[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procamidor Duo 40 mg/ml + 0.036 mg/ml solution for injection (AT, BE, BG, CZ, DE, EE, EL, ES, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK(NI))
Procamidor Comp Vet 40 mg/ml + 0.036 mg/ml solution for injection (FI, DK, IS, NO, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Procaine hydrochloride (equivalent to 34.65 mg procaine)	40 mg
Adrenaline tartrate (equivalent to 0.02 mg adrenaline)	0.036 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium methyl parahydroxybenzoate (E219)	1.14 mg
Sodium metabisulfite (E223)	1 mg
Disodium edetate	
Sodium chloride	
Hydrochloric acid (for pH adjustment)	
Water for injections	

Clear, colourless to almost colourless solution, free of visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle, pigs and sheep

3.2 Indications for use for each target species

Local anaesthesia with an anaesthetic effect of 1 – 2 hours.

- Infiltration anaesthesia
- Perineural anaesthesia

3.3 Contraindications

Do not use in:

- conditions of shock
- in animals with cardiovascular diseases
- in animals under treatment with sulphonamides
- in animals treated with phenothiazines (see also section 3.8)

Do not use in cases of hypersensitivity to local anaesthetics belonging to the esters subgroup or in case of possible allergic cross reactions to p-aminobenzoic acid and sulphonamides.
Do not administer by the intravenous or the intra-articular route.
Do not use to anaesthetise regions with terminal circulation (e.g. ears, tail, penis, etc.), owing to the risk of tissue necrosis following complete circulatory arrest, due to the presence of adrenaline (a vasoconstrictor).
Do not use with cyclopropane- or halothane-based anaesthetics (see also section 3.8).

3.4 Special warnings

The local anaesthetic effect of procaine sets in after 5 to 10 minutes. Duration of effect of procaine itself is short (max. 30 to 60 minutes); with the addition of adrenaline to the solution, the duration of action is prolonged up to 90 - 120 minutes. The onset of anaesthetic effect is also dependent upon the target species and the age of the animal.

3.5 Special precautions for use

Special precautions for safe use in the target species:
To avoid inadvertent intravenous administration, correct placement of the needle should be verified by aspiration.
Due to local tissue damage wounds or abscesses may be difficult to anaesthetise using local anaesthetics.
Perform local anaesthesia at ambient temperature. At higher temperatures, the risk of toxic reactions is higher owing to the greater absorption of procaine.
As with other local anaesthetics containing procaine, the veterinary medicinal product should be used with caution in animals with epilepsy, cardiac conduction disturbances, bradycardia, hypovolaemic shock or with changes in respiratory or renal function.
When injected near to wound edges, the veterinary medicinal product may lead to necrosis along the edges.
The veterinary medicinal product should be used with caution in lower limb blocks due to the risk of digital ischaemia.
Use with caution in horses due to risk of coat colour at the site of injection turning permanently white.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to adrenaline, procaine or other local anaesthetics of the ester group as well as derivatives of p-aminobenzoic acid and sulphonamides should avoid contact with the veterinary medicinal product.
This veterinary medicinal product may be irritant to the skin, eyes and oral mucosa. Avoid contact with the skin, eyes and oral mucosa. Wash any splashes immediately with plenty of water. Seek medical advice if irritation persists.
Accidental self-injection may result in cardiorespiratory 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 the label to the physician. Do not drive.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses, cattle, pigs and sheep:

Common (1 to 10 animals / 100 animals treated):	Allergic reaction[1]

Rare (1 to 10 animals / 10 000 animals treated):	Anaphylaxis[2]
Undetermined frequency (cannot be estimated from the available data):	Hypotension[3], Tachycardia[4]; Agitation[5], Restlessness[6], Tremor[5,6], Convulsion[5,6], Depression[6], Death[6,7].

[1] To procaine. A hypersensitivity to local anaesthetics belonging to the esters subgroup is known. It should be treated with antihistamines or corticoids.
[2] Anaphylactic reactions have been observed in rare cases. Allergic shock should be treated with epinephrine.
[3] Due to procaine.
[4] In exceptional cases. Due to adrenaline.
[5] Particularly in horses, phenomena of excitability to the CNS are observed following the administration of procaine.
[6] Excitation of the central nervous system can occur in case of inadvertent intravascular injection. Short acting barbiturates should be administered, as well as products for acidification of urine, so as to support renal excretion.
[7] Due to respiratory paralysis.

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 and lactation:
Use only according to the benefit-risk assessment by the responsible veterinarian during pregnancy, or lactation. Procaine crosses the placental barrier and is excreted in milk.

