Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

LidoBel 20 mg/ml solution for injection for horses, dogs, and cats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection
Clear, colourless solution

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, dogs and cats.

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

Tachycardia, bradycardia, cardiac conduction disorders, hypotension and allergic reactions may occur in individual cases.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

The local anaesthetic effect is prolonged if vasoconstrictors (e.g. epinephrine) are applied concomitantly. 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 propanolol.

- 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.

4.9 Amounts to be administered and administration route

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).

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

Superficial anaesthesia of mucous membranes:
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdose and intravascular injections are associated with a high risk of central nervous system and cardiac effects. Acute overdose with lidocaine is characterised by anxiety, restlessness, excitation, ataxia, tremor, vomiting, muscle contractions, convulsions, hypotension, bradycardia, unconsciousness, respiratory paralysis or cardiac arrest.
In case of overdose, symptomatic treatment should be instigated as appropriate.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: anaesthetic, local amides, lidocaine.
ATC vet code: QN01BB02.

5.1 Pharmacodynamic properties

Lidocaine reversibly inhibits the formation and conduction of action potential in the central and peripheral nervous systems by inhibiting the transient increase of sodium permeability of the nerve cell membranes. Sensory nerve fibres are affected earlier than motor nerve fibres. The local anaesthetic effect is induced after 2-5 minutes and is maintained for about 60 to 90 minutes.

5.2 Pharmacokinetic particulars

Lidocaine is characterised by a rapid absorption, distribution, metabolism and elimination. It is absorbed from mucous membranes and crosses the placental and blood-milk barrier. In the dog, a volume of distribution of 1.67 L/kg b.w. and a plasma half-life of 30 minutes have been determined. Lidocaine is mainly metabolised in the liver. A decrease of the hepatic clearance of lidocaine due to the inhibition of the microsomal mono-oxygenase (particularly in case of hypotension or decreased hepatic perfusion), may lead to increased (toxic) plasma concentrations. Lidocaine is oxidatively dealkylated and hydroxylated by mono-oxigenases and hydrolysed by carboxylesterases. The following degradation products were identified: monoethylglycerinxylidid, glycinxylidid, 2,6-xylidine, 4-hydroxy-2,6-dimethylaniline, 3-hydroxy-Lidocaine and 3-hydroxy-monoethylglycinxylidid. The parent compound and its metabolites are excreted either in unchanged, sulphated or glucorinated form.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E 218)
Propyl parahydroxybenzoate
Disodium edetate
Sodium chloride
Propylene glycol
Sodium hydroxide (for pH adjustment)

Hydrochloric acid (for pH adjustment)
Water for injection

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the container: 28 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Clear glass vials (type II), bromobutyl rubber stoppers, aluminium caps.

Carton with 1 or 12 vials containing 100 ml
Carton with 1 or 12 vials containing 250 ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co. KG
Lohner Straße 19
D-49377 Vechta
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10445/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th July 2018

10 DATE OF REVISION OF THE TEXT