[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procamidor 20 mg/ml solution for injection (AT, CZ, DE, EE, ES, IT, LT, LV, NL, PT, RO, SI, SK)
Procamidor vet. 20 mg/ml solution for injection (FI, DK, IS, NO, SE)
Procamidor solution for injection (FR)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Procaine hydrochloride 20 mg
(equivalent to 17.3 mg procaine)

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)	1.00 mg
Disodium edetate	
Sodium chloride	
Hydrochloric acid (for pH adjustment)	
Water for injections	

Clear, colourless to slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle, pigs, sheep, dogs and cats.

3.2 Indications for use for each target species

For use in
- Infiltration anaesthesia in horses, cattle, pigs, sheep, dogs and cats
- Conduction anaesthesia in dogs and cats
- Epidural anaesthesia in cattle, sheep, pigs and dogs

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)
- inflammatory tissue alteration at the application site

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of hypersensitivity to local anaesthetics of the ester family or in case of possible allergic cross reactions to derivatives of p-aminobenzoic acid and sulphonamides.
Do not administer intra-articularly.

3.4 Special warnings

The local anaesthetic effect of procaine sets in after 5 to 10 minutes (for epidural injection after 15 to 20 minutes). Duration of effect is short (max. 30 to 60 minutes). The onset of anaesthetic effect is also dependent upon the target species and the age of the animal.
In individual cases epidural application of the local anaesthetic may lead to insufficient anaesthesia in cattle. Possible causes can be incompletely closed intervertebral foramina, which permit the anaesthetic to escape into the peritoneal cavity. Significant accumulation of fat at the application site can also be a cause of insufficient anaesthesia due to a reduced further diffusion of the local anaesthetic into the epidural space.

3.5 Special precautions for use

Special precautions for safe use in the target species:
This veterinary medicinal product contains no vasoconstrictors therefore the duration of action is short.
To exclude an intravascular application correct placement of the needle should be verified by aspiration.
With epidural anaesthesia the head of the animal should be brought into the correct position.
As with other local anaesthetics, procaine should be used with caution in animals suffering from epilepsy, cardiac conduction disturbances, bradycardia, hypovolaemic shock, changes in respiratory function and renal function.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Direct skin contact with the solution for injection should be avoided.
People with known hypersensitivity to procaine hydrochloride should avoid contact with the veterinary medicinal product. In case of accidental spillage onto skin or into eyes immediately wash copiously with water. If irritation occurs seek medical advice immediately.
In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

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

3.6 Adverse events

Horses, cattle, pigs, sheep, dogs and cats:

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] Restlessness[4,5], Tremor[4,5], Convulsion[4,5], Depression[5], Death[5,6].

[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] Occurred more often under epidural anaesthesia than under infiltration anaesthesia.
[4] Especially in horses. Excitation of the central nervous system are observed following the administration of procaine.
[5] 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.
[6] 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

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

3.8 Interaction with other medicinal products and other forms of interaction

An epidural anaesthesia is contraindicated if phenothiazines are concomitantly used as tranquilising agents (as they aggravate the hypotensive effect of procaine).
The antibacterial action of sulphonamides is attenuated at the administration site of procaine.
Procaine prolongs the effect of muscle relaxants.
Procaine increases the action of antiarrhythmics, e.g. procainamide.

3.9 Administration routes and dosage

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

1. Infiltration anaesthesia
Subcutaneous injection into or around the surgical area.

Horses, cattle, pigs, sheep
5 - 20 ml (i.e. 100 - 400 mg procaine hydrochloride)

Dogs, cats
1 - 5 ml (i.e. 20 - 100 mg procaine hydrochloride)

2. Conduction anaesthesia
Injection at the height of a neural branch.

Dogs and cats
2 - 5 ml (i.e. 40 – 100 mg procaine hydrochloride)

3. Epidural anaesthesia
Injection into the epidural space.

Cattle:
Sacral or posterior epidural anaesthesia:

- Tail surgery
  Calf: 5 ml (i.e. 100 mg procaine hydrochloride)
  Yearling: 7.5 ml (i.e. 150 mg procaine hydrochloride)
  Cow or bull: 10 ml (i.e. 200 mg procaine hydrochloride)
- Minor perinatal procedures
  Yearling: 12 ml (i.e. 240 mg procaine hydrochloride)
  Cow: 15 ml (i.e. 300 mg procaine hydrochloride)

Anterior epidural anaesthesia:
- Examination and surgery of the penis
  Calf: 15 ml (i.e. 300 mg procaine hydrochloride)
  Yearling: 30 ml (i.e. 600 mg procaine hydrochloride)
  Bull: 40 ml (i.e. 800 mg procaine hydrochloride)
  At this dosage animals may lie down.

