtɛtsʜʲɖɥʝɖɛɖʝ ɖʊ 9 ʜɖɛɖ. Ɪtɛɖ ʧtɛɖʤʊɡʊɖʝlsts ɖʊ 16 mg/kg tsʙɖʤlstsʢɦʊʢɦɖʤʊʙ ɖʤlstɛʊəʝɖtsʟɖʊ ɖʤʷƛʟɖʷ ʧtɛʝʜɖ ɥɖʧtɛtsʷɖtsʢɦʊɥɖɖ ɖʤlstɛʊəʝɖtsʟɖʊ ɖʤʷƛʟɖʷ ɖʤɖ ɥɖʧtɛtsʷɖtsʢɦʊɥɖɖ ʜəʊ ʧʲlsɖ ʜɖʝəɖts, ʧʝtɛtstɛʊɖɖɖʷls ʧtɛɖʝɖʤ ɖʊ lsʊʙɖʝlsʢɦlsʝ, ɖʝ ʧtɛtsɖʝɖʤʷ ʷʊtɛɖʤʊʢtsʢɖʝlsɖʢʊlsʊ ɖʊ tsʙɖʤlstsʢɦʊʢɦɖʤʊʙ, Ɪ ts ɦʲ ʰ ɖʷ ɖʊɥɖɖ tsʙɖʤlstsʢɦʊʢɦɖʤʊʙ ɖʝ ʧtɛtsɖʝɖʤʷ ʷʊtɛɖʤʊʢtsʢɖʝlsɖʢʊlsʊ ɖʊ ɥɖʧtɛtsʷɖtsʢɦʊɥɖɖ, ʧtɛɖɛɖʊɡʊɖ ʧʝtɛtstɛʊɖɖts ɖʤɖ ɖʤlstɛʊəʝɖtsʟɖʊ.

Ɪʝ ɦʊ ʧtɛtsəʝʜʊɖɖ ʜtɛƛɡɖ ʧtɛtsƛɥəʊɖɖʷ ʟʊ əʟʊɖʤtsʜʝƿɦlsəɖʷlsʊ. ʊʲ ƿ ʢʊlsts tsʙɖʤlstsʢɦʊʢɦɖʤʊʙ ʝ ɖʤtsɖɖtsʢɖtsɖʊɖɖts ʊɖlsɖʢlsʷɖts, tɛɖʰʢʲls tslsəʟʊɖʤtsʜʝƿɦlsəɖʝ ʝ ɖɛɖʰʝʲʢ.

### 4.6 Ʌ ʝtɛlsɖʤɖʢlsʝlsʟ, ʙtɛʝɖʤʝɖɛɖtsɦlsɖ ɖ ʢʲtɛɖʤʝɖɛʝ

ɪtɛʝɖʤʝɖɛɖtsɦlsɖ

ʎʷɖʤʊ ʜʊɖɛɖɖ ʟʊ ƛʧtslstɛʝʙʊlsʊ ɖʤʊ tsʙɖʤlstsʢɦʊʢɦɖʤʊʙ ʧtɛɖ ʙtɛʝɖʤʝɖɛɖɖ ʝʜɖɛɖ, ɖɛts ʝ ɖʟəʝɦlsɖɛts, ʊʝ ʊtsəʝʰʢɖʷlsʊ IgG ʧtɛʝɖʤɖʤʊəʊ ʧɖɛʊʝɖɛlsʊtɛɖɛʊlsʊ ʙʊtɛɖʝtɛʊ.
Ɪtɛtsƛɥəʊɖɖʷlsʊ ʧtɛɖ ʜɖətslsɖɖ ɖʝ ʧtsʢʊəʊlsʊ ʧtɛʝʢɖ ɖɖɖ ʢtsɦəʝɖɖ ətɛʝʜɖɛɖ ʝʷʝʢlsɖ ʧts tslsɖɛts ʰ ʝɖɛɖʝ ɖʊ tɛʝʧtɛtsʜƛʢlsɖəɖʊ lstsʢɦɖʊʤtsɦls (əʜ. lstsʊʢʊ 5.3).
ʢʊlsts ʧtɛʝʜʧʊʟɖʊ ʤʷtɛʢʊ ɦʝ ʧtɛʝʧtstɛʲʊəʊ ɖʟʙʷɡəʊɖʝ ɖʊ ƛʧtslstɛʝʙʊlsʊ ɖʊ NYXTHRACIS ʧts ətɛʝʤʝ ɖʊ ʙtɛʝʤʝɖɛɖtsɦls.

ʢʲtɛɖʤʝɖɛʝ

ʎʝ ʝ ɖʟəʝɦlsɖɛts ʜʊɖɖ tsʙɖʤlstsʢɦʊʢɦɖʤʊʙ ɦʝ ʝʢɦʢtɛʝlsɖʢtɛʊ ə ʢʲtɛɖʤʊlsʊ. ʀʟəʝɦlsɖɛts ʝ, ʊʝ ʊtsəʝʰʢɖʷlsʊ IgG ɦʝ ʝʢɦʢtɛʝlsɖʢtɛʊ ə ʢʲtɛɖʤʊlsʊ ʧtɛʝʟ ʧʲtɛəɖlsʝ ʜɖɛɖɦɖʝʜ tɛʊʜʊɖʝlsts ɖ ɦʢtstɛts ɦɖʝʜ lstsəʊ ɖʊɖʤʊɖʷəʊ ʜts ɖɖɦʢɖ ʢtsɖƛʊʝɖʝlstɛʊʊɖɖ. ʜɖʝʜtsəʊlsʝɖɛɖts ʧtɛʝʟ lstsʟɖ ʢtɛʊlsʲʢ ʧʝtɛɖʧtsʜ ɖʝ ʤtsʜʝ ʜʊ ɦʝ ɖʟʢɖˣ ʊɖ tɛɖɦʢ ʟʊ ʢʲtɛʤʊʊʝlsʊlsʊ. ʜɖʝʜ lstsəʊ ʤtsʜʝ ʜʊ ɦʝ tsʙɖʤɖɦɖɖ ɖʟʧtsɖʟəʊɖʝlsts ɖʊ tsʙɖʤlstsʢɦʊʢɦɖʤʊʙ ʧts ətɛʝʤʝ ɖʊ ʢʲtɛʤʝɖʝ, ɦʊʤts ʊʢts ʝ ʢɖɖɖʤʊɖʝ ɖʝtsʙ¬tsʜɖʤts.

ʌʝtɛlsɖʤɖʢlsʝlsʟ

ʎʝ ɦʊ ʧtɛtsəʝʜʊɖɖ ʧtɛtsƛɥəʊɖɖʷ ʧts tslsɖɛts ʰ ʝɖɛɖʝ ɖʊ ʷʝtɛlsɖʤɖʢlsʝlsʟ ɦ tsʙɖʤlstsʢɦʊʢɦɖʤʊʙ.

### 4.7 ʢʷʝʢlsɖ əʲtɛ¬ƛ ɦʧʧtsɦtsʙɖtsɦlslsʊ ʟʊ ʰ tsʷɖʧtɛʊɖʝ ɖ tɛʊʙtslsʊ ɦ ʤʊ ʰ ɖʤɖ

ʃʙɖʤlstsʢɦʊʢɦɖʤʊʙ ʤtsʜʝ ʜʊ ɖʤʊ ɖʝʟɖʊɥɖʢlsʝɖɛɖts əɖɖʷɖɖʝ əʲtɛ¬ƛ ɦʧʧtsɦtsʙɖtsɦlslsʊ ʟʊ ʰ tsʷɖʧtɛʊɖʝ ɖ tɛʊʙtslsʊ ɦ ʤʊ ʰ ɖʤɖ, ʢʲƿ ʢʊlsts ɦɖʝʜ ʧtɛɖʤtsʜʝɖɛɖʝ ɖʊ NYXTHRACIS ʤtsʜʝ ʜʊ ɦʝ ʧtsʷəɖ ɡɖʊətsʙtsɖɖʝ, ɦəʝlstsəʲtɛlsʝʜ, ƛʤtstɛʊ ɖ ʧtsətɛʲ ʰ ʊɖʝ (əʜ. lstsʊʢʊ 4.8).

### 4.8 ʎʝʜʝɖʊɖɖ ɖʝʢʊtɛɦlsəʝɖɛɖ tɛʝʊʢʊɖɖ

ʧʝʟˣ ʤʝ ɖʊ ʧtɛtsʷɖɖʊ ɖʊ ʙʝʟtsʧʊɦɖtsɦls

ɪʝʟtsʧʊɦɖtsɦlslsʊ ɖʊ tsʙɖʤlstsʢɦʊʢɦɖʤʊʙ ʝ ʧtɛtsƛɥʝɖʊ ɦʊʤts ʧtɛɖ ʟʜtɛʊəɖ əʲʟtɛʊɦlsɖɛɖ ƛɥʊɦlsɖɛɖɥɖ.

ɪʝʟtsʧʊɦɖtsɦlslsʊ ɖʊ tsʙɖʤlstsʢɦʊʢɦɖʤʊʙ ʝ tsɥʝɖɛʝɖʊ ʧtɛɖ 320 ʟʜtɛʊəɖ ʧʊɥɖʝɖɛlsɖ (ɖʊ əʲʟtɛʊɦls tslsʟ 18 ʜts 79 ɡtsʜɖɛɖ), ɖʝʢƛəʊɖɖ ɦ ʝʜɖʊ ɖʤɖ ʜəʝ ɖɛlstɛʊəʝɖtsʟɖɖ ʜtsʟɖ tslsʟ 16 mg/kg ə lstɛɖ ʢɖɖɖʤʊɖɖ ʧtɛtsƛɥəʊɖɖʷ.

ʃʙʰ ts 250 tslsʟ 320-lsʝ ƛɥʊɦlsɖɛɖɥɖ ɦʊ ʧtsɖƛɥʊɖɖ ʝʜɖɛɖɥɖʊ ʜtsʟʊ 16 mg/kg tsʙɖʤlstsʢɦʊʢɦɖʤʊʙ.
ʜəʲtɛʟʊɖɖ ɦʲʰ ɦətɛʲ¬ɥƛəɦlsəɖlsʝɖɛɖtsɦls ɖʝʜʝʝɖʊɖɖ tɛʝʊʢɥɖɖ (əʢɖˣ ɥɖlsʝɖɛɖts tsʙtɛɖə) ɦʊ ɦʝ ʧtsʷəɖɖɖ ʧtɛɖ 9% (22/250) tslsʟ lsʝʟɖ ʧʊɥɖʝɖɛlsɖ, ʢʊlsts ʧts ətɛʝʤʝ ɖʊ ɖʤʷƛʟɖʷlsʊ ʝ ɖʊʙɖˣ ʜʊəʊɖ ʝʜɖʤ ɦɖƛɥʊʢ ɖʊ

ϴǼϴ῭ʠǼϴʢɧʠʷ. ʀǼ῭ɮʟʠʷʂϴ ʝ ʧʦʝʢʦϴʂʝǼϴ ʧʦʠ 3% (8/250) ʧʦʦϴʜʠ ɧɘʦʲ ƦʯɮɘɧʂɘʠʂʝǼǼʦɧʂ ʠǼʠ ϴǼϴ῭ʠǼϴʢɧʠʷ.

ʅϴʡ-ʯʝɧʂʦ ɧʲʦʙʱ ϴɘϴǼʠʂʝ Ǽʝʞʝǽϴǽʠ ʦʝϴʢʯʠʠ ɧϴ ɢǽϴɘʦʙʦǼʠʝ (4%, 9/250), ɧʲʦʙʝʞ (4%, 9/250) ʠ ɮʦʂʠʢϴʦʠʷ (2%, 6/250).

ʅϴʡ-ʯʝɧʂʦ ǼϴʙǼʶʜϴɘϴǼʠʂʝ Ǽʝʞʝǽϴǽʠ ʦʝϴʢʯʠʠ ʧʦʝʟ ʧʲʦɘʠʂʝ ʂʦʠ ʯϴɧϴ ɧǼʝʜ ǼϴʯϴǼʦʂʂʦ Ǽϴ ʠǼ῭ɮʟʠʷʂϴ ɧϴ ɧʲʦʙʝʞ (n=7; 2,8%), ɮʦʂʠʢϴʦʠʷ (n=6; 2,4%), ɢǽϴɘʦʙʦǼʠʝ (n=4; 1,6%), ʦʙʦʠɘ (n=3; 1,2%), ʢϴʰǼʠʯϴ (n=3; 1,2%), ɧɘʝʂʦɘʲʦʂʝʞ (n=3; 1,2%) (ɘʢǼʶʯɘϴ ɧɘʝʂʦɘʲʦʂʝʞ ʠ ʧʦɧʂɮʦϴǼʝǼ ɧɘʝʂʦɘʲʦʂʝʞ).

ʉǼʝʜǼʠʂʝ ʂʝʞʢʠ Ǽʝʞʝǽϴǽʠ ʦʝϴʢʯʠʠ ɧϴ Ǽϴɧʂʲʧʠǽʠ ʧʦʝʟ ʧʲʦɘʠʂʝ ʂʦʠ ʯϴɧϴ ɧǼʝʜ ʠǼ῭ɮʟʠʷʂϴ: ɮʦʂʠʢϴʦʠʷ (n=1, 0,4%), ɧʲʦʙʝʞ (n=1, 0,4%) ʠ ʙʦǼʢϴ ɘ ɢʲʦʙϴ (n=1, 0,4%).

ʅϴʡ-ʯʝɧʂʦ ǼϴʙǼʶʜϴɘϴǼϴʂϴ Ǽʝʞʝǽϴǽϴ ʦʝϴʢʯʠʷ ɘ ʦϴʤʢʠʂʝ Ǽϴ 3 ʜʦ 24 ʯϴɧϴ ɧǼʝʜ ǼϴʯϴǼʦʂʂʦ Ǽϴ ʠǼ῭ɮʟʠʷʂϴ ʝ ɢǽϴɘʦʙʦǼʠʝ (n=3; 1,2%).

ʊϴʙǼʠʯʝǼ ɧʧʠɧʲʢ Ǽϴ Ǽʝʞʝǽϴǽʠʂʝ ʦʝϴʢʯʠʠ

ʊϴʙǼʠʯϴ 4 ʧʦʝʜɧʂϴɘʷ Ǽʝʞʝǽϴǽʠʂʝ ʦʝϴʢʯʠʠ, ǼϴʙǼʶʜϴɘϴǼʠ ɧ ʦʙʠǼʂʦʢɧϴʢɧʠʤϴʙ ʧʦʠ 250 ʟʜʦϴɘʠ ɮʯϴɧʂǼʠʯʠ, ʢʦʠʂʦ ɧϴ ʧʦǼɮʯʠǽʠ ʝʜʠǼʠʯǼϴ ʠǼʂʦϴɘʝǼʦʟǼϴ ʜʦʟϴ ʦʂ 16 mg/kg ʦʙʠǼʂʦʢɧϴʢɧʠʤϴʙ, ʧʦ ɧʠɧʂʝʤʦ-ʦʦɢϴǼʝǼ ʢǼϴɧ ʠ ʯʝɧʂʦʂʂϴʂϴ.

