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 substances:

Lidocaine 20 mg

(equivalent to 24.65 mg lidocaine hydrochloride monohydrate)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product			
Methyl parahydroxybenzoate (E218)	1.3 mg			
Propyl parahydroxybenzoate	0.2 mg			
Sodium chloride				
Sodium hydroxide (for pH adjustment)				
Hydrochloric acid concentrated (for pH adjustment)				
Water for injections				

Clear, colourless to slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses, dogs and cats

3.2 Indications for use for each 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.

3.3 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.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 cardiac 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, hyperkalaemia, diabetes mellitus, acidosis, neurological disorders, shock, hypovolaemia, severe respiratory depression, or marked hypoxia.

<u>Special precautions to be taken by the person administering the veterinary medicinal product to animals:</u>

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 veterinary medicinal 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 veterinary medicinal 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.

<u>Special precautions for the protection of the environment:</u> Not applicable.

3.6 Adverse events

Horses, dogs, cats:

Rare	Hypersensitivity reaction ¹	
(1 to 10 animals / 10 000 animals treated):		
Undetermined frequency (cannot be estimated from the available data):	Excitation ² Clumsy	
	Cardio-vascular system disorders (e.g. Cardiac depression ³ , Bradycardia ³ , Arrhythmia ³ , Low blood pressure ³ , Peripheral vascular disorder ^{3,4});	

Delayed healing⁵

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 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.

Pregnancy:

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.

3.8 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 anaesthetic effect. Morphine-like analgesics may diminish the metabolism of lidocaine and therefore intensify its pharmacological effects.

3.9 Administration routes and dosage

For subcutaneous (s.c.), 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 4.2.

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

¹ Cross-hypersensitivity between local anaesthetics of the amide-type cannot be excluded.

² Moderate, transient.

³ Usually transient.

⁴ Vasodilation.

⁵ If used by infiltration.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

3.12 Withdrawal periods

<u>Horses</u>

Meat and offal: 3 days Milk: 3 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN01BB02

4.2 Pharmacodynamics

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 (anaesthesia by contact) to 10 - 15 minutes for some nerves and the duration of effect may last up to 2 hours.

4.3 Pharmacokinetics

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 dialkylated and hydroxylated by monooxygenases and hydrolysed 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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

5.3 Special precautions for storage

After first opening do not store above 25 °C.

5.4 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

Pack sizes:

Cardbord box with 50 ml, 100 ml, 250 ml, 5 x 50 ml, 5 x 100 ml

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: <{DD/MM/YYYY}> <{DD month YYYY}.>

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

<{MM/YYYY}> <{DD/MM/YYYY}> <{DD month YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the <u>Union Product Database</u> (https://medicines.health.europa.eu/veterinary).

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 (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 20 mg/ml

3. PACKAGE SIZE

50 ml

100 ml

250 ml

5 x 50 ml

5 x 100 ml

4. TARGET SPECIES

Horses, dogs, cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

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

7. WITHDRAWAL PERIODS

Withdrawal periods:

Horses

Meat and offal: 3 days Milk: 3 days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

After first opening do not store above 25 °C.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR A	NIMAL TREATMENT ONLY"
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For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter (logo)

14. MARKETING AUTHORISATION NUMBERS

15. 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 (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 20 mg/ml

3. TARGET SPECIES

Horses, dogs, cats

4. ROUTES OF ADMINISTRATION

s.c., intraarticular, (intra-)ocular, perineural, epidural

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Horses

Meat and offal: 3 days Milk: 3 days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use by...

7. SPECIAL STORAGE PRECAUTIONS

After first opening do not store above 25 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter (logo)

9. BATCH NUMBER

Lot {number}

100 ml

250 ml

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 (AT, BE, CZ, DE, EE, ES, FR, IT, LT, LV, NL, PL, PT) Lidor vet. (FI, DK, IS, SE)



Horses, dogs, cats

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Lidocaine 20 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use by...

50 ml

VetViva Richter (logo)

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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. Composition

Each ml contains:

Active substances:

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

3. Target species

Horses, dogs and cats

4. Indications for use

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. Special warnings

Special warnings:

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

Special precautions for safe use in the target species:

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 cardiac 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, hyperkalaemia, 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 veterinary medicinal_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 veterinary medicinal_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 anaesthetic effect. Morphine-like analgesics may diminish the metabolism of lidocaine and therefore intensify its pharmacological effects.

Overdose:

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.

<Special restrictions for use and special conditions for use:>

Major incompatibilities:

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

7. Adverse events

Horses, dogs, cats:

Rare (1 to 10 animals / 10 000 animals treated): Hypersensitivity reaction¹

¹ Cross-hypersensitivity between local anaesthetics of the amide-type cannot be excluded.

Undetermined frequency (cannot be estimated from the available data): Excitation², Clumsy, Cardio-vascular system disorders (e.g. Cardiac depression³, Bradycardia³, Arrhythmia³, Low blood pressure³, Peripheral vascular disorder^{3,4}), Delayed healing⁵

- ² Moderate, transient.
- ³ Usually transient.
- ⁴ Vasodilation.
- ⁵ If used by infiltration.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

For subcutaneous (s.c.), 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 periods

Horses

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.". The expiry date refers to the last day of that month.

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

After first opening do not store above 25 °C.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:

Cardbord box with 50 ml, 100 ml, 250 ml, 5 x 50 ml, 5 x 100 ml Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>

<{	DD	/MM/	ΥY	YY	/ }>	
<{	DD	mont	h Y	YY	YY	}>

Detailed information on this veterinary medicinal product is available in the <u>Union Product Database</u> (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

< Local representatives and contact details to report suspected adverse events:>

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

17. 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 (anaesthesia by contact) to 10 - 15 minutes for some nerves and the duration of effect may last up to 2 hours.