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 substance:

Procaine hydrochloride	20 mg
(equivalent to 17.3 mg procaine)	

Excipients:

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

Horse, cattle, pig, sheep, dog and cat.

4.2 Indications for use, specifying the 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

4.3 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 4.8)
- 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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals
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 label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Procaine can lead to hypotension. This accessory symptom manifests more often under epidural anaesthesia than under infiltration anaesthesia.
Occasionally excitation of the central nervous system (restlessness, tremors, convulsions) can become apparent after administration of procaine, especially in horses.
Allergic reactions to procaine are common; in rare cases anaphylactic reactions have been observed.
Cross-hypersensitivity between local anaesthetics of the ester-type is known.

In case of inadvertent intravascular injection toxic reactions frequently appear. These manifest in an excitation of the central nervous system (restlessness, tremors, convulsions), followed by a depression; death is the result of respiratory paralysis. In case of CNS excitation short acting barbiturates should be administered, as well as products for acidification of urine, so as to support renal excretion. In case of allergic reactions antihistaminics or corticoids can be given. Allergic shock is treated with epinephrine.

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

Procaine crosses the placental barrier and is excreted in milk. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

4.8 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.

4.9 Amounts to be administered and administration route

For subcutaneous, perineural and epidural administration.
For onset and duration of effect, please see section 5.1.

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.

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

Symptoms related to overdose correlate with symptoms occurring after inadvertent intravascular injection as described in section 4.6.

4.11 Withdrawal period(s)

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

Pig:
Meat and offal: Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Local anaesthetics, esters of aminobenzoic acid.
ATC vet code: QN01BA02

5.1 Pharmacodynamic properties

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.
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.
Besides its local anaesthetic effect procaine also shows vasodilative and antihypertensive effects.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium methyl parahydroxybenzoate (E219)
Sodium metabisulfite (E223)
Disodium edetate
Sodium chloride
Hydrochloric acid (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: 2 years
Shelf-life after first opening the immediate packaging: 28 days

6.4. 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.

6.5 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.

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 product 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:
Date of last renewal:

10. DATE OF REVISION OF THE TEXT

April 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.