3.8 Interaction with other medicinal products and other forms of interaction

Procaine inhibits the action of the sulphonamides owing to biotransformation to p-aminobenzoic acid, a sulphonamide antagonist. Procaine prolongs the effect of muscle relaxants. Procaine increases the action of antiarrhythmics, e.g. procainamide.
Adrenaline potentiates the action of analgesic anaesthetics on the heart.
Do not use with cyclopropane- or halothane-based anaesthetics, as they increase cardiac sensitivity to adrenaline (a sympathomimetic) and may cause arrhythmia.
Do not administer with other sympathomimetic agents as increased toxicity may result.
Hypertension may result if adrenaline is used with oxytocic agents.
An increased risk of arrhythmias may occur if adrenaline is used concomitantly with digitalis glycoside (as digoxin).
Certain antihistaminics (as chlorpheniramine) may potentiate the effects of adrenaline.
Due to these interactions, the veterinarian may adjust the dosage and should carefully monitor the effects on the animal.

3.9 Administration routes and dosage

Subcutaneous and perineural use.
For onset and duration of effect, please see section 3.4.

1. **Local anaesthesia or by infiltration**
   Inject into the subcutis or around the area involved.

   2.5 – 10 ml of the veterinary medicinal product/animal (i.e. 100 - 400 mg procaine hydrochloride + 0.09 - 0.36 mg adrenaline tartrate)

2. **Perineural anaesthesia**
   Inject close to the branch of the nerve.

   5 – 10 ml of the veterinary medicinal product/animal (i.e. 200 – 400 mg procaine hydrochloride + 0.18 - 0.36 mg adrenaline tartrate)

   For lower limb blocks in horses, the dose should be divided between two or more injection sites depending on the dose. See also section 3.5.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Symptoms related to overdose correlate with symptoms occurring after inadvertent intravascular injection as described in section 3.6.

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

Cattle, sheep and horses:
Meat and offal: Zero days.
Milk: Zero hours.

Pigs:
Meat and offal: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN01BA52

4.2 Pharmacodynamics

Procaine
Procaine is a synthetic locally acting anaesthetic of the ester type. Specifically it is an ester of paraaminobenzoic acid, which is seen as the lipophilic part of this molecule. Procaine stabilises the cell membrane, leading to a reduction in membrane permeability of nerve cells and thereby to a reduced diffusion of sodium and potassium ions. This disrupts the formation of action potentials and inhibits signal conduction. This inhibition leads to reversible local anaesthesia. Neuronal axons exhibit a variable responsiveness to local anaesthesia, which is determined by the thickness of the myelin sheaths: neuronal axons which are not covered in myelin sheaths are most responsive, and neuronal axons which are covered with a thin myelin sheath are anaesthetized more rapidly than neuronal axons with thick myelin sheaths.
Besides its local anaesthetic effect procaine also shows vasodilative and antihypertensive effects.

Adrenaline
Adrenaline is a catecholamine with sympathomimetic properties. It causes a local vasoconstriction which, slowing down absorption of procaine hydrochloride, prolongs the anaesthetic effect of procaine. The slow reabsorption of procaine decreases the risk of systemic toxic effects. Adrenaline also has a stimulant action on the myocardium.

4.3 Pharmacokinetics

Procaine
Following parenteral administration procaine is very rapidly absorbed into the bloodstream, especially due to its vasodilative properties. Amongst other factors absorption is also dependent upon vascularisation of the injection site. Its duration of effect is comparatively short, due to a rapid hydrolysis by serum cholinesterase. The addition of adrenaline, which has a vasoconstrictor action, slows down absorption, prolonging the local anaesthetic effect. Procaine shows only slight plasma protein binding (2 %).
Due to its relatively weak lipid solubility procaine shows only a weak penetration into tissues. It does however pass the blood-brain barrier and diffuses into foetal plasma.
Procaine is rapidly and nearly completely hydrolysed into paraaminobenzoic acid and diethylaminoethanol by non-specific pseudocholinesterases, which occur naturally in plasma as well as in microsomal compartments of liver and other tissues. Paraaminobenzoic acid, which inhibits the action of sulphonamides, is in turn conjugated with e.g. glucuronic acid and excreted via the renal pathway. Diethylaminoethanol, which in itself is an active metabolite, is degraded in the liver. The metabolism of procaine varies according to target species.
Procaine is rapidly and completely excreted via the renal route in form of its metabolites. Plasma half-life is short at 1 to 1.5 hours. Renal clearance depends upon the pH of urine: in acidic pH renal excretion is higher, in basic pH excretion is slower.

