*[Version 8.1, 01/2017]*

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lidor 20 mg/ml solution for injection for horses, dogs and cats (AT, BE, CZ, DE, EE, ES, FR, IT, LT, LV, NL, PL, PT)
Lidor vet. 20 mg/ml solution for injection (FI, DK, IS, SE)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substance:**
Lidocaine 20 mg
(equivalent to 24.65 mg lidocaine hydrochloride monohydrate)

**Excipients:**
Methyl parahydroxybenzoate (E218) 1.3 mg
Propyl parahydroxybenzoate 0.2 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution for injection
Clear, colourless to slightly yellow solution

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Horses, dogs and cats

### 4.2 Indications for use, specifying the target species

Horses:
Ophthalmic contact anaesthesia, anaesthesia by infiltration, intra-articular anaesthesia, perineural anaesthesia and epidural anaesthesia.

Dogs, cats:
Anaesthesia in ophthalmology and dentistry, anaesthesia by infiltration and epidural anaesthesia.

### 4.3 Contraindications

Do not use in:
- inflammatory tissue alteration at the application site
- infected tissue
- new-born animals

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

### 4.4 Special warnings for each target species

This product may cause positive anti-doping test results in horses.

## 4.5 Special precautions for use

Special precautions for use in animals
Accidental intravenous injection must be avoided. To exclude an intravascular application correct placement of the needle should be verified by aspiration. Do not exceed doses of 0.5 ml per kg of body weight in dogs and 0.3 ml per kg of body weight in cats. To establish the appropriate dosage, the weight of the individual animal should be determined prior to administering the veterinary medicinal product. Use with caution in cats, as they are very sensitive to lidocaine. Overdoses and accidental intravenous injections bear a high risk for central and cardial effects (vomitus, excitation, muscle tremor up to clonic seizures, respiratory depression, or cardiac arrest). Thus, exact dosing and injection technique have to be employed.

The veterinary medicinal product should be used with caution in animals suffering from liver disease, congestive heart failure, bradycardia, cardiac arrhythmia, hyperkalemia, diabetes mellitus, acidosis, neurological disorders, shock, hypovolaemia, severe respiratory depression, or marked hypoxia.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
- Accidental self-injection may result in cardiovascular and/or CNS effects. Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician. DO NOT DRIVE.
- The lidocaine metabolite 2,6-xylidine has confirmed mutagenic and genotoxic properties and is a confirmed carcinogen in rats.
- This product may be an irritant to skin, eyes and oral mucosa. Direct contact of the solution of injection with skin, eye or oral mucosa should be avoided. Remove contaminated clothes that are in direct contact with skin. In the case of accidental contact of the product with eyes, skin or oral mucosa rinse abundantly with fresh water. If symptoms occur, seek medical advice.
- Hypersensitivity reactions to lidocaine may occur. People with known hypersensitivity to lidocaine or other local anaesthetics should avoid contact with the veterinary medicinal product. If hypersensitivity symptoms occur, seek medical advice.

## 4.6 Adverse reactions (frequency and seriousness)

Motor clumsiness or moderate, transient excitation may occur. Cardiovascular effects such as myocardial depression, bradycardia, cardiac arrhythmia, low blood pressure and peripheral vasodilation may also be observed. These adverse reactions are usually transient. Hypersensitivity reactions to local anaesthetics, especially to those of the amide-type are rare. Cross-hypersensitivity between local anaesthetics of the amide-type cannot be excluded.
Use of the product by infiltration may cause a delay in healing.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

## 4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species. Lidocaine crosses the placental barrier and can produce nervous and cardiorespiratory effects in foetuses or neonates. Therefore, use only according to the benefit/risk assessment of the responsible veterinarian during pregnancy or obstetric procedures.

## 4.8 Interaction with other medicinal products and other forms of interaction

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.

Simultaneous application of vasoconstrictive agents (e.g., epinephrine) prolongs the local anesthetic effect. Morphine-like analgesics may diminish the metabolism of lidocaine and therefore intensify its pharmacological effects.

## 4.9 Amounts to be administered and administration route

For subcutaneous, intraarticular, (intra-)ocular, perineural and epidural use.

