ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box 1 x 50 ml vial
1 x 100 ml vial
1 x 250 ml vial
10 x 100 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pronestesic 40 mg/ml + 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep
procaine hydrochloride/epinephrine tartrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substances:
Procaine hydrochloride 40 mg (equivalent to 34.65 mg of procaine)
Epinephrine tartrate 0.036 mg (equivalent to 0.02 mg of epinephrine).

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 x 50 ml
1 x 100 ml
1 x 250 ml
10 x 100 ml

5. TARGET SPECIES

Horses, cattle, pigs and sheep

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous and perineural use
Read the package leaflet before use

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: zero days.
Milk: zero hours.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month /year}
Once opened, use within 28 days
Once opened, use by …

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC 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.

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

FATRO S.p.A.
Via Emilia, 285
40064 Ozzano Emilia - Bologna
Italy

16. MARKETING AUTHORISATION NUMBERS

Vm 11557/4002

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
50 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pronestesic 40 mg/ml + 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep
procaine hydrochloride/epinephrine tartrate

2. QUANTITY OF THE ACTIVE SUBSTANCES

Each ml contains:
Active substances:
Procaine hydrochloride 40 mg (equivalent to 34.65 mg procaine)
Epinephrine tartrate 0.036 mg (equivalent to 0.02 mg epinephrine).

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) ADMINISTRATION

SC, perineural use

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: zero days.
Milk: zero hours.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month /year}
Once opened, use within 28 days.
Once opened, use by…

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
100 ml label
250 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pronestesic 40 mg/ml + 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep
procaine hydrochloride/epinephrine tartrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substances:
Procaine hydrochloride 40 mg (equivalent to 34.65 mg of procaine)
Epinephrine tartrate 0.036 mg (equivalent to 0.02 mg of epinephrine).

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Horses, cattle, pigs and sheep

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous and perineural use
Read the package leaflet before use

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: zero days.
Milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 28 days
Once opened, use by …

11. SPECIAL STORAGE CONDITIONS

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

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

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

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15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

FATRO S.p.A.
Via Emilia, 285
40064 Ozzano Emilia - Bologna
Italy

16. MARKETING AUTHORISATION NUMBERS

Vm 11557/4002

17. MANUFACTURER'S BATCH NUMBER

Batch {number

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Pronestesic 40 mg/ml + 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep

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:
FATRO S.p.A.
Via Emilia, 285
40064 Ozzano Emilia - Bologna
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pronestesic 40 mg/ml + 0.036 mg/ml solution for injection for horses, cattle, pigs and sheep
procaine hydrochloride/epinephrine tartrate

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER

Each ml contains:
Active substances:
Procaine hydrochloride…… 40 mg
(equivalent to 34.65 mg of procaine)
Epinephrine tartrate…… 0.036 mg
(equivalent to 0.02 mg of epinephrine)

Excipients:
Sodium metabisulfite (E223)……1 mg
Sodium methyl parahydroxybenzoate (E219) 1.15 mg
Disodium edetate …… 0.1 mg.

Clear colourless solution, free of visible particles.

4. INDICATIONS

Horse, cattle, pigs and sheep:
-local anaesthesia with a long-lasting anaesthetic effect.
-infiltration anaesthesia and perineural anaesthesia (see section 12).

5. CONTRAINDICATIONS

Do not use in animals in state of shock.
Do not use in animals with cardiovascular problems.
Do not use in animals treated with sulphonamides.
Do not use in animals treated with phenothiazine (see section 12).
Do not use with cyclopropane- or halothane-based volatile anaesthetics (see section 12).

Do not use to anaesthetise regions with terminal circulation (ears, tail, penis, etc.), owing to the risk of tissue necrosis following complete circulatory arrest, due to the presence of epinephrine (substance with a vasoconstrictor action).
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer by the intravenous or the intra-articular route.
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.

6. ADVERSE REACTIONS

Procaine may cause hypotension in very rare cases.
Particularly in horses, phenomena of excitability to the CNS may be observed (agitation, tremors, convulsions) following the administration of procaine, in very rare occasions.
Allergic reactions to procaine are quite common; only in rare cases anaphylactic reactions have been observed.
A hypersensitivity to local anaesthetics belonging to the esters subgroup is known. Tachycardia may occur (epinephrine) in very rare cases. In case of inadvertent intravascular injection, toxic reactions frequently appear. These reactions manifest in an excitation of the central nervous system (restlessness, tremors, convulsions), followed by depression. Subsequently, death occurs as result of respiratory paralysis. In case of CNS-related 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, antihistamines or corticoids can be given. Allergic shock should be 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).

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, ROUTES AND METHOD OF ADMINISTRATION

For subcutaneous and perineural use.
Local anaesthesia or by infiltration: inject into the subcutis or around the area involved

2.5-10 ml of the product/animal (corresponding to 100-400 mg of Procaine hydrochloride + 0.09-0.36 mg of Epinephrine tartrate)

Perineural anaesthesia: inject close to the branch of the nerve

5-10 ml of the product/animal (corresponding to 200-400 mg of Procaine hydrochloride +

0.18-0.36 mg of Epinephrine 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 12.

The stopper may be broached up to 20 times.

9. ADVICE ON CORRECT ADMINISTRATION

Do not administer by the intravenous or the intra-articular route.
To avoid inadvertent intravascular administration, correct placement of the injection needle should be verified thoroughly by aspiration to check for the absence of blood before injecting.
The vial may be broached up to 20 times.

10. WITHDRAWAL PERIOD(S)

Horses, cattle and sheep:
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 store above 25°C.
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 container: 28 days.

12. SPECIAL WARNINGS

Special warnings for each target species:
None

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 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:
The product may be irritant to the skin, eyes and oral mucosa. Avoid direct contact with the veterinary medicinal product. In case of spillage onto skin, eyes or oral mucosa, rinse immediately with plenty of water. If irritation occurs, seek medical advice immediately and show the package leaflet or label to the physician.
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 label to the physician. Do not drive.
People with known hypersensitivity to procaine**,** epinephrine 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.

Use 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:
Procaine inhibits the action of the sulphonamides owing to biotransformation to p-aminobenzoic acid, a sulphonamide antagonist.
Procaine prolongs the action of myorelaxants.
Procaine potentiates the action of antiarrhythmics e.g. procainamide.
Epinephrine potentiates the action of analgesic anaesthetics on the heart.
Do not use with cyclopropane- or halothane-based volatile anaesthetics, as they increase cardiac sensitivity to epinephrine (a sympathomimetic) and may cause arrhythmia.
Due to these interactions, the veterinarian may adjust the dosage and should carefully monitor the effects on the animal.
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.

Overdose (symptoms, emergency procedures, antidotes):
Symptoms related to overdose correlate with symptoms occurring after inadvertent intravascular injection as described in section 6.

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

April 2021

15. OTHER INFORMATION

Package sizes:
Cardboard box with 1 vial of 50 ml
Cardboard box with 1 vial of 100 ml
Cardboard box with 1 vial of 250 ml
Cardboard box with 10 vials of 100 ml

Not all pack sizes may be marketed.

Approved: 27/05/21