Adrenaline
After parenteral administration, adrenaline is well absorbed, but slowly, owing to the vasoconstriction induced by the substance itself. It can only be found in small quantities in the blood, because it has already been reabsorbed by the tissues.
Adrenaline and its metabolites distribute rapidly to the different organs.
Adrenaline is transformed into inactive metabolites in the tissues and in the liver by monoamine oxidase (MAO) enzymes and catechol-O-methyltransferase (COMT).
The systemic activity of adrenaline is short, owing to the rapidity of its excretion, which takes place largely by the renal route in the form of inactive metabolites.

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.
The solution is incompatible with alkaline products, tannic acid or metal ions.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

Do not store above 25 °C.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Amber glass vial type II (Ph. Eur.) with coated or uncoated bromobutyl rubber stopper type I (Ph.Eur.) and aluminium cap in a cardboard box.

Package sizes:
Cardboard box with 1 vial of 100 ml
Cardboard box with 1 vial of 250 ml
Cardboard box with 5 vials of 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

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (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

Procamidor Duo 40 mg/ml + 0.036 mg/ml solution for injection (AT, BE, BG, CZ, DE, EE, EL, ES, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK(NI))
Procamidor Comp Vet 40 mg/ml + 0.036 mg/ml solution for injection (FI, DK, IS, NO, SE)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Procaine hydrochloride (equivalent to 34.65 mg procaine)	40 mg
Adrenaline tartrate (equivalent to 0.02 mg adrenaline)	0.036 mg

3. PACKAGE SIZE

100 ml
250 ml
5 x 100 ml

4. TARGET SPECIES

Horses, cattle, pigs and sheep

5. INDICATIONS

-

6. ROUTES OF ADMINISTRATION

Subcutaneous and perineural use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal:	Zero days
Milk:	Zero hours

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C. Protect from light.

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

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

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 amber glass vial type II with bromobutyl rubber stopper and alu caps

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procamidor Duo 40 mg/ml + 0.036 mg/ml solution for injection (AT, BE, BG, CZ, DE, EE, EL, ES, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK(NI))
Procamidor Comp Vet 40 mg/ml + 0.036 mg/ml solution for injection (FI, DK, IS, NO, SE)

2. STATEMENT OF ACTIVE SUBSTANCES

Procaine hydrochloride	40 mg /ml
Adrenaline tartrate	0.036 mg/ml

3. TARGET SPECIES

Horses, cattle, pigs, sheep

4. ROUTES OF ADMINISTRATION

Subcutaneous, perineural.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal:	Zero days
Milk:	Zero hours

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Use by:

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C. Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter (logo)

9. BATCH NUMBER

Lot {number}

100 ml
250 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Procamidor Duo 40 mg/ml + 0.036 mg/ml solution for injection (AT, BE, BG, CZ, DE, EE, EL, ES, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK(NI))
Procamidor Comp Vet 40 mg/ml + 0.036 mg/ml solution for injection (FI, DK, IS, NO, SE)

2. Composition

Each ml contains:

Active substances:

Procaine hydrochloride (equivalent to 34.65 mg procaine)	40 mg
Adrenaline tartrate (equivalent to 0.02 mg adrenaline)	0.036 mg

Excipients:

Sodium methyl parahydroxybenzoate (E219)	1.14 mg
Sodium metabisulfite (E223)	1 mg

Clear, colourless to almost colourless solution, free of visible particles.

3. Target species

Horses, cattle, pigs and sheep

4. Indications for use

Local anaesthesia with an anaesthetic effect of 1 – 2 hours.

- Infiltration anaesthesia
- Perineural anaesthesia

5. Contraindications

Do not use in:

- conditions of shock
- in animals with cardiovascular diseases
- in animals under treatment with sulphonamides
- in animals treated with phenothiazines (see also section “Special warnings”)

Do not use in cases of hypersensitivity to local anaesthetics belonging to the esters subgroup or in case of possible allergic cross reactions to p-aminobenzoic acid and sulphonamides.
Do not administer by the intravenous or the intra-articular route.
Do not use to anaesthetise regions with terminal circulation (e.g. ears, tail, penis, etc.), owing to the risk of tissue necrosis following complete circulatory arrest, due to the presence of adrenaline (a vasoconstrictor).
Do not use with cyclopropane- or halothane-based anaesthetics (see also section “Special warnings”).

6. Special warnings

Special warnings:
The local anaesthetic effect of procaine sets in after 5 to 10 minutes. Duration of effect of procaine itself is short (max. 30 to 60 minutes); with the addition of adrenaline to the solution, the duration of action is prolonged up to 90 - 120 minutes. The onset of anaesthetic effect is also dependent upon the target species and the age of the animal.