The total dose administered (including cases of multiple application sites or repeated administration) should not exceed 10 mg lidocaine per kg bodyweight (0.5 ml/kg) in dogs, 6 mg lidocaine per kg bodyweight (0.3 ml/kg) in cats and 4 mg lidocaine per kg bodyweight (0.2 ml/kg) in horses.
In all instances the dosage should be kept to the minimum required to produce the desired effect.

For onset and duration of effect, please see section 5.1.

**Horses**
Ophthalmic contact anaesthesia: 0.4 – 0.5 ml (8 – 10 mg lidocaine) in the conjunctival fornix
Anaesthesia by infiltration: 2 – 10 ml (40 – 200 mg lidocaine) in several applications
Intraarticular use: 3 – 50 ml (60 – 1000 mg lidocaine) depending on the size of the joint
Perineural anaesthesia: 4 – 5 ml (80 – 100 mg lidocaine)
Sacral or posterior epidural anaesthesia: 10 ml (200 mg lidocaine) for a horse weighing 600 kg

**Dogs, cats**
Ophthalmology:
Contact anaesthesia: 0.1 – 0.15 ml (2 – 3 mg lidocaine) in the conjunctival fornix
Retrobulbar infiltration: up to 2 ml (40 mg lidocaine)
Palpebral infiltration: up to 2 ml (40 mg lidocaine)

Dentistry:
For dental extraction: up to 2 ml (40 mg lidocaine) in the infraorbital foramen

Anaesthesia by infiltration: multiple injections of 0.3 – 0.5 ml (6 – 10 mg lidocaine)
Epidural lumbosacral anaesthesia: 1 – 5 ml (20 – 100 mg lidocaine) according to the size of the animal. In cats, the maximum dose is 1 ml (20 mg lidocaine) per animal.

The rubber stopper can be punctured a maximum of 25 times.

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

In the event of an overdose, the first effects will be drowsiness, nausea, vomiting, tremor, excitation, ataxia and anxiety. At higher doses or in the event of accidental intravenous injection, certain more serious effects of lidocaine intoxication may occur, including cardiorespiratory depression and seizures.

The treatment for lidocaine intoxication is purely symptomatic, involving the use of cardiorespiratory resuscitation and anticonvulsants. In case of a severe drop in blood pressure, volume substitution (shock therapy) and vasopressor agents should be administered. In cats, the first sign of intoxication is myocardial depression and, more rarely, symptoms related to the central nervous system.

### 4.11 Withdrawal period(s)

Horse
Meat and offal: 3 days
Milk: 3 days

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Local anaesthetics, amides, lidocaine. ATCvet code: QN01BB02

### 5.1 Pharmacodynamic properties

Lidocaine possesses local anaesthetic activity by inducing reversible nerve block. It is active on all nerve fibres, starting with the neurovegetative nerve fibres, then the sensory and finally also the motor fibres. The onset of effect and duration of effect vary according to the technique used, the location of the nerve to be desensitized in the case of perineural anaesthesia and the dose administered in the case of anaesthesia by infiltration. Overall the onset of effect varies from less than 1 minute (anesthesia by contact) to 10 - 15 minutes for some nerves and the duration of effect may last up to 2 hours.

### 5.2 Pharmacokinetic particulars

Lidocaine is readily absorbed by the mucosae and the absorption rate is also dependent upon vascularisation of the injection site. Lidocaine's diffusion within the tissues is very extensive given its liposolubility. Its metabolism, which takes place primarily in the liver, is complex and elimination occurs mainly via the renal route in form of its metabolites. A reduced hepatic clearance of lidocaine (due to microsomal monooxygenase antagonists, low blood pressure or reduced hepatic perfusion) may cause increased (toxic) plasmatic concentrations. Lidocaine is disalkylated and hydroxylated by monooxygenases and hydrolyzed by carboxylesterases. Monoethylglycerinxylidide, glycinxylidide, 2,6-xylidine, 4-hydroxy-2,6-dimethylaniline, 3-hydroxy-lidocaine and 3-hydroxy-monoethylglycinxylidide were identified as degradation products. Parent substance and metabolites are excreted freely, sulphated or glucuronidated.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxbenzoate
Sodium chloride
Sodium hydroxide (for pH adjustment)
Hydrochloric acid concentrated (for pH adjustment)
Water for injections

### 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: 30 months
Shelf-life after first opening the immediate packaging: 28 days

### 6.4. Special precautions for storage

After first opening do not store above 25 °C.