Sheep
Sacral or posterior epidural anaesthesia:
3 - 5 ml (i.e. 60 - 100 mg procaine hydrochloride)

Anterior epidural anaesthesia:
max. 15 ml (i.e. 300 mg procaine hydrochloride)

Pigs
1 ml (i.e. 20 mg procaine hydrochloride) per 4.5 kg body weight, max. 20 ml (i.e. 400 mg procaine hydrochloride)

Dogs
2 ml (i.e. 40 mg procaine hydrochloride) per 5 kg body weight

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: QN01BA02

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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. In case of epidural administration the absorption rate is slower. 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 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; in cats metabolic degradation occurs up to 40 % in the liver, in individual dog species, e.g. in greyhounds, the effect of serum esterases is only very weak. Procaine is rapidly and completely excreted via the renal route in form of its metabolites. Serum half-life is short at 1 to 1.5 hours. Renal clearance depends upon the pH of urine: in acidic pH renal excretion is more effective, in basic pH excretion is slower.

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

5.3 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.
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 type I (Ph.Eur.) and aluminium cap.
Package sizes: 1 x 100 ml, 10 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

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 x 100 ml, 10 x 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procamidor 20 mg/ml solution for injection (AT, CZ, DE, EE, ES, IT, LT, LV, NL, PT, RO, SI, SK)
Procamidor vet. 20 mg/ml solution for injection (FI, DK, IS, NO, SE)
Procamidor solution for injection (FR)

Procaine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Procaine hydrochloride 20 mg
(equivalent to 17.3 mg procaine)

3. PACKAGE SIZE

100 ml
10 x 100 ml

4. TARGET SPECIES

Horses, cattle, pigs, sheep, dogs, cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For subcutaneous, perineural and epidural use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light. 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 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 clear glass vial type II with bromobutyl rubber stopper and alu caps

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Procamidor 20 mg/ml solution for injection (AT, CZ, DE, EE, ES, IT, LT, LV, NL, PT, RO, SI, SK)
Procamidor vet. 20 mg/ml solution for injection (FI, DK, IS, NO, SE)
Procamidor solution for injection (FR)

Procaine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Procaine hydrochloride 20 mg/ml

3. TARGET SPECIES

Horses, cattle, pigs, sheep, dogs, cats

4. ROUTES OF ADMINISTRATION

Subcutaneous, perineural, epidural.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.
Use by:

7. SPECIAL STORAGE PRECAUTIONS

Protect from light. 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

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Procamidor 20 mg/ml solution for injection (AT, CZ, DE, EE, ES, IT, LT, LV, NL, PT, RO, SI, SK)
Procamidor vet. 20 mg/ml solution for injection (FI, DK, IS, NO, SE)
Procamidor solution for injection (FR)

2. Composition

Each ml contains:

Active substance:

Procaine hydrochloride (equivalent to 17.3 mg procaine)	20 mg

Excipients:

Sodium methyl parahydroxybenzoate (E219)	1.14 mg
Sodium metabisulfite (E223)	1.00 mg

Clear, colourless to slightly yellow solution.

3. Target species

Horses, cattle, pigs, sheep, dogs and cats.

4. Indications for use

For use in
- Infiltration anaesthesia in horses, cattle, pigs, sheep, dogs and cats
- Conduction anaesthesia in dogs and cats
- Epidural anaesthesia in cattle, sheep, pigs and dogs

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”)
- inflammatory tissue alteration at the application site

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of hypersensitivity to local anaesthetics of the ester family or in case of possible allergic cross reactions to derivatives of p-aminobenzoic acid and sulphonamides.
Do not administer intra-articularly.