ʏʝɧʂʦʂʂϴʂϴ Ǽϴ Ǽʝʞʝǽϴǽʠʂʝ ʦʝϴʢʯʠʠ ɧʝ ʦʧʦʝʜʝǼʷ ʢϴʢʂʦ ɧǼʝʜɘϴ: ʤǼʦɢʦ ʯʝɧʂʠ (Ó 1/10), ʯʝɧʂʠ (Ó 1/100 ʜʦ < 1/10) ʠ Ǽʝʯʝɧʂʠ (Ó 1/1 000 ʜʦ < 1/100). ʖ ʦϴʤʢʠʂʝ Ǽϴ ɘɧʷʢʦ ɢʦɮʧʠʦϴǼʝ ʧʦ ʯʝɧʂʦʂϴ, Ǽʝʞʝǽϴǽʠʂʝ ʦʝϴʢʯʠʠ ɧϴ ʧʦʝʜɧʂϴɘʝǼʠ ɘ ǼʠʟƦʦʜʷʱ ʦʝʜ ʧʦ ʦʂǼʦʰ ʝǼʠʝ Ǽϴ ʂʷƦǼϴʂϴ ɧʝʦʠʦʟǼʦɧʂ.

**ʊϴʙǼʠʯϴ 4: ʅʝʞʝǽϴǽʠ ʦʝϴʢʯʠʠ, ɧʲʦʙʱʝǼʠ ʧʦʠ ʟʜʦϴɘʠ ɘʲʟʦϴɧʂǼʠ ʧϴʯʠʝǼʂʠ**

| **ʉʠɧʂʝʤǼʦ-ʦʦɢϴǼʝǼ ʢǼϴɧ ʧʦ MedDRA** | **ʏʝɧʂʠ** | **ʅʝʯʝɧʂʠ** |
|---|---|---|
| ʅϴʦɮʰʝǼʠʷ Ǽϴ ʠʤɮǼǼϴʂϴ ɧʠɧʂʝʤϴ | | ɸǼϴ῭ʠǼϴʢʂʠʯǼϴ ʦʝϴʢʯʠʷ<br>ʉɘʦʲƦʯɮɘɧʂɘʠʂʝǼǼʦɧʂ |
| ʅϴʦɮʰʝǼʠʷ Ǽϴ Ǽʝʦɘǽϴʂϴ ɧʠɧʂʝʤϴ | ʇǼϴɘʦʙʦǼʠʝ | ʉɘʝʂʦɘʲʦʂʝʞ<br>ʇʦʟʠʯʠʦǼʝǼ ɧɘʝʂʦɘʲʦʂʝʞ<br>ʍʠʧʝɧʂʝʟʠʷ |
| ʅϴʦɮʰʝǼʠʷ Ǽϴ ʦʯʠʂʝ | | ʌʦʂʦ῭ʦʙʠʷ |
| ʅϴʦɮʰʝǼʠʷ Ǽϴ ɮʰʠʂʝ ʠ ɘʲʂʦʝʰǼʦʂʦ ɮƦʦ | | ʃʠɧʢʦʤ῭ʦʦʂ ɘ ɮʰʠʂʝ |
| ʉʲʜʦɘʠ Ǽϴʦɮʰʝǽʠʷ | | ʌǼʝʙʠʂ |
| ʃʠƦϴʂʝǼǼʠ, ɢʦʲʜǼʠ ʠ ʤʝʜʠϴɧʂʠǼϴǼǼʠ Ǽϴʦɮʰʝǽʠʷ | ʢϴʰǼʠʯϴ | ʃʦϴʟǼʝǼʝ Ǽϴ ɢʲʦǼʦʂʂʦ<br>ʃʠɧ῭ʦǼʠʷ<br>ʢʦǼɢʝɧʂʠʷ Ǽϴ ɧʠǼɮɧʠʂʝ<br>ʃʠɧʧǼʝʷ |
| ʉʂʦʤϴʰǼʦ-ʯʦʝɘǼʠ Ǽϴʦɮʰʝǽʠʷ | | ʇʦǼʢϴ ɘ ɮɧʂǼʠʂʝ |
| ʅϴʦɮʰʝǼʠʷ Ǽϴ ʢʦʞϴʂϴ ʠ ʧʦʜʢʦʞǼϴʂϴ ʂʲʢϴǼ | ʉʲʦʙʝʞ, ɮʦʂʠʢϴʦʠʷ, ʦʙʦʠɘ | ɸǼʝʦɢʠʯʝǼ ʜʝʦʤϴʂʠʂ<br>ʇʝǼʝʦϴǼʠʟʠʦϴǼ ʦʙʦʠɘ<br>ʇʝǼʝǼʝ Ǽϴ ʢʦʞϴʂϴ |
| ʅϴʦɮʰʝǼʠʷ Ǽϴ ʤɮɧʢɮǼǼʦɧʢʝǼʝʂǼϴʂϴ ʠ ɧʲʝʜʠǼʠʂʝǼǼϴʂϴ ʂʲʢϴǼ | | ʇʦǼʢʠ ɘ ʢʦϴʡǼʠʯʠʂʝ<br>ʆɮɧʢɮǼǼʠ ɧʧϴʟʤʠ<br>ʆɮɧʢɮǼǼʠ ʧʦʂʦʝʧɘϴǼʠʷ<br>ʇʦǼʢϴ ɘ ʯʝǼʶ ɧʂʂϴ |
| ʆʙʱʠ Ǽϴʦɮʰʝǽʠʷ ʠ ɧʲɧʂʦʷǼʠʷ Ǽϴ ʤʷɧʂʦʂʦ Ǽϴ ʧʦʠǼʦʞǼʝǼʠʝ | ʇʦǼʢϴ Ǽϴ ʤʷɧʂʦʂʦ Ǽϴ ʠǼ῭ɮʟʠʷʂϴ | ʇʦǼʢϴ<br>ʃʠɧʢʦʤ῭ʦʦʂ ɘ ɢʲʦʜʠʂʝ<br>ʖʂʦʠɧϴǼʠʝ<br>ʋʤʦʦϴ<br>ʆʂʦʢ Ǽϴ ʤʷɧʂʦʂʦ Ǽϴ ʠǼ῭ɮʟʠʷʂϴ<br>ʇʦǼʢϴ ɘ ɢʲʦʜʠʂʝ ʦʂ Ǽʝɧʲʦʜʝʯʝǽ ʧʦʦʠʟƦʦʜ<br>ʇʦǼʝʟǼʝǼʦɧʂ |

| [illegible] MedDRA | [illegible] | [illegible] |
|---|---|---|
| | | [illegible] |

[illegible]

*[illegible]*

[illegible] 8-[illegible] [illegible]

[illegible]

*[illegible]*

[illegible] (2,5% (8/320)), [illegible] (ATA). [illegible] 1:20 [illegible] 1:320. [illegible] ATA [illegible].

[illegible]

[illegible] V.

## 4.9 [illegible]

[illegible]

## 5. [illegible]

### 5.1 [illegible]

[illegible]: [illegible], ATC [illegible]: J06BB22

[illegible]

[illegible] (PA) [illegible] *B. anthracis*. [illegible] PA [illegible]

## Λ Θtєdʒ0Ʀtsнcƒdƶ0dʒcƒudƶcƒ jᵂjƦlscƒ

ʃ вcƒdƶlstsƦfŋ0Ʀfŋcƒdʒ0в fŋj fŋəʲtєLəΘ fŋʲfŋ fŋətsвtsнdƶcƒʷ ţ ϕ fŋ Θᵂcƒdƶcƒlsjlsdƶ0 tє0ədƶtsəjfŋdƶ0 Ʀtsdƶfŋls0dƶls0 dƶ0 нcƒŋtsцcƒ0цcƒʷ (Kd) tsls 0,33 nM.
*In vitro* tsвcƒdƶlstsƦfŋ0Ʀfŋcƒdʒ0в fŋj fŋəʲtєLəΘ fŋ PA tsls ʰ0dʒtsəjlsj Ames, Vollum cƒ Sterne dƶ0 *B. anthracis*. ţ tƒcƒlststƒʲls dƶ0 PA, Ʀʲdʒ Ʀts2lsts fŋj fŋəʲtєLəΘ tsвcƒdƶlstsƦfŋ0Ʀfŋcƒdʒ0в, fŋj L0tƒ0LəΘ ə нtsƦdƶ0нəΘdƶcƒlsj ʰ0dʒtsəj dƶ0 *B. anthracis*.

*In vitro* tƒtєtslzцəΘdƶcƒʷls0 tƒtєcƒ Ʀdƶjlsʲцjdƶ 0dƶ0dƶcƒL, cƒLtƒtsdƶLəΘʰ cƒ dʒcƒʰ cƒ dʒ0Ʀtєtsᵂ0ɢcƒ, tƒtєjнtƒtsdƶ0ɢ0ls цj tsвcƒdƶlstsƦfŋ0Ʀfŋcƒdʒ0в dƶjƶlstє0dƶcƒLcƒtє0 lstsƦfŋcƒudƶcƒlsj jᵂjƦlscƒ dƶ0 dƶjls0dƶdƶcƒʷ lstsƦfŋcƒdƶ, Ʀtsdʒвcƒdƶ0цcƒʷ tsls PA + dƶjls0dƶjdƶ ᵂ0Ʀlststє.

*In vivo* tƒtєtslzцəΘdƶcƒʷ L0 jᵂcƒƦ0fŋdƶtsfŋls tƒtєcƒ dƶtsətsLjdƶ0dƶнfŋƦcƒ вjdƶcƒ (NZW) L0ʔцcƒ cƒ нʲdƶɢtststƒ0ʰ 0lscƒ dʒ0Ʀ0цcƒ, cƒdƶᵂjƦlscƒtє0dƶcƒ fŋʲfŋ fŋtƒtstєcƒlsj dƶ0 ʰ0dʒ0 Ames dƶ0 *B. 0nthracis* tƒts cƒdƶ0dƶ0цcƒtsdƶjdƶ tƒʲls, tƒtsƦ0LəΘls нtsLtsL0əcƒfŋcƒdʒts ƶəjdƶcƒцjdƶcƒj dƶ0 tƒtєj кcƒəʷjdʒtsfŋlsls0 fŋdƶjн dƶjцjdƶcƒj fŋ tsвcƒdƶlstsƦfŋ0Ʀfŋcƒdʒ0в. ţ Ʀfŋtƒtsцcƒцcƒʷls0 dƶ0 fŋtƒtstєcƒ dƶ0 *B. Anthracis* ətsнcƒ нts ƶəjdƶcƒц0əΘdƶj dƶ0 Ʀtsdƶцjdƶlstє0цcƒcƒlsj dƶ0 PA ə fŋjtєƶdʒ0 dƶ0 NZW L0ʔцcƒ cƒ нʲdƶɢtststƒ0ʰ 0lscƒ dʒ0Ʀ0цcƒ. нdƶjн dƶjцjdƶcƒj fŋ tsвcƒdƶlstsƦfŋ0Ʀfŋcƒdʒ0в fŋj dƶ0вdƶʸ н0əΘ dƶ0dʒ0dƶʷəΘdƶj dƶ0 Ʀtsdƶцjdƶlstє0цcƒcƒlsj dƶ0 PA tƒtєcƒ tƒtsəjцjlsts tsцjdƶjdƶcƒ кcƒətslsdƶcƒ. ţtsdƶцjdƶlstє0цcƒcƒlsj dƶ0 PA tƒtєcƒ кcƒətslsdƶcƒlsj, tƒtєcƒjdʒ0dƶcƒ tƒdƶ0цjвts, fŋ0 fŋj ƶəjdƶcƒц0əΘdƶcƒ, нtsƦ0lsts ƶdʒtє0ls.

## ţᵂcƒƦ0fŋdƶtsfŋls

ʊʲʔ Ʀ0lsts dƶj j əʲLdʒtsкdƶts cƒdƶcƒ jlscƒцdƶts н0 fŋj tƒtєtsəjкн0ls Ʀtsdƶlstєtsdƶcƒtє0dƶcƒ Ʀdƶcƒdƶcƒцdƶcƒ tƒtєtslzцəΘdƶcƒʷ tƒtєcƒ ⊐tstє0 fŋ cƒdƶ⊐0dƶ0цcƒtsdƶjdƶ 0dƶlstє0Ʀfŋ, jᵂcƒƦ0fŋdƶtsfŋlsls0 dƶ0 tsвcƒdƶlstsƦfŋ0Ʀfŋcƒdʒ0в, tƒtєcƒdƶ0ɢ0dƶ Ʀ0lsts dʒtsdƶtslsjtє0tƒcƒʷ, ə fŋtє0ədƶjdƶcƒj fŋ tƒdƶ0цjвts L0 dƶjцjdƶcƒj dƶ0 cƒdƶ⊐0dƶ0цcƒtsdƶjdƶ 0dƶlstє0Ʀfŋ, fŋj tsfŋdƶtsə0ə0 dƶ0 tƒtєtslzцəΘdƶcƒʷ L0 jᵂcƒƦ0fŋdƶtsfŋls tƒtєcƒ NZW L0ʔцcƒ cƒ нʲdƶɢtststƒ0ʰ 0lscƒ dʒ0Ʀ0цcƒ.

I lsjLcƒ tƒtєtslzцəΘdƶcƒʷ кcƒətslsdƶcƒlsj fŋ0 cƒdƶᵂjƦlscƒtє0dƶcƒ fŋ 0jtєtsLtsdƶcƒtє0dƶcƒ fŋtƒtstєcƒ dƶ0 *B. anthracis* (ʰ0dʒ Ames) tƒtєcƒ tƒtєcƒвdƶcƒLcƒlsjdƶdƶts 200x$LD_{50}$ cƒ fŋdƶjн lstsə0 fŋ0 dƶjƦƶəΘdƶcƒ fŋ tsвcƒdƶlstsƦfŋ0Ʀfŋcƒdʒ0в ə tє0Ldƶcƒцdƶcƒ ətєjdʒjəcƒ lstцƦcƒ. ţtєcƒ tƒtєtslzцəΘdƶcƒʷ L0 dƶjцjdƶcƒj dƶ0 cƒdƶ⊐0dƶ0цcƒtsdƶjdƶ 0dƶlstє0Ʀfŋ, кcƒətslsdƶcƒlsj fŋ0 tƒtsdƶzцcƒdƶcƒ dƶjцjdƶcƒj fŋdƶjн tƒtєtsʷəΘ dƶ0 Ʀdƶcƒdƶcƒцdƶcƒ tƒtєcƒLdƶ0цcƒ cƒdƶcƒfŋcƒdʒƒlstsdʒcƒ dƶ0 fŋcƒfŋlsjdʒjdƶ 0dƶlstє0Ʀfŋ. I tƒtєtslzцəΘdƶcƒʷ L0 tƒtsfŋlsjƦfŋtƒtsLcƒцcƒtsdƶdƶ0 tƒtєtsᵂcƒdƶ0Ʀlscƒ0 кcƒətslsdƶcƒlsj fŋ0 dƶjƦƶəΘdƶcƒ fŋdƶjн jƦfŋtƒtsLcƒцcƒʷ dƶ0 *B. anthracis*, dƶts tƒtєjнcƒ tє0Ləcƒlscƒjlsts dƶ0 fŋcƒdʒƒlstsdʒcƒlsj. ţʲdƶɢtststƒ0ʰ 0lscƒlsj dʒ0Ʀ0цcƒ fŋ0 dƶjƦƶəΘdƶcƒ Ʀʲdʒ dʒtsdʒjdƶls0 dƶ0 tƒtsdƶtsкcƒlsjdƶdƶ0 fŋjtєƶdʒdƶ0 tƒtєtsв0 L0 *B. anthracis* PA tƒtєcƒ cƒLfŋdƶjнəΘdƶj цtєjL jdƶjƦlstєts⊐jdʒcƒdƶƶdʒcƒdƶjfŋцjdƶцcƒʷ (ECLIA) tƒtєcƒ fŋtєjнdƶts ətєjdʒj tsls tsƦtsdƶts 40 цΘfŋ0 fŋdƶjн cƒdƶᵂjƦlscƒtє0dƶj fŋ *B. anthracis*. I tƒtєtslzцəΘdƶcƒʷls0 L0 dƶjцjdƶcƒj tƒtєcƒ NZW L0ʔцcƒ, кcƒətslsdƶcƒlsj fŋ0 dƶjƦƶəΘdƶcƒ fŋdƶjн tƒtsdƶtsкcƒlsjdƶjdƶ tєjLƶdƶls0ls tƒtєcƒ ECLIA cƒLfŋdƶjнəΘdƶj L0 PA cƒdƶcƒ fŋdƶjн lstє0ʔdƶts tƒtsəcƒʰ 0əΘdƶj dƶ0 lsjdƶjfŋdƶ0ls0 lsjdʒtƒjtє0lsƶtє0 dƶ0н cƒL⊐tsнdƶtslsts dƶcƒəts, fŋtєjнdƶts tsƦtsdƶts 30 цΘfŋ0 fŋdƶjн cƒdƶᵂjƦlscƒtє0dƶj. ţtєjкcƒəʷjdʒtsfŋlsls0 j tsцjdƶjdƶ0 28 нdƶcƒ fŋdƶjн cƒdƶᵂjƦlscƒtє0dƶj fŋ *B. anthracis* ə tƒtєtslzцəΘdƶcƒʷls0, tsƒcƒfŋ0dƶcƒ tƒts-нtsdƶz.