### 6.5 Nature and composition of immediate packaging

Clear glass vial type II (Ph. Eur.) with bromobutyl rubber stopper or bromobutyl stopper with a fluorinated polymer coating, type I (Ph.Eur.), and pull off or flip off aluminium cap

Package sizes:
50 ml, 100 ml, 250 ml, 5 x 50 ml, 5 x 100 ml

Not all pack sizes may be marketed.

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

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

## 7. MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, AUSTRIA

## 8. MARKETING AUTHORISATION NUMBER(S)

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

## 10 DATE OF REVISION OF THE TEXT

## PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Cardboard box

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lidor 20 mg/ml solution for injection for horses, dogs and cats (AT, BE, CZ, DE, EE, ES, FR, IT, LT, LV, NL, PL, PT)
Lidor vet. 20 mg/ml solution for injection (FI, DK, IS, SE)

Lidocaine

## 2. STATEMENT OF ACTIVE SUBSTANCES

Lidocaine (as hydrochloride monohydrate) 20 mg/ml

## 3. PHARMACEUTICAL FORM

Solution for injection

## 4. PACKAGE SIZE

50 ml
100 ml
250 ml
5 x 50 ml
5 x 100 ml

## 5. TARGET SPECIES

Horse, dog, cat

## 6. INDICATION(S)

-

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For local injection.
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

**Withdrawal period**
Horse
Meat and offal: 3 days
Milk: 3 days

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP {month/year}
Once broached, use within 28 days.

## 11. SPECIAL STORAGE CONDITIONS

After first opening do not store above 25 °C.

## 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. To be supplied only on veterinary prescription.

## 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

VetViva Richter GmbH, 4600 Wels, Austria

## 16. MARKETING AUTHORISATION NUMBER(S)

## 17. MANUFACTURER'S BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

100 ml, 250 ml clear glass vial type II with bromobutyl rubber stopper and alu caps

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lidor 20 mg/ml solution for injection for horses, dogs and cats (AT, BE, CZ, DE, EE, ES, FR, IT, LT, LV, NL, PL, PT)
Lidor vet. 20 mg/ml solution for injection (FI, DK, IS, SE)

Lidocaine

## 2. STATEMENT OF ACTIVE SUBSTANCES

Lidocaine (as hydrochloride monohydrate) 20 mg/ml

## 3. PHARMACEUTICAL FORM

Solution for injection

## 4. PACKAGE SIZE

100 ml
250 ml

## 5. TARGET SPECIES

Horse, dog, cat

## 6. INDICATION(S)

-

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For local injection.
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

**Withdrawal period**
Horse
Meat and offal: 3 days
Milk: 3 days

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP {month/year}
Once broached use by…

## 11. SPECIAL STORAGE CONDITIONS

After first opening do not store above 25 °C.

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

-

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

For animal treatment only. To be supplied only on veterinary prescription.

## 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

VetViva Richter GmbH, 4600 Wels, Austria

## 16. MARKETING AUTHORISATION NUMBER(S)

## 17. MANUFACTURER'S BATCH NUMBER

Lot{number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

50 ml clear glass vial type II with brombutyl rubber stopper and alu-caps

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lidor 20 mg/ml injection for horses, dogs and cats (AT, BE, CZ, DE, EE, ES, FR, IT, LT, LV, NL, PL, PT)
Lidor vet. 20 mg/ml injection (FI, DK, IS, SE)

Lidocaine

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Lidocaine (as hydrochloride monohydrate) 20 mg/ml

## 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

## 4. ROUTE(S) OF ADMINISTRATION

Horse, dog, cat
For local injection.

## 5. WITHDRAWAL PERIOD(S)

**Withdrawal period**
Horse: 3 days

## 6. BATCH NUMBER

Lot {number}

## 7. EXPIRY DATE

EXP {month/year}
Once broached use by …….