6. Special warnings

Special warnings:

The local anaesthetic effect of procaine sets in after 5 to 10 minutes (for epidural injection after 15 to 20 minutes). Duration of effect is short (max. 30 to 60 minutes). The onset of anaesthetic effect is also dependent upon the target species and the age of the animal.
In individual cases epidural application of the local anaesthetic may lead to insufficient anaesthesia in cattle. Possible causes can be incompletely closed intervertebral foramina, which permit the anaesthetic to escape into the peritoneal cavity. Significant accumulation of fat at the application site can also be a cause of insufficient anaesthesia due to a reduced further diffusion of the local anaesthetic into the epidural space.

Special precautions for safe use in the target species:
This veterinary medicinal product contains no vasoconstrictors therefore the duration of action is short. As with other local anaesthetics, procaine should be used with caution in animals suffering from epilepsy, cardiac conduction disturbances, bradycardia, hypovolaemic shock, changes in respiratory function and renal function.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Direct skin contact with the solution for injection should be avoided.
People with known hypersensitivity to procaine hydrochloride should avoid contact with the veterinary medicinal product. In case of accidental spillage onto skin or into eyes immediately wash copiously with water. If irritation occurs seek medical advice immediately.
In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

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

Interaction with other medicinal products and other forms of interaction:
An epidural anaesthesia is contraindicated if phenothiazines are concomitantly used as tranquilising agents (as they aggravate the hypotensive effect of procaine).
The antibacterial action of sulphonamides is attenuated at the administration site of procaine.
Procaine prolongs the effect of muscle relaxants.
Procaine increases the action of antiarrhythmics, e.g. procainamide.

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.

7. Adverse events

Horses, cattle, pigs, sheep, dogs and cats:
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], Restlessness[4,5], Tremor[4,5], Convulsion[4,5], Depression[5], Death[5,6].

[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] Occurred more often under epidural anaesthesia than under infiltration anaesthesia.
[4] Especially in horses. Excitation of the central nervous system are observed following the administration of procaine.
[5] 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.
[6] 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

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

1. Infiltration anaesthesia
Subcutaneous injection into or around the surgical area.

Horses, cattle, pigs, sheep
5 - 20 ml (i.e. 100 - 400 mg procaine hydrochloride)

Dogs, cats
1 - 5 ml (i.e. 20 - 100 mg procaine hydrochloride)

2. Conduction anaesthesia
Injection at the height of a neural branch.

Dogs and cats
2 - 5 ml (i.e. 40 – 100 mg procaine hydrochloride)

3. Epidural anaesthesia
Injection into the epidural space.

Cattle:
Sacral or posterior epidural anaesthesia:

- Tail surgery
  Calf: 5 ml (i.e. 100 mg procaine hydrochloride)
  Yearling: 7.5 ml (i.e. 150 mg procaine hydrochloride)
  Cow or bull: 10 ml (i.e. 200 mg procaine hydrochloride)
- Minor perinatal procedures
  Yearling: 12 ml (i.e. 240 mg procaine hydrochloride)
  Cow: 15 ml (i.e. 300 mg procaine hydrochloride)

Anterior epidural anaesthesia:

- Examination and surgery of the penis
  Calf: 15 ml (i.e. 300 mg procaine hydrochloride)
  Yearling: 30 ml (i.e. 600 mg procaine hydrochloride)
  Bull: 40 ml (i.e. 800 mg procaine hydrochloride)
  At this dosage animals may lie down.

Sheep
Sacral or posterior epidural anaesthesia:
3 - 5 ml (i.e. 60 - 100 mg procaine hydrochloride)

Anterior epidural anaesthesia:
max. 15 ml (i.e. 300 mg procaine hydrochloride)

Pigs
1 ml (i.e. 20 mg procaine hydrochloride) per 4.5 kg body weight, max. 20 ml (i.e. 400 mg procaine hydrochloride)

Dogs
2 ml (i.e. 40 mg procaine hydrochloride) per 5 kg body weight

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

9. Advice on correct administration

To exclude an intravascular application correct placement of the needle should be verified by aspiration. With epidural anaesthesia the head of the animal should be brought into the correct position.

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.
Keep the vial in the outer carton in order to protect from light.
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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Package sizes
1 x 100 ml, 10 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>