INTRAMICINE®

Product information

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intramicine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 mL contains:

Active substance:

Benzylpenicillin (as procain monohydrate)..... 114.0 mg
Dihydrostreptomycin (as sulfate)..... 200.0 mg

Excipients:

Sodium Methyl Parahydroxybenzoate (E219)..... 1.4 mg
Sodium Hydroxymethane sulfinate..... 4.0 mg
Procain (as hydrochloride)..... 17.3 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 | Target species

Cattle, sheep, goats, pigs, cats and dogs.

4.2 | Indications for use, specifying the target species

Cattle, sheep, goats, pigs, cats and dogs:
Treatment of generalized infections of the young and adult, pneumonia and pleuropneumonia, postpartum infections, urinary infections, infected wounds (such as interdigitated panaris, ...), abscesses (such as omphalophlebitis). .), and post-operative infections due to penicillin- and dihydrostreptomycin-sensitive germs.

4.3 | Contraindications

Do not administer in case of known allergies to penicillins or local anesthetics.
Do not administer to rabbits, guinea pigs, hamsters or gerbils.

4.4 | Special warnings for each target species

None.

4.5 | Special precautions for use

i Special precautions for use in animals

Improper use of the product may increase the prevalence of penicillin - or dihydrostreptomycin-resistant bacteria.

In animals with renal or dehydrated insufficiency, the dosage should be evaluated carefully.

ii Special precautions to be taken by the person administering the veterinary medicinal product to animals

Penicillins and cephalosporins may cause hypersensitivity reactions (allergy) after injection, inhalation, ingestion or skin contact. This hypersensitivity to penicillins can result in cross-reactions with cephalosporins, and vice versa. These hypersensitivity reactions can be occasionally severe.

In case of symptoms after exposure (redness of the skin), seek medical advice by presenting the leaflet to the doctor. Oedema of the face, lips or eyes, or difficult breathing are serious signs, which require urgent medical treatment.

Similarly, the use of local anesthetics may cause hypersensitivity reactions.

Do not handle this product if you are aware of sensitization, or if you have been advised not to come into contact with this type of molecule.

In case of contact with eyes, rinse immediately with plenty of water.

iii Other precautions

None.

4.6 | Adverse reactions (frequency and seriousness)

Dose-independent hypersensitivity reactions to penicillin and procaine may be induced. Allergic reactions (skin reactions, anaphylactic shock) may occasionally occur.

Local tissue reactions at the injection site may occur following drug administration.

4.7 | Use during pregnancy, lactation or lay

Studies on laboratory animals have not revealed any teratogenic effect of the active ingredients. In the absence of studies in the target species, the use of the drug will depend on the veterinarian's assessment of the benefit / risk ratio.

4.8 | Interaction with other medicinal products and other forms of interaction

Unknown.

4.9 | Amounts to be administered and administration route

Cattle, sheep, goats, pigs: 11.4 to 17.1mg of benzylpenicillin and 20 to 30mg of dihydrostreptomycin per kg of live weight per day by intramuscular or subcutaneous route for 3 to 5 days, ie 1 to 1.5ml of suspension per 10 kg live weight by intramuscular

or subcutaneous route; corresponding to 10ml of suspension per 100kg live weight in adult cattle, sheep, goats and swine and 1.50ml per 10kg live weight in calves, lambs, goats and piglets.

Dogs, Cats: 22.8mg of benzylpenicillin and 40mg of dihydrostreptomycin per kg of body weight per day by intramuscular or subcutaneous route for 3 to 5 days, ie 2ml of suspension per 10kg of body weight intramuscularly or subcutaneously.

Shake the bottle well to homogenize the suspension before use.

The bottle can be punctured up to 50 times.

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

During massive overdose, dihydrostreptomycin can induce neuromuscular blockage, especially in the cat, resulting in flaccid paralysis and cardiorespiratory depression, which can be controlled by calcium intravenous administration.

4.11 | Withdrawal periods

Bovine and caprine:

Meat and offals: 30 days.
Milk: 7 days.

Ovine:

Meat and offals: 30 days.
Milk: 6 days.

Porcine:

Meat and offals: 30 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibiotics, penicillins
ATCvet code: QJ01RA01

5.1 | Pharmacodynamic properties

Penicillin G is a time-dependent bactericidal antibiotic that acts on bacteria in the multiplication phase by blocking the biosynthesis of their wall. Its narrow spectrum is limited to Gram positive and pasteurellas.

Dihydrostreptomycin is a bactericidal antibiotic that acts by disrupting the biosynthesis of bacterial proteins and the permeability of the bacterial membrane. Its spectrum is oriented Gram-negative.

The combination of the two antibiotics is translated in vitro by a synergistic effect, penicillin enhances the penetration of dihydrostreptomycin into the bacterium. It provides additional activity on Gram-positive bacteria (staphylococci, streptococci, corynebacteria, anaerobic bacilli, erysipelothrix), gram-negative bacteria (pasteurellas, histophilus, actinobacilli) and spirochetes.

5.2 | Pharmacokinetic particulars

After parenteral administration, penicillin G in the form of procaine salt is released more slowly than in the sodium form to maintain serum concentrations effective for 24 hours. It is rapidly and mainly eliminated (80%) in its unchanged form by urine.

Most of the dihydrostreptomycin administered parenterally is rapidly excreted as unchanged form by the kidneys; however, the remaining fraction accumulates in the renal cortex leading to prolonged elimination.

6. PHARMACEUTICAL PARTICULARS

6.1 | List of excipients

Sodium Methyl Parahydroxybenzoate (E219)
Sodium Hydroxymethane sulfinate
Procain (as hydrochloride)
Anti-foam Silbione
Sodium citrate
70% sorbitol
Water for injections

6.2 | Major incompatibilities

None.

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 (keep between of 2 °C and 8 °C).

Shelf life after first opening the immediate packaging: 14 days (keep below of 25 °C).

6.4 | Special precautions for storage

Store in fridge (between 2 °C and 8 °C).

6.5 | Nature and composition of immediate packaging

Type II colored glass vial.
Polypropylene colored bottle - ethylene-vinyl alcohol copolymer - polypropylene
Chlorobutyl stopper
Aluminium capsule

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.