## 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**

Lidor 20 mg/ml solution for injection for horses, dogs and cats (AT, BE, CZ, DE, EE, ES, FR, IT, LT, LV, NL, PL, PT)
Lidor vet. 20 mg/ml solution for injection (FI, DK, IS, SE)

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

Marketing authorisation holder and manufacturer responsible for batch release:
VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lidor 20 mg/ml solution for injection for horses, dogs and cats (AT, BE, CZ, DE, EE, ES, FR, IT, LT, LV, NL, PL, PT)
Lidor vet. 20 mg/ml solution for injection (FI, DK, IS, SE)

Lidocaine

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

Each ml contains:

**Active substance:**
Lidocaine 20 mg
(equivalent to 24.65 mg lidocaine hydrochloride monohydrate)

**Excipients:**
Methyl parahydroxybenzoate (E218) 1.3 mg
Propyl parahydroxybenzoate 0.2 mg

Clear, colourless to slightly yellow solution

## 4. INDICATIONS

Horses:
Ophthalmic contact anaesthesia, anaesthesia by infiltration, intra-articular anaesthesia, perineural anaesthesia and epidural anaesthesia.

Dogs, cats:
Anaesthesia in ophthalmology and dentistry, anaesthesia by infiltration and epidural anaesthesia.

## 5. CONTRAINDICATIONS

Do not use in:
- inflammatory tissue alteration at the application site
- infected tissue
- new-born animals

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

## 6. ADVERSE REACTIONS

Motor clumsiness or moderate, transient excitation may occur. Cardiovascular effects such as myocardial depression, bradycardia, cardiac arrhythmia, low blood pressure and peripheral vasodilation may also be observed. These adverse reactions are usually transient. Hypersensitivity reactions to local anaesthetics, especially to those of the amide-type are rare. Cross-hypersensitivity between local anaesthetics of the amide-type cannot be excluded.
Use of the product by infiltration may cause a delay in healing.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated )
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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.

## 7. TARGET SPECIES

Horses, dogs and cats

## 8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

For subcutaneous, intraarticular, (intra-)ocular, perineural and epidural use.

The total dose administered (including cases of multiple application sites or repeated administration) should not exceed 10 mg lidocaine per kg bodyweight (0.5 ml/kg) in dogs, 6 mg lidocaine per kg bodyweight (0.3 ml/kg) in cats and 4 mg lidocaine per kg bodyweight (0.2 ml/kg) in horses.
In all instances the dosage should be kept to the minimum required to produce the desired effect.

For onset and duration of effect, please see section ”Other information”.

**Horses**
Ophthalmic contact anaesthesia: 0.4 – 0.5 ml (8 – 10 mg lidocaine) in the conjunctival fornix
Anaesthesia by infiltration: 2 – 10 ml (40 – 200 mg lidocaine) in several applications
Intraarticular use: 3 – 50 ml (60 – 1000 mg lidocaine) depending on the size of the joint
Perineural anaesthesia: 4 – 5 ml (80 – 100 mg lidocaine)
Sacral or posterior epidural anaesthesia: 10 ml (200 mg lidocaine) for a horse weighing 600 kg

**Dogs, cats**
Ophthalmology:
Contact anaesthesia: 0.1 – 0.15 ml (2 – 3 mg lidocaine) in the conjunctival fornix
Retrobulbar infiltration: up to 2 ml (40 mg lidocaine)
Palpebral infiltration: up to 2 ml (40 mg lidocaine)

Dentistry:
For dental extraction: up to 2 ml (40 mg lidocaine) in the infraorbital foramen

Anaesthesia by infiltration: multiple injections of 0.3 – 0.5 ml (6 – 10 mg lidocaine)
Epidural lumbosacral anaesthesia: 1 – 5 ml (20 – 100 mg lidocaine) according to the size of the animal. In cats, the maximum dose is 1 ml (20 mg lidocaine) per animal.

The rubber stopper can be punctured a maximum of 25 times.

