B. PACKAGE LEAFLET

PACKAGE LEAFLET:

LidoBel
20 mg/ml solution for injection for horses, dogs, and cats.
AT, BE, EE, ES, FI, SE, SI, PL: 16 mg/ml solution for injection for horses, dogs, and cats.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. 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)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 ml solution for injection contains:

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

Excipients:
Methyl parahydroxybenzoate (E 218): 1.8 mg
Propyl parahydroxybenzoate: 0.2 mg

Clear, colourless solution

4. INDICATION(S)

For local/nerve block (regional infiltration) including field block anaesthesia.
Superficial anaesthesia of mucous membranes.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipient.
Do not use in cases of inflammatory tissue disorders at the site of application.
Do not use in infected tissue.
Do not use in new-born animals.

6. ADVERSE REACTIONS

Tachycardia, bradycardia, cardiac conduction disorders, hypotension and allergic reactions may occur in individual cases.
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}". For details regarding the national system please contact NCA.

7. TARGET SPECIES

Horses, dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For subcutaneous, intramuscular or perineural injection or for application onto the mucosa. To avoid intravascular administration, correct placement of the needle should be verified by aspiration.

The necessary amounts to be administered vary depending on indication (intended purpose, administration route, site of application and general condition of the patient).

The following dosage recommendations may serve as a general guidance (adjustment is needed for animals of a bodyweight below 5 kg in order to not exceed the recommended maximum dose).

<u>Local/nerve block anaesthesia in horses:</u>
1 – 10 ml

<u>Superficial anaesthesia of mucous membranes:</u>
Instil a thin layer topically to site where anaesthesia is required.

The total dose shall not exceed 2-4 mg lidocaine hydrochloride per kg body weight (equivalent to 1 ml of the product per 5 – 10 kg b.w.).

Maximum number of punctures of the rubber stopper is 50 times in case of the 100 ml vial and 100 times in case of the 250 ml vial.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD(S)

Horse:
Meat and offal: 5 days
Milk: 5 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date, which is stated on the bottle.

Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Do not administer by intravenous injection.
Use with extreme care in animals with cardiac insufficiency, cardiac arrhythmia, hyperkalaemia, liver dysfunction, Diabetes mellitus, acidosis and neurological diseases.
Exact dosing and appropriate injection technique must therefore be ensured.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to lidocaine hydrochloride or any of the excipients should avoid contact with the veterinary medicinal product.

Pregnancy:
Lidocaine may cross the placental barrier and is excreted in milk in lactating animals. Use only according to the benefit/risk assessment by the responsible veterinarian in pregnant or lactating animals.

Interaction with other medicinal products and other forms of interaction:
The local anaestethic effect is prolonged if vasoconstrictors (e.g. epinephrine) are applied concomitantly. Morphine-type analgesics may decrease the metabolism of lidocaine.
Morphine-type analgesics may decrease the metabolism of lidocaine.

Lidocaine may interact with:

- antibiotics: co-administration of ceftiofur may cause an increase in the free lidocaine concentration due to an interaction with plasma protein binding.
- antiarrhythmic agents: amiodarone may cause increases in plasma lidocaine concentrations and therefore heighten its pharmacological effects. This effect may also be observed when it is administered with metoprolol or propranolol.
- injected anaesthetics and anaesthetic gases: co-administration of anaesthetics enhances their effect and their dosages may need to be adjusted.

muscle relaxants: a significant dose of lidocaine may boost the action of succinylcholine and may prolong succinylcholine induced apnoea.

Overdose (symptoms, emergency procedures, antidotes):
Overdose and intravascular injections are associated with a high risk of central and cardiac effects.

Acute overdose with lidocaine is characterised by anxiety, restlessness, excitation, ataxia, tremor, vomiting, muscle contractions, convulsions, hyotension, bradycardia, unconsciousness, respiratory paralysis and cardiac arrest.
In case of overdose, symptomatic treatment should be instigated as appropriate.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Not all pack sizes may be marketed.

Pack Sizes:
100 ml
250 ml
12 x 100 ml
12 x 250 ml