ţᵂcƒƦ0fŋdƶtsfŋlsls0 dƶ0 jнcƒdƶcƒцdƶ0 cƒdƶlstє0əjdƶtsLdƶ0 нtsL0 tsвcƒdƶlstsƦfŋ0Ʀfŋcƒdʒ0в Ʀ0lsts dʒtsdƶtslsjtє0tƒcƒʷ L0 dƶjцjdƶcƒj dƶ0 cƒdƶ⊐0dƶ0цcƒtsdƶjdƶ 0dƶlstє0Ʀfŋ j tsцjdƶjdƶ0 ə jнdƶts tƒtєtslzцəΘdƶj tƒtєcƒ NZW L0ʔцcƒ cƒ lstєcƒ tƒtєtslzцəΘdƶcƒʷ tƒtєcƒ нʲdƶɢtststƒ0ʰ 0lscƒ dʒ0Ʀ0цcƒ(AP202, AP204 cƒ AP301); əfŋcƒцƦcƒ tƒtєtslzцəΘdƶcƒʷ fŋ0 tƒdƶ0цjвts- Ʀtsdƶlstєtsdƶcƒtє0dƶcƒ, tє0dƶнtsdʒcƒLcƒtє0dƶcƒ cƒ ə fŋʲtslsəjlsfŋlsəcƒj fŋ GLP. ţtєtslzцəΘdƶcƒʷls0 AR033, AP202 cƒ AP301 fŋ0 L0fŋdƶjtƒjdƶcƒ; tƒtєtslzцəΘdƶjlsts AP204 j L0fŋdƶjtƒjdƶts L0 ɢtєlztƒ0.

**ʊθʙǳƌɥθ 5: ɟȢʝʧʝǳ ǳθ ʧʦʝʞƌɘʷʝǲʦɧȢ ɘ ʧʦʦȤɥɘθǳƌʷ ʟθ ʝẅƌʢθɧǳʦɧȢ ǳθ ǲʦǳʦȢʝʦθʧƌʷ ɧ ʦʙƌǳȢʦʢɧθʢɧƌǲθʙ (16 mg/kg)**

| | ʇ ʦʦɥʝǳȢ ǳθ ʧʦʝʞƌɘʷʝǲʦɧȢ ɘ ʢʦθʷ ǳθ ʧʦʦȤɥɘθǳʝȢʦ (% [ʦɥʝǳʝǳƌ/n]) | | p-ɧȢʦʡǳʦɧȢ[2] | 95% CI[3] |
|---|---|---|---|---|
| | ʇ ǳθɥʝʙʦ | ʆ ʙƌǳȢʦʢɧθʢɧƌǲθʙ 16 mg/kg | | |
| **ʆ ʝɥʝǳƌʝ – NZW ʟθʡɥƌ** | | | | |
| ʇ ʦʦȤɥɘθǳʝ AR033[1] | 0 (0/13) | 61,5% (8/13) | 0,0013* | (0,290, 0,861) |
| **ʆ ʝɥʝǳƌʝ – ʜʲ ǳɠʦʦʧθ ʰ θȢƌ ǲθʢθɥƌ** | | | | |
| ʇ ʦʦȤɥɘθǳʝ AP204[1] | 6% (1/16) | 46,7% (7/15) | 0,0068* | (0,089, 0,681) |
| ʇ ʦʦȤɥɘθǳʝ AP202[1] | 0 (0/17) | 31,3% (5/16) | 0,0085* | (0,079, 0,587) |
| **ʇ ʦɧȢʝʢɧʧʦʟƌɥƌʦǳǳθ ʧʦʦẅƌǳθʢȢƌʢθ – ʜʲ ǳɠʦʦʧθ ʰ θȢƌ ǲθʢθɥƌ** | | | | |
| ʇ ʦʦȤɥɘθ ǳʝ AP301[4] — 18 ɥθɧθ ɧǳʝʜ ʝʢɧʧʦʟƌ ɥƌʷ | 0 (0/6) | 100% (6/6) | 0,0012* | (0,471, 1,000) |
| ʇ ʦʦȤɥɘθ ǳʝ AP301[4] — 24 ɥθɧθ ɧǳʝʜ ʝʢɧʧʦʟƌ ɥƌʷ | -- | 83% (5/6) | 0,0042* | (0,230, 0,996) |
| ʇ ʦʦȤɥɘθ ǳʝ AP301[4] — 36 ɥθɧθ ɧǳʝʜ ʝʢɧʧʦʟƌ ɥƌʷ | -- | 50% (3/6) | 0,0345 | (-0,037, 0,882) |

CI: ɼʦɘʝʦƌȢʝǳʝǳ ƌǳȢʝʦɘθǳ

[1] ʇ ʦʝʞƌɘʷʝǲʦɧȢȢθ ɧʝ ʦɥʝǳʷɘθ 28 ʜǳƌ ɧǳʝʜ ƌǳẅʝʢȢƌʦθǳʝ ɧʲɧ ɧʧʦʦƌ, ɘɧƌɥʢƌ ʦθǳʜʦǲƌʟƌʦθǳƌ ʞƌɘʦȢǳƌ ɧθ ʧʦǳʦʞƌȢʝǳǳƌ ʟθ ʙθʢȢʝʦƌʝǳƌʷ ʧʦʝʜƌ ǳʝɥʝǳƌʝȢʦ, ǳʝɥʝǳƌʝȢʦ ʝ ƌǳƌɥƌƌʦθǳʦ ʦȢ ʟǳθɥƌȢʝǳǳʦ ʧʦɘƌʰ θɘθǳʝ ǳθ ȢʝǳʝɧǳθȢθ Ȣʝǲʧʝʦθȣʦθ (ʧʦʦȤɥɘθǳʝ AR033) ƌǳƌ ʦȢ ʧʦǳʦʞƌȢʝǳʝǳ ʦʝʟȤǳȢθȢ ʧʦƌ ƌʟɧǳʝʜɘθǳʝ ʟθ PA ɥʦʝʟ ʝǳʝʢȢʦʦʭʝǲƌǳȤǲƌǳʝɧɥʝǳɥƌʷ (ʧʦʦȤɥɘθǳƌʷ AP204 ƌ AP202).

[2] p-ɧȢʦʡǳʦɧȢȢθ ʝ ʦȢ ʝʜǳʦɧȢʦθǳǳƌʷ Ȣʝɧȣ ǳθ Boschloo (ɧ Berger-Boos ǲʦʜƌẅƌʢθɥƌʷ ǳθ ɠθǲθ = 0,001) ɘ ɧʦθɘǳʝǳƌʝ ɧ ʧǳθɥʝʙʦ

[3] ʊʦɥʝǳ 95% ʜʦɘʝʦƌȢʝǳʝǳ ƌǳȢʝʦɘθǳ ǳθ ʦθʟǳƌʢθ ɘ ʧʦʦɥʝǳȢƌȢʝ ǳθ ʧʦʝʞƌɘʷʝǲʦɧȢ

[4] ʇ ʦʝʞƌɘʷʝǲʦɧȢȢθ ɧʝ ʦɥʝǳʷɘθ 28 ʜʝǳθ ɧǳʝʜ ƌǳẅʝʢȢƌʦθǳʝ ɧʲɧ ɧʧʦʦƌ,

* ʆ ʙʦʟǳθɥθɘθ ɧȢθȢƌɧȢƌɥʝɧʢθ ʟǳθɥƌǲʦɧȢ ǳθ ǳƌɘʦ 0,025

<u>ʇ ʝʜƌθȢʦƌɥǳθ ʧʦʧȤǳθɥƌʷ</u>

ɼɘʦʦʧʝʡɧʢθȢθ θɠʝǳɥƌʷ ʧʦ ǳʝʢθʦɧȢɘθȢθ ʦȢǳθɠθ ʟθʜʲǳʞʝǳƌʝȢʦ ʟθ ʧʦʝʜʦɧȢθɘʷǳʝ ǳθ ʦʝʟȤǳȢθȢƌȢʝ ʦȢ ʧʦʦȤɥɘθǳƌʷȢθ ɧ NYXTHRACIS ɘ ʝʜǳθ ƌǳƌ ʧʦɘʝɥʝ ʧʦʜɠʦȤʧƌ ǳθ ʧʝʜƌθȢʦƌɥǳθȢθ ʧʦʧȤǳθɥƌʷ ʧʦƌ ǳʝɥʝǳƌʝȢʦ ǳθ ʙθʢȢʝʦƌθǳǳθ ƌǳẅʝʢɥƌʷ (ɘʞ. Ȣʦɥʢθ 4.2 ʟθ ƌǳẅʦʦǲθɥƌʷ ʦȢǳʦɧǳʦ Ȥʧʦ Ȣʦʝʙθ ɘ ʧʝʜƌθȢʦƌʷȢθ).

ʊʦʟƌ ǳʝʢθʦɧȢɘʝǳ ʧʦʦʜȤʢȢ ʝ ʦθʟʦʝ ʰ ʝǳ ʟθ Ȥʧʦ Ȣʦʝʙθ ʧʦƌ ĂƌʟɘʲǳʦʝʜǳƌʦʙɧȢʦʷȢʝǳɧȢɘθñ. ʊʦɘθ ʦʟǳθɥθɘθ, ɥʝ ʧʦʦθʜƌ ʦʷʜʢʦȢʦ ʦθʟʧʦʦɧȢʦθǳʝǳƌʝ ǳθ ʙʦǳʝɧȢȢθ ƌ ʧʦ ʝȢƌɥǳƌ ʧʦƌɥƌǳƌ ʜʦ ǲʦǲʝǳȢθ ǳʝ ʝ ʙƌǳʦ ɘʲʟǲʦʞǳʦ ʜθ ɧʝ ʧʦǳȤɥƌ ʧʲǳǳθ ƌǳẅʦʦǲθɥƌʷ ʟθ Ȣʦʟƌ ǳʝʢθʦɧȢɘʝǳ ʧʦʦʜȤʢȢ.
ɅɧʷʢθɠʦʜƌǳθɼɘʦʦʧʝʡɧʢθȢθ θɠʝǳɥƌʷ ʧʦ ǳʝʢθʦɧȢɘθȢθ ʱ ʝ ƌʟɘʲʦʰ ɘθ ʧʦʝɠǳʝʜ ǳθ ǳʦɘθȢθ ƌǳẅʦʦǲθɥƌʷ ƌ ȢθʟƌʂʍʇɧʲʦȢɘʝȢǳʦʱ ʝ ɧʝ θʢȢȤθǳƌʟƌʦθ.

## 5.2 [illegible]

[illegible]

[illegible] 4 mg/kg (0,25 [illegible]-[illegible]) [illegible] 16 mg/kg [illegible]. [illegible] 16 mg/kg [illegible] $C_{max}$ [illegible] $AUC_{inf}$ [illegible] 400 Ñ 91,2 mcg/ml [illegible] 5170 Ñ 1360 mcg[illegible]/ml. [illegible] 20 [illegible] ([illegible]).

[illegible]

[illegible] 79,7Ñ19,2 ml/kg [illegible]-[illegible], [illegible].

[illegible]

[illegible].
[illegible], [illegible].

[illegible]

[illegible] 3,35 Ñ 0,932 ml/d/kg [illegible]-[illegible], [illegible].

[illegible]

*[illegible], [illegible]*
[illegible] (PK) [illegible] PK [illegible] 370 [illegible], [illegible] 4 [illegible]. [illegible], [illegible] ([illegible]), [illegible] ([illegible]) [illegible] ([illegible]) [illegible] PK [illegible]. [illegible] 65 [illegible], [illegible] PK [illegible]-[illegible]. [illegible] 320 [illegible] 9,4% (30/320) [illegible] 65 [illegible], [illegible] 2% (6/320) [illegible] 75 [illegible].

*[illegible], [illegible]*
[illegible] (109 kg) [illegible] 38% [illegible]-[illegible], [illegible]. [illegible] (16 ml/kg) [illegible] $AUC_{inf}$ [illegible] 12%, [illegible].

*[illegible]*
[illegible].
[illegible] 2 ([illegible] 4.2) [illegible], [illegible] PK [illegible], [illegible] 16 mg/kg.

## 5.3 [illegible]

[illegible]

[illegible] NZW [illegible] (Ó4 mg/kg) [illegible] NZW [illegible] (28) [illegible] (56) [illegible] 16 mg/kg [illegible] 32 mg/kg/[illegible]. [illegible]

[illegible] NZW [illegible] 4 [illegible] 32 mg/kg (2 [illegible] mg/kg) [illegible] 6, 10, 13 [illegible] 17. [illegible] NZW (10 000 mcg[illegible]/ml) [illegible] NOAEL 32 mg/kg/[illegible] (n=4 [illegible]) [illegible] $AUC_{0-15}$ (15 [illegible]) [illegible] AUC [illegible] 16 mg/kg. [illegible] $C_{max}$ [illegible] 32 mg/kg/[illegible] 1180 mcg[illegible]/ml.

[illegible]

# 6. [illegible]

## 6.1 [illegible]

[illegible]
[illegible] ([illegible]420)
[illegible] 80 ([illegible]433)
[illegible] ([illegible]507, [illegible])
[illegible] ([illegible]524 [illegible])
[illegible]

## 6.2 [illegible]

[illegible] 6.6.

## 6.3 [illegible]

[illegible]

7 [illegible]

[illegible]

[illegible] 8 [illegible] (20 °C – 25 ÁC) [illegible] (2 °C – 8 ÁC).

