SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maycetam 400 mg/ml Solution for Use in Drinking Water for Pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Paracetamol 400 mg

Excipients:
Ponceau 4R (E124) 0.150 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for use in drinking water.
Clear viscous pink solution

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

Symptomatic treatment of fever in the context of respiratory diseases in combination with an appropriate anti-infective therapy, if necessary.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with severe hepatic impairment.
Do not use in animals with severe renal impairment. See also section 4.8.
Do not use in animals suffering from dehydration or hypovolaemia.

4.4 Special warnings for each target species

Animals with reduced water intake and/or disturbed general condition have to be treated parenterally.
In case of combined viral and bacterial aetiology of the disease, an appropriate anti-infective therapy should be given concomitantly.

The anti-pyretic effect of the veterinary medicinal product is expected at 12 - 24 hours after the onset of treatment.

4.5 Special precautions for use

Special precautions for use in animals
None

Special precautions to be taken by the person administering the veterinary medicinal product to animals.
This veterinary medicinal product may be harmful in case of accidental ingestion. Do not smoke, eat or drink while handling the veterinary medicinal product. In the case of accidental ingestion, seek medical advice immediately and show the label to the physician.
This veterinary medicinal product may be harmful in case of accidental contact with unprotected skin or eyes. Wear appropriate clothes, gloves, goggles and mask during the handling of the product. In the case of skin or eyes contact rinse immediately with a large amount of water. If symptoms persist, seek medical advice. Wash the hands after use of the veterinary medicinal product.
This veterinary medicinal product may cause hypersensitivity (allergy). People with known hypersensitivity to paracetamol or any of the excipients (dimethyl sulfoxide, Ponceau 4R (E124), and macrogol) should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment
Not applicable.

Other precautions
None

4.6 Adverse reactions (frequency and seriousness)

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Loose Stool*

* Can persist for up to 8 days after the withdrawal of treatment. This does not have any effect on the general condition of animals and resolves without any specific treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats have not produced any evidence of teratogenic or foetotoxic effects at therapeutic doses. The administration of the veterinary medicinal product up to three times the recommended dose, during pregnancy

or lactation, did not result in adverse effects. The veterinary medicinal product can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration of nephrotoxic drugs should be avoided.

4.9 Amount(s) to be administered and administration route

For use in drinking water.
30 mg of paracetamol per kg body weight per day, for 5 days, orally, administered in the drinking water, equivalent to 0.75 ml of oral solution per 10 kg body weight per day for 5 days.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{0.075 ml veterinary medicinal product/kg b.w./ day} \times \text{mean b.w. of individual animals (kg)} \times \text{number of animals to be treated}}{\text{Total water consumption (litres) of these animals on the previous day}}$$

The intake of medicated drinking water depends on the clinical condition of the animals. To obtain a correct dosage, the concentration in the drinking water must be adjusted accordingly.

To avoid underdosing and to ensure a correct dosage, bodyweight should be determined as accurately as possible.

Recommendation for dissolution:

First add the necessary quantity of water for the preparation of the final solution in the container. Then add the product while stirring the solution.
Preferably prepare the solution in water at ambient temperature (20°C – 25°C).
For water at 25°C, there is an upper concentration limit of 40 ml of veterinary medicinal product per litre of drinking solution.
When using the veterinary medicinal product with a water proportioner, adjust the setting to 3% - 5%. Do not set proportioners below 3%.

The solution should be prepared freshly every 24 hours. No other source of drinking water should be available during the medication period.

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

After administration of 5 times the recommended dose of paracetamol, liquid faeces with solid particles may occasionally occur. It does not have any effect on general body condition of animals.
N-acetylcysteine can be used in cases of accidental overdose.
Excessive overdoses can cause hepatotoxicity.

4.11 Withdrawal period(s)

Meat and offal: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other Analgesics and Antipyretics

ATC Vet Code: QN02BE01

5.1 Pharmacodynamic properties

Paracetamol or acetaminophen or N-acetyl-para-aminophenol is a paraminophenol derivative with analgesic and antipyretic properties. Its antipyretic effect may be explained by its ability to inhibit brain cyclo-oxygenases. Paracetamol is only a weak inhibitor of COX-1 synthesis and, thus, it has no gastro-intestinal side effects and has no effect on platelet aggregation.

5.2 Pharmacokinetic particulars

Paracetamol is rapidly and almost completely absorbed after oral administration (bioavailability of about 90% after administration in the drinking water). Peak concentrations are reached in a little less than 2 hours after ingestion.
Paracetamol is mainly metabolised in the liver. The two major metabolic pathways are conjugation to glucuronate and conjugation to sulphate. The latter route is rapidly saturable at dosages higher than therapeutic doses. A minor pathway, catalysed by cytochrome P450 (CYP), leads to the formation of the intermediary reagent, N-acetyl-benzoquinoneimine which, under normal conditions of use, is rapidly detoxified by reduced glutathione and removed in urine after conjugation with cysteine and mercapturic acid. On the contrary, after massive intoxication, the quantity of this toxic metabolite is increased.
Paracetamol is mainly eliminated in the urine. In the pig, 63% of the ingested dose is eliminated by the kidneys in 24 hours mainly conjugated to glucuronate and sulphate. Less than 5% is eliminated in unchanged form. The elimination half-life is approximately 5 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimethyl sulfoxide
Ponceau 4R (E124)
Macrogol 300.

6.2 Major Incompatibilities

The product has been proved to be physically-chemically compatible with the active's substances Amoxicillin, Sulfadiazine/Trimethoprime, Doxycycline, Tylosine, Tetracycline, Colistin.

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: 3 years.
Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dilution according to directions: 24 hours.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
After first opening, keep the bottle or can tightly closed.
Keep out of the sight and reach of children.

6.5 Nature and composition of immediate packaging

Container 1 liter:
a) Bottle of high density polyethylene (HDPE) with HDPE screw cap, including an induction seal liner made of AL/PET/PE.
b) Bottle of high density polyethylene (HDPE) with HDPE screw cap with a warranty heat-seal combined plastic/aluminum (PEHD/PP/PE/AL).

Container 5 liter:
Can of high density polyethylene (HDPE) with HDPE screw cap, including an induction seal liner made of AL/PET/PE.

Package sizes:
Bottle of 1L
Can of 5L

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

Medicines should not be disposed of via wastewater.
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

Laboratorios Maymó, S.A.
Via Augusta 302
Barcelona
08017
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 42204/5000

9. DATE OF FIRST AUTHORISATION

15 May 2024

10. DATE OF REVISION OF THE TEXT

May 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
To be supplied only on veterinary prescription.

Approved 15 May 2024

Gavin Hall