PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box:
50 ml vial
100 ml vial
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

2. STATEMENT OF ACTIVE SUBSTANCES

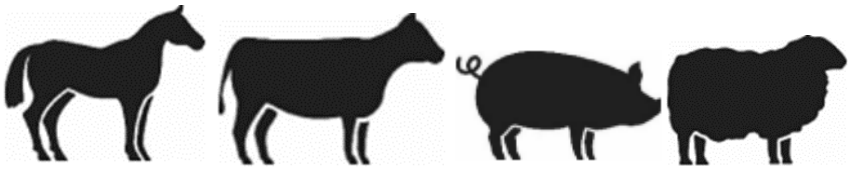
Each ml contains:

Procaine hydrochloride 40 mg
(equivalent to 34.65 mg of procaine)
Epinephrine tartrate 0.036 mg
(equivalent to 0.02 mg of epinephrine).

3. PACKAGE SIZE

50 ml
100 ml
250 ml
10 x 100 ml

4. TARGET SPECIES



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous and perineural use.

7. WITHDRAWAL PERIODS

Withdrawal period(s):
Horses, cattle and sheep:
Meat and offal: Zero days.
Milk: Zero hours.

Pigs:
Meat and offal: Zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.
Once broached, use by …

9. SPECIAL STORAGE PRECAUTIONS

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

FATRO S.p.A.

14. MARKETING AUTHORISATION NUMBER

Vm 11557/4002

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml label
250 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

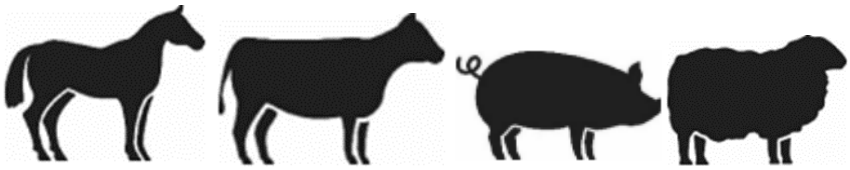
Pronestesic 40 mg/ml + 0.036 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Procaine hydrochloride 40 mg
(equivalent to 34.65 mg of procaine)
Epinephrine tartrate 0.036 mg
(equivalent to 0.02 mg of epinephrine).

3. TARGET SPECIES



4. ROUTES OF ADMINISTRATION

Subcutaneous and perineural use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Horses, cattle and sheep:
Meat and offal: Zero days.
Milk: Zero hours.
Pigs:
Meat and offal: Zero days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.
Once broached, use by …

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

FATRO S.p.A.

9. BATCH NUMBER

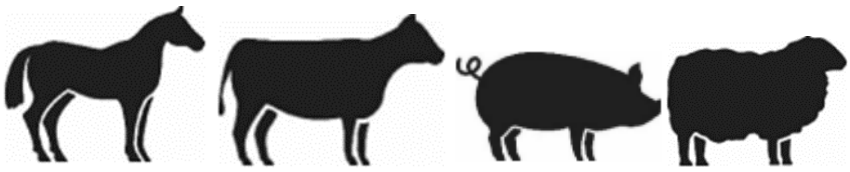
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pronestesic



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:

Procaine hydrochloride 40 mg
(equivalent to 34.65 mg of procaine)
Epinephrine tartrate 0.036 mg
(equivalent to 0.02 mg of epinephrine).

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.
Once broached, use by …

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substances:

Procaine hydrochloride (equivalent to 34.65 mg of procaine)	40 mg
Epinephrine tartrate (equivalent to 0.02 mg of epinephrine)	0.036 mg

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.

3. Target species

Horses, cattle, pigs and sheep

4. Indications for use

- Local anaesthesia with a long-lasting anaesthetic effect.
- Infiltration anaesthesia and perineural anaesthesia (see section “Special warnings”).

5. Contraindications

Do not use in:
- animals in state of shock;
- animals with cardiovascular problems;
- animals treated with sulphonamides;
- animals treated with phenothiazine (see section “Special warnings”);
- cases of hypersensitivity to the active substance or to any of the excipients;
- 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 use:
- with cyclopropane- or halothane-based volatile anaesthetics (see section “Special warnings”);
- 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);
- intravenously or intra-articularly.

6. Special warnings

Special warnings:

None.

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 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 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.

The veterinary medicinal 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 the 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 the label to the physician. Do not drive.

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:

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 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 and sheep

Common (1 to 10 animals / 100 animals treated):	Allergic reaction[a].
Rare (1 to 10 animals / 10,000 animals treated):	Anaphylactic-type reaction(severe allergic reaction) [b].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypotension (low blood pressure); Agitation[c], Tremor[c], Convulsion[c]; Tachycardia (rapid heart rate)[d]
Undetermined frequency (cannot be estimated from the available data):	Hypersensitivity reaction[e] Restlessness[f], Tremor[f], Convulsion[f], Depression[f], Death[f,g]

[a]It should be treated with antihistamines or corticoids.
[b]It should be treated with epinephrine.

[c]Particularly in horses, phenomena of excitability to the CNS are observed following the administration of procaine.
[d]Epinephrine-caused
[e]To local anaesthetics belonging to the esters subgroup.
[f]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.
[g]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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Subcutaneous and perineural use.

Local anaesthesia or by infiltration: inject into the subcutis or around the area involved

2.5-10 ml of the veterinary medicinal product/animal (corresponding to 100-400 mg of procaine hydrochloride + 0.09-0.36 mg of epinephrine bitartrate).

Perineural anaesthesia: inject close to the branch of the nerve

5-10 ml of the veterinary medicinal product/animal (corresponding to 200-400 mg of procaine hydrochloride + 0.18-0.36 mg of epinephrine bitartrate).

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 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.

10. Withdrawal periods

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 carton after Exp. The expiry date refers to the last day of that month.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 11557/4002
Pack 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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
FATRO S.p.A.
Via Emilia, 285
I-40064 Ozzano dell'Emilia (Bologna), Italy.

Local representatives and contact details to report suspected adverse reactions:
DUGV (UK) Ltd.
Union House, 111 New Union Street,
Coventry, CV1 2NT, UK
Phone: +353 (0) 504 43169
uksales@dugganvet.com

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

For animal treatment only.

POM-V

Gavin Hall
Approved: 17 March 2025