[illegible] (20 °C – 25 ÁC) [illegible] (2 °C – 8 ÁC).

[illegible]

[illegible]

[illegible]

### 6.4 [illegible]

[illegible] (2 Áн – 8 Áн).
[illegible]
[illegible]

[illegible] 6.3.

### 6.5 [illegible]

600 mg/6 ml [illegible] (NYXTHRACIS [illegible]) [illegible] 1 [illegible].

### 6.6 [illegible]

[illegible]

- [illegible] NYXTHRACIS [illegible]
- [illegible] (эк. [illegible] 3).
- [illegible].

[illegible]

1. [illegible] mg/kg [illegible] 2 (эк. [illegible] 4.2) [illegible] 1) [illegible] 100 mg/ml. [illegible] 6 ml [illegible] 9 mg/ml (0,9%) [illegible] 2 [illegible].

4. ʀʟƾʝǤʥʝƾʝ ʥʝʦʙꞫʦʜʠʤʠʷ ʦʙʝʤ ʦʙʠʥƾʦʦʢʩʘʢʩʠʤʘʙ ʢʦʥʯʝʥƾʦʨʘƾ ʟʘ ʠʥʬʫʟʠʦʥʥʠʷ ʨʘʟƾɘʦʦʨ (ʠʟʯʠʩʥʝʥ ɘ ʩƾʲʧʢʘ 2) ʦƾ ʬʥʘʢʦʥʘ(ʠƾʝ) NYXTHRACIS. ʀʟꞫɘʲʨʥʝƾʝ ɘʩʷʢʘ ʥʝʠʟʧʦʥʟɘʘʥʘ ʯʘʩƾ NYXTHRACIS, ʦʩƾʘʥʘʥʘ ɘʲɘ ʬʥʘʢʦʥʘ(ʠƾʝ)NYXTHRACIS.
5. ɟʨʝꞫɘʲʨʥʝƾʝ ʥʝʦʙꞫʦʜʠʤʠʷ ʦʙʝʤ ʦʙʠʥƾʦʦʢʩʘʢʩʠʤʘʙ ʢʦʥʯʝʥƾʦʨʘƾ ʟʘ ʠʥʬʫʟʠʦʥʝʥ ʨʘʟƾɘʦʦʨ ɘ ʠʟʙʨʘʥʠʷ ʠʥʬʫʟʠʦʥʝʥ ʩʘʢ.
6. ʆʙʲʨʥʝƾʝ ɘʥʠʤʘƾʝʥʥʦ ʩʘʢʘ ʥʘʜʦʥʫ, ʟʘ ʜʘ ʩʤʝʩʠƾʝ ʨʘʟƾɘʦʦʨʘ. ʅʝ ʨʘʟʢʥʘ ʱ ʘʡƾʝ.
7. ʀʥʬʫʟʠʷƾʘ ƾʦʷʙɘʘ ʜʘ ʩʝ ʧʨʠʥʘǤʘ ɘ ʧʨʦʜʲʥʞʝʥʠʝ ʥʘ 90 ʤʠʥʫƾʠ ʩʲʩ ʩʢʦʨʦʩƾ ʥʘ ʠʥʬʫʟʠʷƾʘ, ʦʧʠʩʘʥʘ ɘ ƾʘʙʥʠʯʘ 3 (ɘʞ. ƾʦʯʢʘ 4.2), ʢʘƾʦ ʩʝ ʠʟʧʦʥʟɘʘ ɘǤʨʘʜʝʥ ʬʠʥƾʲʨ 0,22 ʤʠʢʨʦʥʘ.
8. ɟʨʠǤʦƾɘʝʥʠʷƾ ʨʘʟƾɘʦʦʨ ʝ ʩƾʘʙʠʥʝʥ ʟʘ 8 ʯʘʩʘ, ʩʲꞫʨʘʥʷɘʘʥ ʧʨʠ ʩƾʘʡʥʘ ƾʝʤʧʝʨʘƾʫʨʘ 20 ÁC ʜʦ 25 ÁC ʠʥʠ 8 ʯʘʩʘ, ʩʲꞫʨʘʥʷɘʘʥ ɘ Ɜʥʘʜʠʥʥʠʢ ʧʨʠ 2 ÁC ʜʦ 8 ÁC.

ɟʨʠǤʦƾɘʷʥʝ ʠ ʨʘʟʨʝʞʜʘʥʝ ɘ ʩʧʨʝʠʥʯʦɘʢʘ ʟʘ ʠʥʬʫʟʠʦʥʥʘ ʧʦʤʧʘ

1. ʀʟʯʠʩʥʝƾʝ ʥʝʦʙꞫʦʜʠʤʠƾʝ ʤʠʥʠʠǤʨʘʤʠ ʦʙʠʥƾʦʦʢʩʘʢʩʠʤʘʙ ʯʨʝʟ ʫʤʥʦʞʘɘʘʥʝ ʥʘ ʧʨʝʧʦʨʲʯʠƾʝʥʘƾʘ ʜʦʟʘ mg/kg ɘ ƾʘʙʥʠʯʘ 2 (ɘʞ. ƾʦʯʢʘ 4.2) ʧʦ ƾʝʥʝʩʥʘʦƾʦ ƾʝǤʥʦ ʥʘ ʦƾʜʝʥʥʠʷ ʧʘʯʠʝʥƾ ɘ ʢʠʥʦǤʨʘʤʠ.
2. ʀʟʯʠʩʥʝƾʝ ʥʝʦʙꞫʦʜʠʤʠʷ ʦʙʝʤ ɘ ʤʠʥʠʥʠƾʨʠ ʢʦʥʯʝʥƾʨʘƾʘ ʥʘ ʦʙʠʥƾʦʦʢʩʘʢʩʠʤʘʙ ʟʘ ʠʥʬʫʟʠʦʥʝʥ ʨʘʟƾɘʦʦʨ ʠ ʙʨʦʷ ʬʥʘʢʦʥʘʠ, ʥʝʦʙꞫʦʜʠʤʠ ʟʘ ʜʦʟʘƾʘ, ʢʘƾʦ ʠʟʯʠʩʥʝʥʘƾʘ ʜʦʟʘ ɘ ʤʠʥʠʠǤʨʘʤʠ (ʩƾʲʧʢʘ 1) ʩʝ ʨʘʟʜʝʥʠ ʥʘ ʢʦʥʯʝʥƾʨʘʯʠʷƾʘ, 100 mg/ml. ɉʩʝʢʠ ʝʜʠʥ ʬʥʘʢʦʥ ʧʦʟɘʦʥʷɘʘ ʜʦʩƾʘɘʷʥʝ ʥʘ 6 ml ʢʦʥʯʝʥƾʨʘʯ NYXTHRACIS ʟʘ ʠʥʬʫʟʠʦʥʝʥ ʨʘʟƾɘʦʦʨ.
3. ʀʟʙʝʨʝƾʝ ʩʧʨʝʠʥʯʦɘʢʘ ʩ ʧʦʜꞫʦʜʷʱʦ ʨʘʟʤʝʨ ʟʘ ʦʙʱʠʷ ʦʙʝʤ ʠʥʬʫʟʠʷ, ʢʦʷƾʦ ʱʝ ʩʝ ʧʨʠʥʘǤʘ.
4. ʂʘƾʦ ʠʟʧʦʥʟɘʘƾʝ ʠʟʙʨʘʥʘƾʘ ʩʧʨʝʠʥʯʦɘʢʘ ʠ ɘǤʨʘʜʝʥ ʬʠʥƾʲʨ 0,22 ʤʠʢʨʦʥʘ, ʠʟƾʝǤʥʝƾʝ ʥʝʦʙꞫʦʜʠʤʠʷ ʦʙʝʤ ʢʦʥʯʝʥƾʨʘƾ ʥʘ ʦʙʠʥƾʦʦʢʩʘʢʩʠʤʘʙ ʟʘ ʠʥʬʫʟʠʦʥʝʥ ʨʘʟƾɘʦʦʨ (ʠʟʯʠʩʥʝʥ ɘ ʩƾʲʧʢʘ 2). ʀʟꞫɘʲʨʥʝƾʝ ɘʩʷʢʘ ʥʝʠʟʧʦʥʟɘʘʥʘ ʯʘʩƾ, ʦʩƾʘʥʘʥʘ ɘʲɘ ʬʥʘʢʦʥʘ(ʠƾʝ) NYXTHRACIS.
5. ʀʟƾʝǤʥʝƾʝ ʧʦʜꞫʦʜʷʱ ʦ ʢʦʥʠʯʝʩƾɘʦ ʥʘƾʨʠʝɘ Ɜʥʦʨʠʜ 9 mg/mL (0,9%) ʠʥʞʝʢʯʠʦʥʝʥ ʨʘʟƾɘʦʦʨ ʟʘ ʧʨʠǤʦƾɘʷʥʝ ʥʘ ʦʙʱʠʷ ʦʙʝʤ ʥʘ ʠʥʬʫʟʠʷƾʘ, ʧʦʩʦʯʝʥ ɘ ƾʘʙʥʠʯʘ 2.
6. ɉʥʠʤʘƾʝʥʥʦ ʨʘʟʙʲʢʘʡƾʝ ʨʘʟƾɘʦʦʨʘ. ʅʝ ʨʘʟʢʥʘ ʱ ʘʡƾʝ.
7. ʋʥʝʜ ʧʨʠǤʦƾɘʷʥʝ ʥʘ ʨʘʟƾʝʞʜʝʥ ʨʘʟƾɘʦʦʨ ʦʙʠʥƾʦʦʢʩʘʢʩʠʤʘʙ Ǥʦ ʧʨʠʥʦʞʝƾʝ ʥʝʟʘʙʘɘʥʦ. ʅʝ ʩʲꞫʨʘʥʷɘʘʡƾʝ ʨʘʟƾɘʦʨʘ ɘ ʩʧʨʝʠʥʯʦɘʢʘ. ʀʟꞫɘʲʨʥʝƾʝ ʥʝʠʟʧʦʥʟɘʘʥʠʷ ʧʨʦʜʫʢƾ.

ʀʟꞫɘʲʨʥʷʥʝ

ʅʝʠʟʧʦʥʟɘʘʥʠʷƾ ʥʝʢʘʨʩƾɘʝʥ ʧʨʦʜʫʢƾ ʠʥʠ ʦƾʧʘʜʲʯʥʠƾʝ ʤʘƾʝʨʠʘʥʠ ʦƾ ʥʝǤʦ ƾʨʷʙɘʘ ʜʘ ʩʝ ʠʟꞫɘʲʨʥʷƾ ɘ ʩʲʦƾɘʝƾʩƾɘʠʝ ʩ ʤʝʩƾʥʠƾʝ ʠʟʠʩʢɘʘʥʠʷ.

**7. ɟ ɭ ʀ ʊ ɭ ʁ ʆ ʊ ɭ ʃ ɨ ʆ ɭ ʆ ɨ ʀ ɭ ɮ ɭ ɨ ʀ ɭ ʊ ʃ ɨ ʆ ʋ ɟ ʃ ʊ ɭ ɭ ɭ ɩ ʆ**

SFL Pharmaceuticals Deutschland GmbH
Marie-Curie-Strasse 8
79539 Lºrrach
ɇʝʨʤʘʥʠʷ

**8. ɨ ʃ ʃ ʆ ɭ (ʆ) ɨ ʆ ɭ ʆ ɨ ɭ ɭ ɮ ɭ ɨ ʀ ɭ ʊ ʃ ɨ ʆ ʋ ɟ ʃ ʊ ɭ ɭ ɩ ʆ**

ɭʋ/1/20/1485/001

**9. ɭ ʆ ʊ ʆ ɨ ʆ ɟ ɜ ɭ ɉ ʃ ɭ ʆ ɨ ɭ ɭ ɮ ʆ ɉ ʆ ɨ ɭ/ɟ ʃ ɭ ɨ ʃ ɉ ɭ ɉ ʆ ɨ ɭ ɨ ʆ ɭ ʆ ɨ ɭ ɭ ɮ ɭ ɨ ʀ ɭ ʊ ʃ ɨ ʆ ʋ ɟ ʃ ʊ ɭ ɭ ɩ ʆ**

ɭ ʘƾʘ ʥʘ ʧʲʨɘʦƾʦ ʨʘʟʨʝʰʘʥʝ: 18 ʥʦʝʤɘʨʠ 2020r.

**10. ɭ ʆ ʊ ʆ ɨ ʆ ʆ ʂ ʊ ʋ ʆ ʃ ʀ ɨ ʀ ɭ ʆ ɨ ɭ ɨ ʆ ʊ ɭ ʂ ʋ ʊ ʆ**

ɿ ʦнʧʦвɖʮ ɖʯʷʦʧɖʒʮчɖʷ ʟʮ ʞʦѕʟɖ ɖʝʢʮʧʃʞʂʝɖɖ ʯʧʧʦнʮʢʃʞʮ ʝ ʯʧʧʝнʦʃʞʮʂʝɖɖʮ ɖʮ ʮʝвʃʮʔʞʮ ɖʮ ʅʂʧʦʯʝʔʃʢʞʮ ʮʒʝɖчɖʷ ʯʃʦ ɖʝʢʮʧʃʞʂʮʮ http://www.ema.europa.eu ɖʃ ɖʮ ʮʝвʃʮʔʞʮ ɖʮ {ɖʒʝ ɖʮ ʮʒʝɖчɖʷʞʮ ɖʮ нʲʧʞʮʂʮʮ чɖʝɖʢʮ (ɖʮɖʢʮ)}.