## 9. ADVICE ON CORRECT ADMINISTRATION

Accidental intravenous injection must be avoided. To exclude an intravascular application correct placement of the needle should be verified by aspiration.

## 10. WITHDRAWAL PERIOD(S)

Horse
Meat and offal: 3 days
Milk: 3 days

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after "EXP".
Shelf-life after first opening the container: 28 days
After first opening do not store above 25 °C.

## 12. SPECIAL WARNING(S)

Special warnings for each target species
This product may cause positive anti-doping test results in horses.

Special precautions for use in animals
Do not exceed doses of 0.5 ml per kg of body weight in dogs and 0.3 ml per kg of body weight in cats. To establish the appropriate dosage, the weight of the individual animal should be determined prior to administering the veterinary medicinal product. Use with caution in cats, as they are very sensitive to lidocaine. Overdoses and accidental intravenous injections bear a high risk for central and cardial effects (vomitus, excitation, muscle tremor up to clonic seizures, respiratory depression, or cardiac arrest). Thus, exact dosing and injection technique have to be employed.
The veterinary medicinal product should be used with caution in animals suffering from liver disease, congestive heart failure, bradycardia, cardiac arrhythmia, hyperkalemia, diabetes mellitus, acidosis, neurological disorders, shock, hypovolaemia, severe respiratory depression, or marked hypoxia.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
- Accidental self-injection may result in cardiovascular and/or CNS effects. Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician. DO NOT DRIVE.
- The lidocaine metabolite 2,6-xylidine has confirmed mutagenic and genotoxic properties and is a confirmed carcinogen in rats.
- This product may be an irritant to skin, eyes and oral mucosa. Direct contact of the solution of injection with skin, eye or oral mucosa should be avoided. Remove contaminated clothes that are in direct contact with skin. In the case of accidental contact of the product with eyes, skin or oral mucosa rinse abundantly with fresh water. If symptoms occur, seek medical advice.
- Hypersensitivity reactions to lidocaine may occur. People with known hypersensitivity to lidocaine or other local anaesthetics should avoid contact with the veterinary medicinal product. If hypersensitivity symptoms occur, seek medical advice.

Pregnancy and lactation
The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species. Lidocaine crosses the placental barrier and can produce nervous and cardiorespiratory effects in foetuses or neonates. Therefore, use only according to the benefit/risk assessment of the responsible veterinarian during pregnancy or obstetric procedures.

Interaction with other medicinal products and other forms of interaction
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.

Simultaneous application of vasoconstrictive agents (e.g., epinephrine) prolongs the local anesthetic effect. Morphine-like analgesics may diminish the metabolism of lidocaine and therefore intensify its pharmacological effects.

Overdose (symptoms, emergency procedures, antidotes)
In the event of an overdose, the first effects will be drowsiness, nausea,vomiting, tremor, excitation, ataxia and anxiety. At higher doses or in the event of accidental intravenous injection, certain more serious effects of lidocaine intoxication may occur, including cardiorespiratory depression and seizures.
The treatment for lidocaine intoxication is purely symptomatic, involving the use of cardiorespiratory resuscitation and anticonvulsants. In case of a severe drop in blood pressure, volume substitution (shock therapy) and vasopressor agents should be administered. In cats, the first sign of intoxication is myocardial depression and, more rarely, symptoms related to the central nervous system.

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

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

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

## 15. OTHER INFORMATION

The onset of effect and duration of effect vary according to the technique used, the location of the nerve to be desensitized in the case of perineural anaesthesia and the dose administered in the case of anaesthesia by infiltration. Overall the onset of effect varies from less than 1 minute (anesthesia by contact) to 10 - 15 minutes for some nerves and the duration of effect may last up to 2 hours.
Lidocaine’s diffusion within the tissues is very extensive given its liposolubility. Its metabolism, which takes place primarily in the liver, is complex and elimination occurs mainly via the renal route in form of its metabolites. A reduced hepatic clearance of lidocaine (due to microsomal

monooxygenase antagonists, low blood pressure or reduced hepatic perfusion) may cause increased (toxic) plasmatic concentrations.

Package sizes
50 ml, 100 ml, 250 ml, 5 x 50 ml, 5 x 100 ml
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.