Special precautions for safe use in the target species:
Due to local tissue damage wounds or abscesses may be difficult to anaesthetise using local anaesthetics.
Perform local anaesthesia at ambient temperature. At higher temperatures, the risk of toxic reactions is higher owing to the greater absorption of procaine.
As with other local anaesthetics containing procaine, the veterinary medicinal product should be used with caution in animals with epilepsy, cardiac conduction disturbances, bradycardia, hypovolaemic shock or with changes in respiratory or renal function.
When injected near to wound edges, the veterinary medicinal product may lead to necrosis along the edges.
The veterinary medicinal product should be used with caution in lower limb blocks due to the risk of digital ischaemia.
Use with caution in horses due to risk of coat colour at the site of injection turning permanently white.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to adrenaline, procaine or other local anaesthetics of the ester group as well as derivatives of p-aminobenzoic acid and sulphonamides should avoid contact with the veterinary medicinal product.
This veterinary medicinal product may be irritant to the skin, eyes and oral mucosa. Avoid contact with the skin, eyes and oral mucosa. Wash any splashes immediately with plenty of water. Seek medical advice if irritation persists.
Accidental self-injection may result in cardiorespiratory 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 the label to the physician. Do not drive.
Wash hands after use.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species. Use only according to the benefit-risk assessment by the responsible veterinarian during pregnancy, or lactation. Procaine crosses the placental barrier and is excreted in milk.

Interaction with other medicinal products and other forms of interaction:
Procaine inhibits the action of the sulphonamides owing to biotransformation to p-aminobenzoic acid, a sulphonamide antagonist. Procaine prolongs the effect of muscle relaxants. Procaine increases the action of antiarrhythmics, e.g. procainamide.
Adrenaline potentiates the action of analgesic anaesthetics on the heart.
Do not use with cyclopropane- or halothane-based anaesthetics, as they increase cardiac sensitivity to adrenaline (a sympathomimetic) and may cause arrhythmia.
Do not administer with other sympathomimetic agents as increased toxicity may result.
Hypertension may result if adrenaline is used with oxytocic agents.
An increased risk of arrhythmias may occur if adrenaline is used concomitantly with digitalis glycoside (as digoxin).
Certain antihistaminics (as chlorpheniramine) may potentiate the effects of adrenaline.
Due to these interactions, the veterinarian may adjust the dosage and should carefully monitor the effects on the animal.

Overdose:
Symptoms related to overdose correlate with symptoms occurring after inadvertent intravascular injection as described in section “Adverse events”.

<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. The solution is incompatible with alkaline products, tannic acid or metal ions.

7. Adverse events

Horses, cattle, pigs and sheep:
Common (1 to 10 animals / 100 animals treated):
Allergic reaction[1]

Rare (1 to 10 animals / 10 000 animals treated):
Anaphylaxis[2]

Undetermined frequency (cannot be estimated from the available data):
Hypotension[3], Tachycardia[4]; Agitation[5], Restlessness[6], Tremor[5,6], Convulsion[5,6], Depression[6], Death[6,7].

[1] To procaine. A hypersensitivity to local anaesthetics belonging to the esters subgroup is known. It should be treated with antihistamines or corticoids.
[2] Anaphylactic reactions have been observed in rare cases. Allergic shock should be treated with epinephrine.
[3] Due to procaine.
[4] In exceptional cases. Due to adrenaline.
[5] Particularly in horses, phenomena of excitability to the CNS are observed following the administration of procaine.
[6] Excitation of the central nervous system can occur in case of inadvertent intravascular injection. Short acting barbiturates should be administered, as well as products for acidification of urine, so as to support renal excretion.
[7] Due to respiratory paralysis.

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

Subcutaneous and perineural use.
For onset and duration of effect, please see section “Special warnings”.

1. **Local anaesthesia or by infiltration**
   Inject into the subcutis or around the area involved.

   2.5 – 10 ml of the veterinary medicinal product/animal (i.e. 100 - 400 mg procaine hydrochloride + 0.09 - 0.36 mg adrenaline tartrate)

2. **Perineural anaesthesia**
   Inject close to the branch of the nerve.

5 – 10 ml of the veterinary medicinal product/animal (i.e. 200 – 400 mg procaine hydrochloride + 0.18 - 0.36 mg adrenaline tartrate)

For lower limb blocks in horses, the dose should be divided between two or more injection sites depending on the dose. See also section "Special warnings".

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

9. Advice on correct administration

To avoid inadvertent intravenous administration, correct placement of the needle should be verified by aspiration.

10. Withdrawal periods

Cattle, sheep and horses:
Meat and offal: Zero days.
Milk: Zero hours.

Pigs:
Meat and offal: Zero 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.
Do not store above 25 °C.
Keep the vial in the outer carton in order to protect from light.
Shelf-life after first opening the immediate packaging: 28 days

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

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

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (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>