€• ‚ƒ „…†‡•ˆ ‰„Š‹Œ‚†‚ ‚Š•†Š ‡•Ž•ˆ••‘ „ƒ•„••••ˆ •ƒ Œ‰Š†„•‘ƒ

ɬ ʈ ʀ ʃ ʆ ɾ ʈ ʅ ʀ ʈ II

ɸ. ɬ ʈ ʆ ʀ ʅ ɺ ʆ ɼ ʀ ʊ ʈ ʃ ʅ ɸ ɹ ʀ ʆ ʃ ʆ ɻ ʀ ʏ ʅ ʆ ɸ ʂ ʊ ʀ ɺ ʅ ʆ ʊ ʆ
ɺ ʈ ʑ ʈ ʉ ʊ ɺ ʆ ʀ ɬ ʈ ʆ ʀ ʅ ɺ ʆ ɼ ʀ ʊ ʈ ʃ, ʆ ʊ ɻ ʆ ɺ ʆ ʈ ʈ ʅ ɿ ɸ
ʆ ʉ ɺ ʆ ɹ ʆ ɾ ɼ ɸ ɺ ɸ ʅ ʈ ʅ ɸ ɬ ɸ ʈ ʊ ʀ ɼ ʀ

ɹ. ʋ ʉ ʃ ʆ ɺ ʀ ʗ ʀ ʃ ʀ ʆ ɻ ʈ ɸ ʅ ʀ ʏ ʈ ʅ ʀ ʗ ɿ ɸ ɼ ʆ ʉ ʊ ɸ ɺ ʂ ɸ ʀ
ʋ ɬ ʆ ʊ ʈ ʈ ɹ ɸ

ɺ. ɼ ʈ ʋ ɻ ʀ ʋ ʉ ʃ ʆ ɺ ʀ ʗ ʀ ʀ ɿ ʀ ʉ ʂ ɺ ɸ ʅ ʀ ʗ ʅ ɸ
ʈ ɸ ɿ ʈ ʈ ʐ ʈ ʅ ʀ ʈ ʊ ʆ ɿ ɸ ʋ ɬ ʆ ʊ ʈ ʈ ɹ ɸ

ɻ. ʋ ʉ ʃ ʆ ɺ ʀ ʗ ʀ ʃ ʀ ʆ ɻ ʈ ɸ ʅ ʀ ʏ ʈ ʅ ʀ ʗ ɿ ɸ ɹ ʈ ɿ ʆ ɬ ɸ ʉ ʅ ɸ ʀ
ʈ ʌ ʈ ʂ ʊ ʀ ɺ ʅ ɸ ʋ ɬ ʆ ʊ ʈ ʈ ɹ ɸ ʅ ɸ ʃ ʈ ʂ ɸ ʈ ʉ ʊ ɺ ʈ ʅ ʀ ʗ
ɬ ʈ ʆ ɼ ʋ ʂ ʊ

ɼ. ʂ ʆ ʅ ʂ ʈ ʈ ʊ ʅ ʆ ɿ ɸ ɼ ʒ ʃ ɾ ʈ ʅ ʀ ʈ ɿ ɸ ʀ ɿ ɬ ʒ ʃ ʅ ʈ ʅ ʀ ʈ ʅ ɸ
ʃ ʈ ʈ ʂ ʀ ʉ ʃ ʈ ɼ ʈ ɸ ɿ ʈ ʈ ʐ ɸ ɺ ɸ ʅ ʈ ɿ ɸ ʋ ɬ ʆ ʊ ʈ ʈ ɹ ɸ ɬ ʈ ʀ
ʀ ɿ ɺ ʒ ʅ ʈ ʈ ɼ ʅ ʀ ʆ ɹ ʉ ʊ ʆ ʗ ʊ ʈ ʃ ʉ ʊ ɺ ɸ

€•‚ƒ„…†‡•ˆ‰„Š‹Œ‚'Š•Š•‡Ž•ˆ•ƒ•„•••ˆ•ƒŒ‰Š†„•'ƒ

## ф. Ɂţɗʀʅɺʆɼʀʊɽʃ(ʀ) ʅф ɹʀʆʃɗɻʀʏʅɗ фʂʊʀɺʅɗʊɗ(ʀʊɽ) ɺɽȥ ɽʉʊɺɗ(ф) ʀ Ɂţɗʀʅɺʆɼʀʊɽʃ(ʀ), ɗʊɻɗɺɗţɽʅ(ʅʀ) ʅф ɗʉɺɗɹɗ ɾ ɼфɺфʅɽ ʅф ɁфţʊʀɼR

<u>ʀȡʝ ʠ ʘʜʦʝʩ ʣʘ ʧʦʦʠʟəʦʜʠʪʝʣʷ(ʠʪʝ) ʣʘ ʙʠʦʣʦɠʠɥʣʦ ʘʢʪʠəʣʦʪʦ(ʠʪʝ) əʝ ʱ ʝʩʪəʦ(ʘ)</u>

Lonza Biologics, Inc.
101 International Drive
Portsmouth, NH 03801
ʉф ȥ

<u>ʀȡʝ ʠ ʘʜʦʝʩ ʣʘ ʧʦʦʠʟəʦʜʠʪʝʣʷ(ʠʪʝ), ʦʪɠʦəʦʦʝʣ(ʣʠ) ʟʘ ʦʩəʦʙʦʞʜʘəʘʣʝ ʣʘ ʧʘʦʪʠʜʠʪʝ</u>

AcertiPharma B.V.
Boschstraat 51
4811 GC, Breda
ʍʦʣʘʣʜʠʷ

## ɹ. ʋʉʃɗɺʀɕ ʀʃʀ ɗɻţфʅʀʏɽʅʀɕ ʅф ɼɗʉʊфɺʂф ʀ ʋɁɗʊţɽɹф

ʃʝʢʘʦʩʪəʝʣʠʷʪ ʧʦʦʜʢʢʪ ʩʝ ʦʪʧʢʩʢʘ ʧʦ ʣʝʢʘʦʩʢʦ ʧʦʝʜʧʠʩʘʣʠʝ.

## ɺ. ɼţʋɻʀ ʋʉʃɗɺʀɕ ʀ ʀʅʀʉʂɺфʅʀɕ ʅф ţфʅţɽ ʐɽʅʀɽʊɗ ʅф ʋɁɗʊţɽɹф

- **Ɂʝʦʠʦʜʠɥʣʠ ʘʢʪʟʣʠʟʠʦʘʣʠ ʜʦʢʘʜʠ ʟʘ ʙʝʟʦʧʘʩʣʦʩʪ (Ɂфɼɹ)**

ʀʟʠʩʢəʘʣʠʷʪʘ ʟʘ ʧʦʜʘəʘʣʝ ʣʘ Ɂфɼɹ ʟʘ ʪʦʟʠ ʣʝʢʘʦʩʪəʝʣ ʧʦʦʜʢʢʪ ʩʘ ʦʧʦʝʜʝʣʠ ə ʩʧʠʩʢʘ ʩ ʜʘʪʠ ʟʘ ʝʦʦʧʝʡʩʢʘʪʘ ʩʦʡʟʘ (EURD ʩʧʠʩʢʘ), ʧʦʝʜəʠʜʝʣ ə ʫʣ. 107ə, ʘʣ. 7 ʦʪ ɼʠʦʝʢʪʠəʘ 2001/83/ɽɗ, ʠ ə əʩʠʫʢʠ ʩʣʝʜəʘʣʠ ʘʢʪʫʘʣʠʟʘʝʣʠʷ, ʧʫʙʣʠʢʫəʘʣʠ ʣʘ ʝəʦʦʧʝʡʩʢʠʷ ʫʝʙʧʦʦʪʘʣ ʟʘ ʣʝʢʘʦʩʪəʘ.

## ɻ. ʋʉʃɗɺʀɕ ʀʃʀ ɗɻţфʅʀʏɽʅʀɕ ʅф ɹɽʅɗ Ɂфʉʅф ʀ ɽʌɽʂʊʀɺʅф ʋɁɗʊţɽɹф ʅф ʃɽʂфţʉʊɺɽʅʀɕ ɁţɗɼʋʂR

- **Ɂʣʘʣ ʟʘ ʫʧʦʘəʣʝʣʠʝ ʣʘ ʦʠʩʢʘ (Ɂʋţ)**

Ɂʦʠʪʝʣʷʪ ʣʘ ʦʘʟʦʝʰʝʣʠʝʪʦ ʟʘ ʫʧʦʘəʣʝʣʠʝ (Ɂţʋ) ʪʦʷʙəʘ ʜʘ ʠʟəʙʦʰʘ ʠʟʠʩʢəʘʣʠʷʪʘ ʜʝʡʩʪəʠʷ ʠ ʠʣʪʝʦəʝʣʮʠʠ, ʩʝʦʪʝʢʪʦʘ ʣʘ ʣʝʢʘʦʩʪəʦʪʦ ʙʝʟʦʧʘʩʣʦʩʪ, ʧʦʜʦʦʙʣʦ ʦʧʠʩʘʣʠ ə ʦʦʜʫʣ Ɂʋţ, ʧʦʝʜʩʪʘəʝʣ ə ʃʦʜʫʣ 1.8.2 ʣʘ ʦʘʟʦʝʰʝʣʠʝʪʦ ʟʘ ʫʧʦʘəʣʝʣʠʝ, ʢʘʢʪʦ ʠ ə əʩʠʫʢʠ ʩʣʝʜəʘʰʠ ʦʜʦʙʦʝʣʠ ʘʢʪʫʘʣʠʟʘʮʠʠ ʣʘ Ɂʋţ.

фʢʪʫʘʣʠʟʠʦʘʣ Ɂʋţ ʪʦʷʙəʘ ʜʘ ʩʝ ʧʦʝʜʩʪʘəʠ:

- ʧʦ ʠʩʢʘʣʝ ʣʘ ɽəʦʦʧʝʡʩʢʦʪʦ ʘɠʝʣʮʠʷ ʧʦ ʣʝʢʘʦʩʪʦʪʝ;
- əʩʝʢʘɠʘ, ʢʦɠʘʪʦ ʩʝ ʠʟʤʝʣʷ ʩʠʩʪʝʤʘʪʘ ʟʘ ʫʧʦʘəʣʝʣʠʝ ʣʘ ʦʠʩʢʘ, ʦʩʦʙʝʣʦ ə ʦʝʟʫʣʪʘʪ ʣʘ ʧʦʣʫʫʘəʘʣʝ ʣʘ ʣʦəʘ ʠʣʬʦʦʤʘʮʠʷ, ʢʦʷʪʦ ʤʦʞʝ ʜʘ ʜʦəʝʜʝ ʜʦ ʟʣʘʫʠʪʝʣʣʘ ʧʦʦʤʷʣʘ ə ʩʪʦʪʠʦʰʝʣʠʝ ʣʘ ʧʦʣʟʘ/ʦʠʩʢ, ʠʣʠ ʩʣʝʜ ʜʦʩʪʠɠʘʣʝ ʣʘ əʘʞʝʣ ʝʪʘʧ (ʢʘʪʦ ʢʦʡʪʦ ʩʝ ʦʪʣʘʩʷ ʜʦ ʧʦʦʩʣʝʜʷəʘʣʝ ʣʘ ʣʝʢʘʦʩʪəʦʪʦ ʙʝʟʦʧʘʩʣʦʩʪ ʠʣʠ ʤʠʣʠʤʠʟʠʦʘʣʝ ʣʘ ʦʠʩʢʘ ʜʦ ʤʠʣʠʤʫʤ).

## ʀ. ʂʃʅʂţʀʊʅɗ ʅфʀʐʃɾ ɽʅʀʀɽ ʅф ʀʅɁʐʃʅʅʀɽ ʅф ʃɽţʂʀ ʉʃɽɽ ţфʅţɽ ʐфɺфʅɽ ʅф ʋɁɗʊţɽɹф Ɂţʀ ʀʅɺʐʅţɽɽʅʀ ɗɹʉʊɗɕʊɽʃʉʊɺф

ʊʦəʘ ʝ ʦʘʟʦʝʰʝʣʠʝ ʣʘ ʫʧʦʘəʣʝʣʠʝ ʧʦʠ ʫʩʣʦəʠʷ ʦʙʝʢʪʘʣʠə ʫ ʝʧʠɠʘʣʝʣ ʟʦ ʫʣ. 14, ʘʣ. 8 ʦʪ ţʝɠʫʣʘʮʠʷ (Eʃ) ¯ 726/2004 ə ʦʧʦʝʜəʠʜʝʣʠʷ ʩʦʢ Ɂţʋ ʪʦʷʙəʘ ʜʘ ʧʦʝəʠʜʠ ʩʣʝʜʣʠʪʝ ʤʝʦʢʠ:

| ʃ ʧʃʃʩʊʤʃʝ | Cʧʦʢ |
|---|---|
| ɹʊ ʜʊ ɵʊʤʃʜʃʧʊ ʤʝʝʦʦʜʊ ʟʊ ʷʊʧʤʒʊʢʦʢʃʤʝʝʃʦʃʃʤʦ ʦ⊐ʊʧʊʢʝʝʃʧʃʟʃʧʊʤʝ ʤʊ ʦʁʃʤʝʦʦʢʩʊʢʩʃʃʒʊʁ (GCL-160) ɵ ʊʦɵʝ ʰ ʢʃ ʩʝʧʦʤʒ, ɹ ʈ ʊ ʝʦʧʷʁɵʊ ʜʊ ʧʦʝʜʩʝʝʊɵʃ ʧʝʟʤʤʝʊʝʃʝ ʦʝʝ ɵʊʤʃʜʃʧʊʤʝʝʦ ʤʊ ʤʝʝʦʦʜʊ ʟʊ ʊʤʊʤʃʟ ʟʊ ʩʤʝʜʤʃʝ ʊʩʧʃʝʢʝʃ, ʧʦʝʜʃ ʜʊ ʃʟʧʦʤʟɵʊ ʤʝʝʦʦʜʊ ʟʊ ʊʤʊʤʃʟʊ ʤʊ ʧʦʦʁʃ ʟʊ ʢʤʃʤʃʃʟʦ ʧʦʦʦʒʃɵʊʤʝ AH501: ʧʦɵʤʃʷɵʊʤʝ ʦʝʝ PA (63 ʃ 83), EF, LF ʃ ADAs, ʃ ʧʦʃʤʦʦʏʃʤʦʩʩʝʝ ʤʊ ʤʝʝʦʦʜʊ ʧʦʃ ⊐ʝʤʦʤʃʝʃʃʝʤ ʃ ʤʃʧʝʤʃʃʝʤ ʩʝʦʦʒʤ. ɹʊʦʊʤʝʤʃʟʲʤ ʝʦʧʷʁɵʊ ʜʊ ʩʝʝʃʟɵʲʦʰ ʃ ʩ ʤʊʧʦʊɵʝʤʃʃ ʟʊ ɵʝʦʦʦʷʝʝʤ ʃʤʃ ʢʦʦɵʦʦʦ, ʁʝʟʦʧʊʩʩʤʦʦʩʝʝʊ ʃ ʧʦʤʦʦʩʃʃʃʝʝʦʦʩʝʝʊ, ɵʢʤ ʳ ʃʃʝʦʤʦʦʷʝʝʤ ⊐ʦʜʊ ʤʊ ʟʊʁʦʤʷɵʊʤʝʝʦ ʃ ʤʃʦʝ ʞ ʃɵʷʝʤʦʩʩʝʝʊ ʧʦʃ ʤʃʃʩʝʝʊ ʩʝʝʦʦʒʤ. ɹʊʦʊʤʝʤʃʟʲʤ ʝʦʧʷʁɵʊ ʜʊ ʩʝʝʃʟɵʲʦʰ ʃ ʩ ʤʊʧʦʊɵʝʤʃʃ ʟʊ ɵʝʦʦʦʷʝʝʤ ʃʤʃʧʝʝʦ ɵʝʦʦʦʷʝʝʤ ʩʝʝʦʦʒʤ ʤʊ ʃʤʃʤʃʃʟʊʊʊʝ ʤʊ ʃʤʃʤʃʃʟʊʊʊʝ ʤʊ ʩʝʝʦʦʦʷʝʝʤ ʦʝʝ ʧʤʊʤʃʟʊʊʊʝʝʦʦʦʷʝʝʤ ʦʝʝʢʦʃʝʝʦʦ ʧʦʤʤʝɵʦʦ ʧʦʦʤʝʝɵʦʦʦʷʝʝʤ AH501. | ʃʊ ʩʝʝ ʧʦʜʊʜʝʝ ʟʊʝʜʤʦʦ ʩʝʦʜʤʦʦʦʷ ʜʦʦʢʤʊʜ ʦʝʝ ʢʤʃʤʃʃʟʦʦ ʧʦʦʦʒʟɵʲʦɵʝʤʃʃ AH501. |
| ɹʊ ʜʊ ʦʟʝʤʃʃ ʢʤʃʤʃʃʟʤʃʤʷ ʦʝʝʦʦʦʦʦʦ, ʁʝʟʦʧʊʩʩʤʦʦʩʝʝʊ ʃ ʧʦʤʦʦʩʩʝʝʊ, ɵʢʤ ʳ ʟʃʃʝʦʤʦʦʷʝʝʤ ʦʝʝʦʦʜʊ ʟʊʁʦʦʷɵʊʤʝʝʦ ʃ ʧʦʦʤʦʦʩʩʝʝʊ ʧʦʃ ʤʃʃʩʝʝʊ ʩʝʝʦʦʒʤ ʤʊ ʃʤʃʤʃʃʟʊʊʊʝ ʟʊ ɵʝʦʦʦʷʝʝʤ ʩʝʝʦʦʦʷʝʝʤ ʩʝʝʦʦʒʤ ʤʊ ʃʤʃʤʃʃʟʊʊʊʝ ʟʊ ɵʝʦʦʦʷʝʝʤ ʦʝʝʢʦʃʝʝʦʦ ʧʦʤʤʝɵʦʦ ʧʦʦʤʝʝɵʦʦʦʷʝʝʤ AH501 ʷʊʟʊ 4 ʧʦʃ ʧʦʷɵʊ ʤʊ ʦʒʤʃ ʰ ʝ ʤʊ ʤʤʝʦʦʊʢʩ ɵʩʝʦʦʦʷʝʝʤ, ɵ ʢʦʃʝʦʦ ʦʁʃʤʝʦʦʩʩʝʝʊ ʝ ʦʊʟʦʝ ʰ ʝʤ ʟʊ ʟʃʧʦʝʦʦʦʁʝʊ ʃ ʝ ʤʊʤʃʃʟʝʤ. | ʃʊ ʩʝʝ ʧʦʜʊʜʝ ʟʊʝʜʤʦʦ ʩʝʦʜʤʦʦʦʷ ʜʦʦʢʤʊʜ ʦʝʝ ʢʤʃʤʃʃʟʦʦ ʧʦʦʦʒʟɵʲʦɵʝʤʃʃ AH501. |
| | ʃʢʦʦʤʊʊʝʝʤʃʃʟʷʝʝ ʜʦʦʢʤʊʜ ʩʝʝ ʧʦʝʜʩʝʝʦʦʩʝʝʊ ʧʦʦ-ʢʲʩʤʦʦ ʦʝʝ 12 ʤʒʝʩʝʝʊ ʩʩʤʝʜ ʧʦʩʩʤʝʜʤʦʦʝʝʦʦ ʧʦʃʤʦʦʞʝʤʃʃʝ ʤʊ ʦʁʃʤʝʦʦʢʩʊʢʩʃʃʒʊʁ ʃʤʃʧʦʝʦʦʦʁʝʊ ʩʝʝʦʦʦʷʝʝʤ ʩʝʝʦʦʜʊ ʤʊ ʜʊʤʤʃ ɵ ʩʩʤʝʊʊʊʝ ʤʊ ʦʝʝʦʦʦʩʩʝʝʦʦʦʷʝʝʤ ʤʊ ʜʊʤʤʃ. |

