

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboardboxes with 1, 10 or 12 vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LidoBel 20 mg/ml solution for injection for horses, dogs, and cats (CZ, HU, IE, LT, LV, PT, RO, SK)

LidoBel 16 mg/ml solution for injection for horses, dogs, and cats (AT, BE, ES, SI, PL)

Lidobel 16 mg/ml solution for injection for horses, dogs, and cats (EE)

Lidobel vet. 16 mg/ml solution for injection for horses, dogs, and cats (FI, SE)

Lidobel vet. 20 mg/ml solution for injection for horses, dogs, and cats (NO)

BelOcain vet. 20 mg/ml solution for injection for horses, dogs, and cats (IS)

Lidocaine hydrochloride

Lidocaine (AT, BE, EE, ES, FI, SE, SI, PL)

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml solution for injection contains:

Active substance:

Lidocaine hydrochloride:	20 mg
(equivalent to lidocaine:	16.23 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

250 ml

12 x 100 ml

12 x 250 ml

5. TARGET SPECIES

Horses, dogs and cats.

6. INDICATION(S)

[Not applicable]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For subcutaneous, intramuscular or perineural injection or for application onto the mucosa.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:

Horse:

Meat and offal: 5 days

Milk: 5 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the container: 28 days.

Once opened use by...

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

bela-pharm GmbH & Co. KG
Lohner Str. 19
49377 Vechta
Germany

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

<Batch><Lot> {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Vials of 100 and 250 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LidoBel 20 mg/ml solution for injection for horses, dogs, and cats (CZ, HU, IE, LT, LV, PT, RO, SK)

LidoBel 16 mg/ml solution for injection for horses, dogs, and cats (AT, BE, ES, SI, PL)

Lidobel 16 mg/ml solution for injection for horses, dogs, and cats (EE)

Lidobel vet. 16 mg/ml solution for injection for horses, dogs, and cats (FI, SE)

Lidobel vet. 20 mg/ml solution for injection for horses, dogs, and cats (NO)

BelOcain vet. 20 mg/ml solution for injection for horses, dogs, and cats (IS)

Lidocaine hydrochloride

Lidocaine (AT, BE, EE, ES, FI, SE, SI, PL)

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml solution for injection contains:

Active substance:

Lidocaine hydrochloride: 20 mg

(equivalent to lidocaine: 16.23 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

250 ml

5. TARGET SPECIES

Horses, dogs and cats.

6. INDICATION(S)

[Not applicable]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:

Horse:

Meat and offal: 5 days

Milk: 5 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the container: 28 days.

Once opened use by...

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

[Not requested on the immediate label]

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

bela-pharm GmbH & Co. KG
Lohner Str. 19
49377 Vechta
Germany

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

<Batch><Lot> {number}