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

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. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 ml
5 x 100 ml

5. TARGET SPECIES

Horses, cattle, pigs and sheep

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For subcutaneous and perineural use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:

Meat and offal:	Zero days
Milk:	Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

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10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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

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)

Vm 57446/4013

17. MANUFACTURER'S 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

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Horses, cattle, pigs, sheep

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous, perineural.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

-

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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

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

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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)

Vm 57446/4013

17. MANUFACTURER’S BATCH NUMBER

Lot{number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Procamidor Duo 40 mg/ml + 0.036 mg/ml solution for injection

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

Procamidor Duo 40 mg/ml + 0.036 mg/ml solution for injection

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

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

4. INDICATION(S)

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. ADVERSE REACTIONS

Procaine can lead to hypotension.
In a few cases, particularly in horses, phenomena of excitability to the CNS (agitation, tremors, convulsions) may be observed following the administration of procaine.
Allergic reactions to procaine are common; in rare cases anaphylactic reactions have been observed.
A hypersensitivity to local anaesthetics belonging to the esters subgroup is known.
In exceptional cases, tachycardia may occur (adrenaline).

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 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 adrenaline.

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.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Horses, cattle, pigs and sheep

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For subcutaneous and perineural use.
For onset and duration of effect, please see section “Other information”

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

   2.5 – 10 ml of the 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 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 PERIOD(S)

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

Pig:
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”.
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 container: 28 days

12. SPECIAL WARNING(S)

Special precautions for use in animals

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 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 product may lead to necrosis along the edges.

The 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 product.
This 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, emergency procedures, antidotes)
Symptoms related to overdose correlate with symptoms occurring after inadvertent intravascular injection as described in section “Adverse reactions”.

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.

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

July 2023

15. OTHER INFORMATION

Pharmacodynamic properties

Procaine
Procaine is a synthetic locally acting anaesthetic of the ester type. 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.
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.

Pharmacokinetic particulars

Procaine
Following parenteral administration procaine is very rapidly absorbed into the bloodstream, especially due to its vasodilative properties. 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 %).
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. 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. Adrenaline and its metabolites distribute rapidly to the different organs.

Adrenaline is transformed into inactive metabolites in the tissues and in the liver.
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.

Package sizes
100 ml, 250 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.

Approved 07 December 2023