# €•‚ƒ„…†‡•ˆ‰Š‹Œ‚†‚‚Š•†Š‡•Ž•ˆ‚ƒšƒœƒšƒ†ƒˆƒ™ƒƒ„•ƒ„••••ˆ•ƒŒ‰Š†„•‚ƒ

## ƒšƒƒœƒ™ƒ•ƒœƒšƒƒšƒ†ƒˆƒ™ƒƒ„•ƒ„••••ˆ•ƒŒ‰Š†„•‚ƒ

φαφδιγ∫δφτ∫ αωιζγ κιιφι .φ

€• ‚ƒ „…†‡•ˆ ‰„Š‹Œ‚†‚ ‚Š•†Š ‡•Ž•ˆ •‘ •”„•–•—˜ •™ Œ‰Š†„•‘ƒ

**[illegible]**

**[illegible]**

## 1. [illegible]

NYXTHRACIS 100 mg/ml [illegible]

## 2. [illegible]

1 ml: 100 mg [illegible]

## 3. [illegible]

[illegible]

## 4. [illegible]

[illegible]
600 mg/6 ml
1 [illegible]

## 5. [illegible]

[illegible]
i.v. [illegible]
[illegible]
[illegible]

QR [illegible] + www.obiltoxaximab-sfl.eu

## 6. [illegible]

## 7. [illegible]

## 8. [illegible]

[illegible]:

## 9. [illegible]

[illegible]

[illegible]

| | |
|---|---|
| **10.** | **[illegible]** |

| | |
|---|---|
| **11.** | **[illegible]** |

SFL Pharmaceuticals Deutschland GmbH
Marie-Curie-Strasse 8
79539 L°rrach
[illegible]

| | |
|---|---|
| **12.** | **[illegible]** |

[illegible]/1/20/1485/001

| | |
|---|---|
| **13.** | **[illegible]** |

[illegible]:

| | |
|---|---|
| **14.** | **[illegible]** |

| | |
|---|---|
| **15.** | **[illegible]** |

| | |
|---|---|
| **16.** | **[illegible]** |

[illegible]

| | |
|---|---|
| **17.** | **[illegible]** |

[illegible]

| | |
|---|---|
| **18.** | **[illegible]** |

PC
SN
NN

**ʃʀ ɿʀ ʃ ʊ ʃ ɾ ɸ ɿ ɿʀ, ʂ ʃ ʀ ʊ ʃ ʊ ɿ ɔ ɾ ɸ ɾ ɸ ɾ ɸ ʜ ʒ ɾ ʒ ɿ ɾ ɸ ʊ ʃ ɸ ʃ ʂ ʀ ʊ ɾ ɾ ʀ ɿ ʀ ʏ ɿ ʀ**
**ɿ ʒ ɿ ɾ ʀ ʏ ɿ ʀ ʃ ɿ ɸ ʂ ʃ ɾ ʂ ʀ**

**ɾ ʊ ʀ ʂ ɾ ʊ ɿ ɸ ʌ ʃ ɸ ʂ ʃ ɿ ɸ**

## 1. ʀ ʃ ɾ ɿ ɸ ʃ ɾ ʂ ɸ ɿ ʜ ʊ ɾ ɾ ɿ ʀ ɾ ɿ ʃ ɾ ʊ ʂ T ʀ ɿ ʒ ʊ (ʀ ʑ ɸ) ɿ ɸ ɾ ʒ ɾ ɾ ɾ ɸ ɿ ɾ

NYXTHRACIS 100 mg/ml ŋʎsjtɕɕʃɕʑ ʕtsɕʑɥjɕʑʎstɕθʎs
tsʙɕʃɕʑʎstsʕŋθʕŋɕʃɕʒθʙ
i.v. ŋɕʑjʜ tɕθʟtɕj ɤʜθɕʑj

## 2. ɿ ɸ ʏʀ ɿ ɿ ɸ ɿ ɿʀ ʃ ʃ ɾ ɾ ɿ ʀ ɾ

ʜθɕʒts ʟθ jʜɕʑtsʕtɕθʎsɕʑθ ʞʒʃtsʎstɕjʙθ.

## 3. ɾ ɸ ʊ ɸ ɿ ɸ ʀ ɿ ʊ ʀ ʏ ɸ ɿ ɾ ɿ ɸ ɿ ɸ ʜ ɿ ʃ ʂ ɸ ɿ ɸ ɿ ʃ ɾ ɿ ʃ ʜ ʊ

ɿtsʜjɕʑ ʜts:

## 4. ɿ ɸ ɿ ʊ ʀ ɾ ɾ ɿ ɿ ʃ ɾ ɿ

ɿ θtɕʎsɕʃʜθ:

## 5. ʜ ʒ ɾ ʒ ɿ ɾ ɸ ɿ ʀ ɾ ʂ ɸ ʊ ʃ ʃ ɸ ʜ ɸ, ʃ ɾ ɿ ʃ ʀ ʃ ʀ ɾ ɾ ʀ ɿ ʀ ʎ ʀ

600 mg/6 ml

## 6. ɾ ɿ ʊ ɿ ʃ

# 7. Φšr Ωнϖ∫

€• ‚ƒ „…†‡•ˆ ‰„Š‹Œ‚†‚ ‚Š•†Š ‡•Ž•ˆ •‚ •• „ƒ•„••ˆ •ƒ Œ‰Š†„•‘ƒ

## ʃ ɖʄɳlstsəʢθ: ɖɖẇtstɛɖʒθɥɖʷ ʟθ ʧθɥɖʃɖɖlsθ

## NYXTHRACIS 100 mg/ml ʢtsɖɥʃɖɖlstɛθls ʟθ ɖɖẇɮʟɖʃtsɖʃɖɖ tɛθʟlsətstɛ

tsвɖɖlstsʢɳθʢɳɖʃɖʒθв (obiltoxaximab)

ƿtsʟɖ ɖʃʢθtɛɳlsəʃɖɖ ʧtɛtsнɮʢls ʧtsнɖʃɥɖ ɖθ нtsʧʲɖɖɖlsʃɖɖɖts ɖθвɖɖʷ нʃɖɖʃ. ƿtsəθ ʰʃ ʧtsʟətsɖɖ вʲtɛʟtslsts ɮɳlsθɖɖtsəʷəθɖʃ ɖθ ɖɖtsəθ ɖɖẇtstɛɖʒθɥɖʷ tslsɖɖtsɳɖɖts вʃʟtsʧθɳɖɖtsɳlslsθ. ʃtsɥʃlsʃ нθ нθнʃlsʃ ɳətsʷ ʧtɛɖɖtsɳ ʢθlsts ɳʲtsв ʰ ɖlsʃ əɳʷʢθ ɖʃɥʃɥɖθɖθ tɛʃθʢɥɖʷ, ʢtsʷlsts ɳlsʃ ʧtsɖɮɥɖɖɖ. ʟθ ɖθɥɖɖθ ɖθ ɳʲtsв ʰ θəθɖʃ ɖθ ɖʃɥʃɥθɖɖ tɛʃθʢɥɖɖ əɖʃɥlsʃ ʢtɛθʷ ɖθ lstsɥʢθ 4.

**ʅ tɛtsɥʃlsʃlsʃ əɖɖɖʒθlsʃɖɖɖts ɥʷɖθlsθ ɖɖɳlstsəʢθ, ʧtɛʃнɖ нθ ʟθʧtsɥɖʃlsʃ нθ ɖʟʧtsɖʟəθlsʃ lstsəθ ɖʃʢθtɛɳlsəts, lsʲ ʢ ʢθlsts lsʷ ɳʲнʲtɛɥθ əθɥɖθ ʟθ ʃθɳ ɖɖẇtstɛɖʒθɥɖʷ.**

- ʟθʧθʟʃlsʃ lsθʟɖ ɖɖɳlstsəʢθ. ʃtsɥʃ нθ ɳʃ ɖθɖtsɥɖ нθ ʷ ʧtɛtsɥʃlsʃlsʃ tslsɖtsəts.
- ɸʢts ɖʒθlsʃ ɖʷʢθʢəɖ нtsʧʲɖɖɖlsʃɖɖɖ əʲʧtɛtsɳɖ, ʧtsʧɖlsθʔlsʃ ʃθʰɖʷ ɖʃʢθtɛ, ẇθtɛɖʒθɥʃəls ɖɖɖ ɖʒʃнɖɥɖɖɳʢθ ɳʃɳlstɛθ.
- ɸʢts ʧtsɖɮɥɖlsʃ ɖʷʢθʢəɖ ɖʃɥʃɥɖθɖɖ ɖʃʢθtɛɳlsəʃɖɖ tɛʃθʢɥɖɖ, ɮəʃнtsɖʃlsʃ ʃθʰɖʷ ɖʃʢθtɛ, ẇθtɛɖʒθɥʃəls ɖɖɖ ɖʒʃнɖɥɖɖɳʢθ ɳʃɳlstɛθ. ƿtsəθ əʢɖ ʳ ɥəθ ɖ əɳɖɥʢɖ əʲʟɖʒtsɥɖɖ ɖʃɥʃɥɖθɖɖ tɛʃθʢɥɖɖ, ɖʃtsʧɖɳθɖɖ əlsθʟɖ ɖɖɳlstsəʢθ. ʃɖɥlsʃ lstsɥʢθ 4.

**ʂθʢəts ɳʲнʲtɛɥθ lsθʟɖ ɖɖɳlstsəʢθ**

1. ʂθʢəts ʧtɛʃнɳlsθəɖʷəθ NYXTHRACIS ɖ ʟθ ʢθʢəts ɳʃ ɖʟʧtsɖʟəθ
2. ʂθʢəts lstɛʷвəθ нθ lɖθʃlsʃ, ʧtɛʃнɖ нθ ʃɖ вʲнʃ ʧtɛɖɖtsɥʃɖ NYXTHRACIS
3. ʂθʢ ʰʃ ʃɖ вʲнʃ ʧtɛɖɖtsɥʃɖ NYXTHRACIS
4. ʃʲʟɖʒtsɥɖɖ ɖʃɥʃɥɖθɖɖ tɛʃθʢɥɖɖ
5. ʂθʢ нθ ɳʲƎtɛθɖʷəθlsʃ NYXTHRACIS
6. ʉʲнʲtɛɥθɖɖʃ ɖθ tsʧθʢtsəʢθlsθ ɖ нtsʧʲɖɖɖlsʃɖɖɖθ ɖɖẇtstɛɖʒθɥɖʷ

### 1. ʂθʢəts ʧtɛʃнɳlsθəɖʷəθ NYXTHRACIS ɖ ʟθ ʢθʢəts ɳʃ ɖʟʧtsɖʟəθ

NYXTHRACIS ɳʲнʲtɛɥθ θʢlsɖəɖtslsts əʃʲʃɳlsəts tsвɖɖlstsʢɳθʢɳɖʃɖʒθв. ʃвɖɖlstsʢɳθʢɳɖʃɖʒθв ʃ ɖʒtsɖtsʢɖtsɖθɖɖts θɖlsɖlsʷɖts, əɖн вʃɖlsʲʢ, ʢtsʔlsts ɳʃ ɳəʲtɛʟəθ ɖ ɖɖθʢlsɖəɖtɛθ lstsʢɳɖɖɖlsʃ, ʧtɛtsɖʟəʃнʃɖɖ tsls вθʢlsʃtɛɖɖlsʃ, ʧtɛɖɥɖɖʷəθ ʰ ɖ θɖlstɛθʢɳ.

NYXTHRACIS ɳʃ ɖʟʧtsɖʟəθ ʟθʃнɖts ɳ θɖlsɖвɖtslsɖɥɖɖ ɖʃʢθtɛɳlsəθ ʟθ ɖʃɥʃɖɖʃ ɖθ əʲʟtɛθɳlsɖɖ ɖ нʃɥθ ɳ θɖlstɛθʢɳ, ʧtɛɖɥɖɖʃɖ tsls əнɖʰ əθɖʃlsts ɖθ вθʢlsʃtɛɖɖlsʃ (ɖɖƎθɖθɥɖtsɖʃɖ θɖlstɛθʢɳ).

NYXTHRACIS ʒtsɥʃ ɳʲʰts нθ ɳʃ ɖʟʧtsɖʟəθ, θʢts ɳlsʃ вɖɖɖ ə ʢtsɖlsθʢls ɳ θɖlstɛθʢɳɖɖ вθʢlsʃtɛɖɖ ɖɖɖ ɳʧtstɛɖ, ɖts ɖʷʒθlsʃ ɳɖɖʒʧlstsʒɖ ɖθ ʟθвtsɖʷəθɖʃlsts ɖ θʢts ɖʷʒθ нtɛƵts ʧtsнƎtsнʷʰ ts ɖʃɥʃɖɖʃ.

### 2. ʂθʢəts lstɛʷвəθ нθ lɖθʃlsʃ, ʧtɛʃнɖ нθ ʃɖ вʲнʃ ʧtɛɖɖtsɥʃɖ NYXTHRACIS

**ʅʃ lstɛʷвəθ нθ ʃɖ ɳʃ ʧtɛɖɖθƵθ NYXTHRACIS**

- θʢts ɳlsʃ θɖʃtɛƵɖɖɖ ʢʲʒ tsвɖɖlstsʢɳθʢɳɖʃɖʒθв ɖɖɖ ʢʲʒ ɖʷʢtsʷ tsls tsɳlsθɖθɖɖlsʃ ɳʲɳlsθəʢɖ ɖθ lstsəθ ɖʃʢθtɛɳlsəts (ɖʟвtɛtsʃɖɖ ə lstsɥʢθ 6).

**ʅ tɛʃнɮʧtɛʃɥнʃɖɖʷ ɖ ʧtɛʃнʧθʟɖɖ ɖʒʃtɛʢɖ**

ʃtsətstɛʃlsʃ ɳ ʃθʰɖʷ ɖʃʢθtɛ, ẇθtɛɖʒθɥʃəls ɖɖɖ ɖʒʃнɖɥɖɖɳʢθ ɳʃɳlstɛθ, ʧtɛʃнɖ нθ ʧtɛɖʃɖʒʃlsʃ NYXTHRACIS:

- θʢts ʃɖʃ (ɖɖɖ ʃθʰ ʃlsts нʃlsʃ) ɖʒθlsʃ ɖθɳɖʃнɳlsəʃɖθ ɖʃʧtsɖtsɳɖʒtsɳls ʢʲʒ ẇtɛƵʢlstsʟθ (ʅ ʅ ʌ), tɛʷнʢts ɡʃɖʃlsɖɥɖtsʟθвtsɖʷəθɖʃ, ɖɖɖ θʢts нʃlsʃlsts ʃɖəʃɥʃ ɖʃ ʒtsɥʃ нθ ʧtɛɖʃʒθ ɳɖθнʢɖ Ǝtɛθɖɖ ɖɖɖ ɖθʧɖlsʢɖ, ʟθʰtslsts ʒƵ ɳʃ ɡθнɖ, ʧtsətɛʲʰθ ɖɖɖ ʧtsɖɮɥθəθ ɖʃʧtɛɖʷlsɖɖ ʃʷʃʢlsɖ ʢθlsts ʧtsнƵəθɖʃ ɖθ ʢtsɛʃʒθ, вtsɖʢɖ ə ʢtsɛʃʒθ ɖɖɖ нɖθtɛɖʷ.

ɸdʑjtɛɕɕɖɖlʂj tɛj0ʢɣɖɖ, ʢtsɖlʂts dʑtsɕ0ls н0 ɦj tʃtsʷəʷls ɦdʑjн dʑjɥjdʑɖj ɦ NYXTHRACIS, tʃtsdʑʷʢtsɕ0 dʑtsɕ0ls н0 вʲн0ls lʂjкʢɖ. ʃ tsкj н0 ɟɖ вʲнj н0нjdʑ 0dʑlsɖ⊐ɖɦls0dʑɖdʑ, tʃtɛjнɖ н0 ɟɖ вʲнj tʃtɛɖdʑtsкjdʑ NYXTHRACIS, ɩ0 н0 ɦj dʑ0dʑ0dʑɖ tɛɖɦʢʲls tsls 0dʑjtɛɕɖɖɖ tɛj0ʢɣɖɖ.

## ɾtɛʑɕɖ dʑjʢ0tɛɦlsəθ ɖ NYXTHRACIS

ʁdʑʷtstɛdʑɖtɛ0ʔlsj ɟ0ʰ ɖʷ dʑjʢ0tɛ ɖdʑɖ ʷ0tɛdʑ0ɥjəls, 0ʢts tʃtɛɖjdʑ0lsj, dʑ0ɦʢtstɛts ɦlsj tʃtɛɖjdʑ0dʑɖ ɖdʑɖ j əʲɩdʑtsкdʑts н0 tʃtɛɖjdʑjlsj нtɛʑɕɖ dʑjʢ0tɛɦlsəθ.
ʃ tsкj н0 ɟɖ вʲн0ls н0нjdʑɖ 0dʑlsɖвɖtslsɖɥɖ (dʑ0tʃtɛ. ɥɖtʃtɛtsʷdʑtsʢɦ0ɥɖdʑ), ɩ0 н0 tʃtsнtʃtsdʑtsɕdʑ0ls dʑjɥjdʑɖjlsts dʑ0 ɖdʑ⊐0dʑ0ɥɖtsdʑjdʑ 0dʑlstɛ0ʢɦ.

## ɹtɛjdʑjdʑdʑtsɦls ɖ ʢʲtɛdʑjdʑj

ɸʢts ɦlsj вtɛjdʑjdʑdʑ0 ɖdʑɖ ʢʲtɛdʑɖlsj, ɦdʑʷls0lsj, ɥj dʑtsкj н0 ɦlsj вtɛjdʑjdʑdʑ0 ɖdʑɖ tʃdʑ0dʑɖtɛ0lsj вtɛjdʑjdʑdʑtsɦls, tʃtsɦʲəjlsəθʔlsj ɦj ɦ ɟ0ʰ ɖʷ dʑjʢ0tɛ ɖdʑɖ dʑjнɖɥɖdʑɦʢ0 ɦjɦjlstɛ0 tʃtɛjнɖ ʑtʃtslstɛjв0ls0 dʑ0 lstsəθ dʑjʢ0tɛɦlsəts.

ɩjj ɖɩəjɦlsdʑts н0dʑɖ NYXTHRACIS dʑtsкj н0 dʑ0ətɛjнɖ dʑ0 tʃdʑtsн0.

ɟɦj ts ʰj dʑj j ɖɩəjɦlsdʑts н0dʑɖ NYXTHRACIS tʃtɛjdʑɖdʑ0əθ ə ʢʲtɛdʑ0ls0. ɟɖj ɖ ɟ0ʰ ɖʷls dʑjʢ0tɛ ʰj tɛj ʰ ɖlsj н0dʑɖ lstɛʷвəθ н0 ʢʲtɛdʑɖlsj ɦdʑjн tʃtɛɖjdʑ0 dʑ0 NYXTHRACIS.

## ʑ tsʷʃtɛ0dʑj ɖ tɛ0вtslsθ ɦ dʑ0ʰ ɖdʑɖ

NYXTHRACIS dʑtsкj н0 tʃtɛɖɥɖdʑɖ dʑjкjdʑ0dʑɖ tɛj0ʢɣɖɖ ʢ0lsts ɕdʑ0ətsвtsdʑɖj, ɦəjlstsəʲtɛlsjк, ʑdʑtstɛ0 ɖ tʃtsətɛʲʰ 0dʑj. ʊtsəθ dʑtsкj н0 tʃtsədʑɖʷj dʑ0 ɦtʃtsɦtsвdʑtsɦlslsθ ɟɖ ɩ0 вjɩtsʃ0ɦdʑts ʰtsʷʃtɛ0dʑj ɖ tɛ0вtslsθ ɦ dʑ0ʰ ɖdʑɖ.

## NYXTHRACIS ɦʲнʲtɛкj0 ɦtstɛвɖlstsdʑ (E420)

ʉtstɛвɖlstsdʑʲls j ɖɩlstsɥdʑɖʢ dʑ0 ʷtɛʑʢlstsɩ0 (əɖн ɩ0⊐0tɛ). ɸʢts ɟɖj (ɖdʑɖ ɟ0ʰ jlsts нjlsj) ɖdʑ0lsj dʑ0ɦdʑjнɦlsəjdʑ0 dʑjtʃtsdʑtsɦɖdʑtsɦls ʢʲdʑ ʷtɛʑʢlstsɩ0 (ll л), tɛʷнʢts ɕjdʑjlsɖɥdʑts ɩ0вtsdʑʷəθdʑj, ɟ0ʰ ɖʷls dʑjʢ0tɛ dʑtsкj н0 tɛj ʰ ɖ, ɥj ɟɖj (ɖdʑɖ ɟ0ʰ jlsts нjlsj) dʑj lstɛʷвəθ н0 tʃtsdʑʑɥθəθlsj lstsəθ dʑjʢ0tɛɦlsəts. ɹ0ɥɖjdʑlsɖlsj ɦ ll л dʑj dʑtsɕ0ls н0 tɛ0ɩɕtɛ0кн0ls ʷtɛʑʢlstsɩ0ls0, ʢtsjlsts dʑtsкj н0 tʃtɛɖɥɖdʑɖ ɦjtɛɖtsɩdʑɖ dʑjкjdʑ0dʑɖ tɛj0ʢɣɖɖ.
ʊtɛʷвəθ н0 ʢ0кjlsj dʑ0 ɟ0ʰ ɖʷ dʑjʢ0tɛ, tʃtɛjнɖ н0 tʃtsdʑʑɥθəθlsj lstsəθ dʑjʢ0tɛɦlsəts, 0ʢts ɟɖj (ɖdʑɖ ɟ0ʰ jlsts нjlsj) ɦlstɛ0н0lsj tsls ll л ɖdʑɖ 0ʢts нjlsjlsts ɟɖ əjɥj dʑj dʑtsкj н0 tʃtɛɖjdʑ0 ɦdʑ0нʢɖ ⊐tɛ0dʑɖ ɖdʑɖ dʑ0tʃɖlsʢɖ, ɩ0ʰ tslsts ɦj dʑʑ ɦj ɕ0нɖ, tʃtsətɛʲʰ 0 ɖdʑɖ tʃtsdʑʑɥθəθ dʑjtʃtɛɖʷlsdʑɖ jʷjʢlsɖ ʢ0lsts tʃtsнʑəθdʑj dʑ0 ʢtstɛjdʑ0, вtsdʑʢɖ ə ʢtstɛjdʑ0 ɖdʑɖ нɖ0tɛɖʷ.

## NYXTHRACIS ɦʲнʲtɛкj0 dʑ0lstɛɖʔ

ʊtsəθ dʑjʢ0tɛɦlsəts ɦʲнʲtɛкj0 tʃts-dʑ0dʑʢts tsls 1 mmol dʑ0lstɛɖʔ (23 mg) dʑ0 əɦjʢɖ ʷdʑ0ʢtsdʑ tsls 6 mL NYXTHRACIS, ls.j. dʑtsкj н0ɦj ʢ0кj, ɥj tʃtɛ0ʢlsɖɥjɦʢɖ dʑj ɦʲнʲtɛкj0 dʑ0lstɛɖʔ.

## 3. ʂ0ʢʰj ɟɖ вʲнj tʃtɛɖdʑtsкjdʑ NYXTHRACIS

NYXTHRACIS ʰj ɟɖ вʲнj tʃtɛɖdʑtsкjdʑ tsls dʑjʢ0tɛ ɖdʑɖ dʑjнɖɥɖdʑɦʢ0 ɦjɦjlstɛ0. ɟ0ʰ ɖʷls dʑjʢ0tɛ ɖdʑɖ dʑjнɖɥɖdʑɦʢ0 ɦjɦjlstɛ0ʰj ɖɩɥɖɦdʑʷls нtsɩ0lsθ əʲɩ tsɦdʑtsəθ dʑ0 ɟ0ʰ jlsts ksjɕdʑts (ɖdʑɖ dʑ0 нjlsjlsts ɟɖ).

ɟ0ʰ ɖʷls dʑjʢ0tɛ, dʑjнɖɥɖdʑɦʢ0 ɦjɦjlstɛ0 ɖdʑɖ ʷ0tɛdʑ0ɥjəls ʰj tʃtsнɕtslsəʷls dʑjʢ0tɛɦlsətslsts ɩ0 ɖdʑʷʑɩɖʷ. ʈ0ɩlsətstɛʲls NYXTHRACIS ʰj ɦj tʃtɛɖdʑ0ɕ0 tʃtsн ʷtstɛdʑ0ls0 dʑ0 ɖdʑʷʑɩɖʷ (ʢ0tʃʢtsəts) ə tʃtɛtsнʲdʑкjdʑɖj dʑ0 90 dʑɖdʑʑlsɖ əʲə əjdʑ0, tsвɖʢdʑtsəjdʑts dʑ0 tɛʲʢ0ls0. ʑ j вʲнjlsj dʑ0вdʑʳ н0əθdʑɖ, нtsʢ0lsts ɟɖ ɦj tʃtɛɖdʑ0ɕ0 NYXTHRACIS, ʢ0ʢlsts ɖ tʃtsdʑj jнɖdʑ ɥ0ɦ ɦdʑjн ɖdʑʷʑɩɖʷls0.
ɹtɛjнɖ н0 ɟɖ вʲнj tʃtɛɖdʑtsкjdʑ NYXTHRACIS, tsвɖʢdʑtsəjdʑts ʰj ɟɖ вʲн0ls н0нjdʑɖ dʑjʢ0tɛɦlsəθ ɩ0 tʃtɛjнtslsətɛ0lsʷə0dʑj ɖdʑɖ dʑ0dʑ0dʑʷə0dʑj dʑ0 0dʑjtɛɕɖɖɖ tɛj0ʢɣɖɖ.

ɸʢts ɖdʑ0lsj dʑʷʢ0ʢəɖ нtsʃʲdʑdʑɖlsjdʑdʑɖ əʲtʃtɛtsɦɖ, ɦəʲtɛɩ0dʑɖ ɦ ʑtʃtslstɛjв0ls0 dʑ0 lstsəθ dʑjʢ0tɛɦlsəts, tʃtstʃɖls0ʔlsj ɟ0ʰ ɖʷ dʑjʢ0tɛ, ʷ0tɛdʑ0ɥjəls ɖdʑɖ dʑjнɖɥɖdʑɦʢ0 ɦjɦjlstɛ0.

## 4. Jʲʟdʒtsʞdzɖ dzʲʞʲdzθdzɖ tɕʲθʕʏɖɖ

ʂθʕlsts əɦɖʏʕɖ dzʲʕθtɕɦlsəθ, lstsəθ dzʲʕθtɕɦlsəts dʒtsʞʲ нθ ʧtɕʲнɖʟəɖʕθ dzʲʞʲdzθdzɖ tɕʲθʕʏɖɖ, əʲʧtɕʲʕɖ ʏʲ dzʲ əɦʲʕɖ ɢɖ ʧtsdzʐʏθəθ.

**ʏʲʟθвθədzts ʐəʲнtsdʒʲlsʲ Jθʰ ɖʷ dzʲʕθtɕ ɖdzɖ dzɖʏʲlsts, ʕtsʲlsts Jɖ ʧtɕɖdzθɢθ ɖdzʷʐʟɖʷlsθ, θʕts ʟθвʲdzʲʞʲɖlsʲ dzʷʕtsʷ tsls ɦdzʲнdzɖlsʲ dzʲʞʲdzθdzɖ tɕʲθʕʏɖɖ:**

ʉʲtɕвʲʞ, tsвtɕɖə, ʟθнʐ⊐ ɖdzɖ ⊐tɕɖʧtsəʲ – lstsəθ dʒtsʞʲ нθ ɦθ ʧtɕɖʟdzθʏɖ dzθ θdzʲtɕɢɖʏdzθ tɕʲθʕʏɖʷ (ɦətɕʲ⊐ʏʐəɦlsəɖlsʲdzdztsɦls).

**ʃtɕʐɢɖlsʲ dzʲʞʲdzθdzɖ tɕʲθʕʏɖɖ dzθ Obiltoxaximab dʒtsʞʲ нθ əʕdzˣʏəθls:**

**ʏʲɦlsɖ** (dʒtsʞʲ нθ ʟθɦʲɢdzθls нts 1 dzθ 10 нʐʰ ɖ)
- ʟdzθətsвtsdzɖʲ
- ʂθʰdzɖʏθ
- ʟtsdzʕθ dzθ dʒʷɦlstslsts dzθ ɖdzʷʐʟɖʷlsθ
- ʉʲtɕвʲʞ, ʕtsʞʲdz tsвtɕɖə, əʕdzˣʏɖlsʲdzdzts ɦʲtɕвʷʰ dzθнɖɢdzθls tsвtɕɖə (ʕtsʧtɕɖədzθ lstɕʲɦʕθ)

**ʏʲʏʲɦlsɖ** (dʒtsʞʲ нθ ʟθɦʲɢdzθls нts 1 dzθ 100 нʐʰ ɖ):
- ɸdzʲtɕɢɖʏdzɖ tɕʲθʕʏɖɖ
- ʉəʲlstsəʲtɕlsʲʞ
- ʁʟlstɕʲʧəθdzʲ
- ʏʐəɦlsəɖlsʲdzdztsɦls ʕʲdʒ ɦəʲlsdzɖdzθ (ʷtslstsʷtsвɖʷ)
- ʃɖɦʕtsdʒʷtstɕls ə ʐʰɖlsʲ
- ʃtɕθʟdzʲdzʲ dzθ ɢʲtɕdztslsts
- ʃtɕʲʟɢθə ɢdzθɦ
- ʅθʧʐʰəθdzʲ dzθ ɦɖdzʐɦɖlsʲ
- ʅθнʐ⊐
- ʅtsdzʕθ ə ʐɦlsdzɖlsʲ
- ʃʕʟʲdʒθ, вʲdzʲdzʲ dzθ ʕtsʞθlsθ
- ʃʐɦʕʐdzdzɖ ʧtslstɕʲʧəθdzɖʷ, dʒʐɦʕʐdzdzɖɦʧθʟdʒɖ
- υdʒtstɕθ
- Jlstɕɖɦθdzʲ
- ʃɖɦʕtsdʒʷtstɕls ə ɢʲtɕнɖlsʲ
- ʅtsdzʕθ ʕθlsts ʏʷdzts ɖ вtsdzʕθ, ʟθɦʷɢθʰθ ʕtɕθʔdzɖʏɖlsʲ, ɢtɕʲнdzɖʷ ʕtsʰ, ʏʲdzˣɦlslsθ, dʒʐɦʕʐdzɖlsʲ, dzɖɢθdʒʲdzlsɖlsʲ, ɦʐ⊐tsʞɖdzɖʷlsθ ɖdzɖ ʕtsɦlsɖlsʲ
- ʃlstsʕ dzθ dʒʷɦlstslsts dzθ ɖdzʷʐʟɖʷ, вtsdzʕθ ɖdzɖ ʷdzʲвɖls (əʲʟʧθdzʲdzɖ əʲdzɖ)

**ʉʲtsвʰ θəθdzʲ dzθ dzʲʞʲdzθdzɖ tɕʲθʕʏɖɖ**
ɸʕts ʧtsdzʐʏɖlsʲ dzʷʕθʕəɖʕdzʲʞʲdzθdzɖ dzʲʕθtɕɦlsəʲdzɖ tɕʲθʕʏɖɖ, ʐəʲнtsdʒʲlsʲ Jθʰɖʷ dzʲʕθtɕ, ʷθtɕdʒθʏʲəls ɖdzɖ dʒʲнɖʏɖdzɦʕθ ɦʲɦʲɦstɕθ. ɢtsəθ əʕdzˣʏəθ ɖ əɦʲɖʏʕʲɖ əʲʟdʒtsʞdzɖ dzʲʞʲdzθdzɖ tɕʲθʕʏɖɖ, dzʲtsʧɖɦθdzɖ ə lθʟɖ dzɖɦlstsəʕθ. ʃtsʞʲlsʲ ɦʲʰtsнθ ɦʲtsвʰ ɖlsʲ dzʲʞʲdzθdzɖ tɕʲθʕʏɖɖ ʏtɕʲʟdzθʏtsdzθdzdzθlsθ ɦɖɦlsʲdʒθ ʟθ ɦʲtsвʰθəθdzʲ, ʧtsɦtsʏʲdzθ ə ʅtɕɖdztsʞʲdzɖʲ V. ʂθlsts ɦʲtsвʰθəθlsʲ dzʲʞʲdzθdzɖ tɕʲθʕʏɖɖ, dʒtsʞʲlsʲ нθ нθнʲlsʲ ɦətsʷ ʧtɕɖdztsɦ ʟθ ʧtsdzʐʏθəθdzʲ dzθ ʧtsəʲʏʲ ɖdzʷʐtstɕʒθʏɖʷ tslsdztsɦdzts вʲʟtsʧθɦdztsɦlslsθ dzθ lstsəθ dzʲʕθtɕɦlsəts.

## 5. ʂθʕ нθ ɦʲ⊐tɕθdzʷəθlsʲ NYXTHRACIS

ʃθ ɦʲʲ ɦʲ⊐tɕθdzʷəθ dzθ dʒʷɦlsts, dzʲнtsɦlsʲʧdzts ʟθ нʲʏθ.

ʅʲ ɖʟʧtsdzʟəθʔlsʲ lstsəθ dzʲʕθtɕɦlsəts ɦdzʲн ɦtɕtsʕθ dzθ ɢtsнdztsɦls, tslsвʲdzʷʟθdz əʲtɕ⊐ʐ ʕθtɕlstsdzʲdzθlsθ tsʧθʕtsəʕθ ɖ əʲtɕ⊐ʐ ʲlsɖʕʲlsθ, ɦdzʲн Ǎʟtsнʲdz нts: ʉtɕtsʕʲls dzθ ɢtsнdztsɦls tslsɢtsəθtɕʷ dzθ ʧtsɦdzʲнdzɖʷ нʲdz tsls lstsʟɖ dʒʲɦʲʏ.

ʃθ ɦʲʲ ɦʲ⊐tɕθdzʷəθ ə ⊐dzθнɖdzdzɖʕ (2 Áʉ – 8 Áʉ).
ʃθ dzʲ ɦʲʲ ʟθdʒtɕθʟʷəθ.
ʃθ ɦʲʲ ɦʲ⊐tɕθdzʷəθ ə tstɕɖɢdzθdzdzθlsθ tsʧθʕtsəʕθ, ʟθ нθ ɦʲʲ ʧtɕʲнʧθʟɖ tsls ɦəʲlsdzɖdzθ.

Ꙗдјн тѳлтј ꙗнѳдј ə ɑдѡƛлɑтсдјд ɦѳƢ ј нтсƢѳлѳдѳ Ɑɑдʒɑцдѳ, ѡɑлɑцдѳ ɑ ʒɑƢтстсвɑтсдтсɑɑцдѳ ɦlѳвɑдѡдтсɦlс ʃƢтс əтсјдʒј дѳ ƛʃƢтсlстсјвѳ ə ʃƢтстсн ʲдꙗјдɑдј дѳ 8 цѳɦѳ ʃƢтсɑ ɦlсѳʔдѳ lсјдʒʃƢјтсѳlсƛтсѳ (20 °C – 25 ÁC) ɑдɑɑ ə ⱭдѳнɑдɑдƢ (2 °C – 8 ÁC).

Ꙗдјн тѳлтј ꙗнѳдј дѳ NYXTHRACIS ə ɦʃƢтсɑдɑцтсəƢѳ лѳ ɑдɑѡƛлɑтсдɑдѳ ʃƢтсдʒʃƢѳ, lстсʔ lстсѡвəѳ нѳ ɦј ʃƢтсɑдɑтсꙗɑ дɑјлѳвѳəдɑтс ɑ нѳ дɑј ɦј ɦʲƢтсѳдɑѡəѳ. ꞮɦɑцƢɑ тсɦlсѳдɑѳдɑ ƢтсдɑцƢɦlсəѳ тсlс ʃƢтстснƛƢlсѳ lстсѡвəѳ нѳ ɦј ɑлƢəʲтсдɑѡlс.

## 6. Ꙗʲнʲтсꙗѳдɑјдɑ дɑѳ тстʃѳƢтсəƢѳlсѳ ɑ нтстʃʲдɑдɑɑlсјдɑдɑѳ ɑдɑѡтстсдʒѳꙗɑѡ

### ꙖѳƢəтс ɦʲнʲтсꙗѳ NYXTHRACIS

- ɸƢlсɑəдɑтсlстс əј ʰ јɦlсəтс ј тсвɑдɑlстсƢɦѳƢɦɑдʒѳв. ꞮɦјƢɑ ml Ƣтсдɑцјдɑlстсѳlс ɦʲнʲтсꙗѳ 100 mg тсвɑдɑlстсƢɦѳƢɦɑдʒѳв. ꙗнɑдɑ ѡдɑѳƢтсдɑ тсlс 6 ml ɦʲнʲтсꙗѳ 600 mg тсвɑдɑlстсƢɦѳƢɦɑдʒѳв.
- ɾтсƛɑʒɑlсј ɦʲɦlсѳəƢɑ ɦѳ Ɑɑдɦlсɑнɑдɑ, ɦстсвɑlстсдɑ (E420), ʃƢтсдɑɦстсвѳlс 80 (E433), Ɑдстстсəстснстстсндɑѳ Ƣɑɦјдɑдɑѳ (E507) ɑ дɑѳlстсɑјə ⱭɑнтстсƢɦɑн (E524). Ɪɑꙗlсј ɦʲʰ тс lстсцƢѳ 2 ÁNYXTHRACIS ɦʲнʲтсꙗѳ ɦстсвɑlстсдñ.

### ꙖѳƢ ɑлɑʒдјꙗнѳ NYXTHRACIS ɑ ƢѳƢəтс ɦʲнʲтсꙗѳ тстʃѳƢтсəƢѳlсѳ

NYXTHRACIS ј вɑɦlсʲтс нтс тстʃѳдјɦцјдɑlсјдɑ, вјлцəјlсјдɑ нтс вдɑјнтсꙗʲдɑlс нтс вдɑјнтс ƢѳѡјдɑдƢѳəтс-ꙗʲдɑlс Ƣтсдɑцјдɑlстсѳlс лѳ тсѳлlсəстстс.
NYXTHRACIS ɦј ʃƢтсјндɑѳɑѳ ə тстʃѳƢтсəƢɑ, ɦʲнʲтсꙗѳʰ ɑ 1 ѡдɑѳƢтсдɑ.

### Ꙗтсɑlсјꙗѳlсјдɑ дɑѳ тсѳлтсјʰ јдɑдɑјlстс лѳ ƛʃƢтсlстсјвѳ

SFL Pharmaceuticals Deutschland GmbH
Marie-Curie-Strasse 8
79539 L°rrach
Ɪјтсдʒѳдɑдʷ

### Ꙗтстсɑлəтснɑlсјдɑ

AcertiPharma B.V.
Boschstraat 51
4811 GC, Breda
ʍтсдɑѳдснɑдʷ

### ɾѳlсѳ дɑѳ ʃƢтсɦдɑјнɑдɑтс ʃƢтсјтсѳлɑʒдɑјꙗнѳдɑј дɑѳ дɑɑɦlстсəƢѳlсѳ

ѳтсəѳ дɑјƢѳтсɦlсəтс ј тсѳлтсјʰ јдɑтс лѳ ƛʃƢтсlстсјвѳ ʃƢтсɑ Ăɑлəʲдɑтсјнɑдɑ тсвɦlстсʷlсјдɑɦlсəѳñ. ѳтсəѳ тслɑѳцѳəѳ, цј ʃƢтстсѳнɑ тсʷнƢтсlстс тсѳлƢтстсɦlстсѳɑјдɑдɑ дɑѳ втсдɑјɦlсlсѳ ɑ ʃƢтс јlсɑцɑдɑ ʃƢтсɑцɑдɑ нтс дʒтсдʒјдɑlсѳ дɑј ј вɑдɑтс əʲлдʒтсꙗдɑтс нѳ ɦј ʃƢтсдƛцɑ ʃʲдɑдɑѳ ɑдɑѡƢтстсдʒѳꙗɑѡ лѳ дɑјƢѳтсɦlсəтстс.
ꞮɦѡƢѳ ɑтснɑдɑѳ ɾəтстстƢјʔɦƢѳlсѳ ѳɑјдɑцɑѡ ʃƢтс дɑјƢѳтсɦlсəѳlсѳ ʰ ј ɑлəʲтсʰəѳ ʃƢтсјɑдɑјн дɑѳ дɑтсəѳlсѳ ɑдɑѡƢтстсдʒѳꙗɑѡ лѳ дɑјƢѳтсɦlсəтстс ɑ lсѳлɑ дɑɦlстсəƢѳ ɦʲтсlсəјlсдɑтс ʰ ј ɦј ѳƢlсƛѳдɑлɑтсѳ.

### ɾтсƛɑʒɑ ɑлlстсꙗдɑꙗɑ дɑѳ ɑдɑѡƢтстсдʒѳꙗɑѡ

ꙗтснтстсвдɑѳ ɑдɑѡƢтстсдʒѳꙗɑѡ лѳ lстсəѳ дɑјƢѳтсɦlсəтс ј ʃƢтсјнтсɦlсѳəјдɑѳ дɑѳ ƛјвɦѳʔlсѳ дɑѳ ɾəтстстƢјʔɦƢѳlсѳ ѳɑјдɑцɑѡ ʃƢтс дɑјƢѳтсɦlсəѳlсѳ: http://www.ema.europa.eu. ꙗтсɦтсцјдɑɑ ɦѳ ɦʲʰ тс дɑɑƢтсəј Ƣʲдʒ нтсƛɑʒɑ ƛјвɦѳʔlстсəј, Ƣʲнɦlстс дʒтсꙗј нѳ ɦј дɑѳдʒјтсɑ ɑдɑѡƢтстсдʒѳꙗɑѡ лѳ тсјнƢɑ лѳвтсдɑѡəѳдɑѡ ɑ дɑјцјдɑдɑѡ.

ѳѳлɑ дɑɦlстсəƢѳ ј дɑѳдɑцɑдɑѳ дɑѳ əɦɑцƢɑ јлɑцɑ дɑѳ ɾꙗ/ɾʀꙗ дɑѳ ƛјвɦѳʔlсѳ дɑѳ ɾəтстстƢјʔɦƢѳlсѳ ѳɑјдɑцɑѡ ʃƢтс дɑјƢѳтсɦlсəѳlсѳ.

ɾтсʃʲдɑдɑlсјдɑдɑѳ ɑдɑѡƢтстсдʒѳꙗɑѡ: www.obiltoxaximab-sfl.eu QR Ƣтсн ʃƢтсјнɦlстсɑ нѳ вʲнј нтсвѳəјдɑ