MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, I.e. Combined label and package leaflet {NATURE/TYPE}

[This template should only be used when all printed information is directly visible on the immediate container and cannot be used if a fold-out or concertina format is proposed.]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each ml contains:

Active substance:

Paracetamol ..... 400 mg

Excipients:

Ponceau 4R (E124) ..... 0.150 mg

Clear viscous pink solution.

3. PACKAGE SIZE

Bottle of 1 L

Can of 5 L

4. TARGET SPECIES

Pigs

5. INDICATIONS FOR USE

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

6. 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 "Interaction with other medicinal products and other forms of interaction".

Do not use in animals suffering from dehydration or hypovolaemia.

7. SPECIAL WARNINGS

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.

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.

Pregnancy and lactation:

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.

Interaction with other medicinal products and other forms of interaction:

Concurrent administration of nephrotoxic drugs should be avoided.

Overdose (symptoms, emergency procedures, antidotes):

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 case of accidental overdose.

Excessive overdoses can cause hepatotoxicity.

Incompatibilities:

The product has been proved to be physically-chemically compatible with the actives 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.

8. ADVERSE REACTIONS

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 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 using the contact details at the end of this leaflet, or via your national reporting system https://www.gov.uk/report-veterinary-medicine-problem

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

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:

0.075 ml veterinary medicinal product/kg b.w./ day	x	mean b.w. of individual animals (kg)	x	number of animals to be treated
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. In order 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.

10. ADVICE ON CORRECT ADMINISTRATION

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.

11. WITHDRAWAL PERIOD

Meat and offal: zero days.

12. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

After first opening, keep the bottle or can tightly closed.

Keep out of the sight and reach of children.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

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.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V (Veterinary medicinal product subject to prescription)

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42204/5000

Package size: 1 l bottle and 5 l can

Not all pack size may be marketed.

16. 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.

17. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:

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

Contact details to report suspected adverse reactions:
Pending confirmation. Will be informed before marketing

18. OTHER INFORMATION

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

20. EXPIRY DATE

EXP {mm/yyyy}

Once opened use by…

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle {can}. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.

Shelf life after dilution according to directions: 24 hours

21. BATCH NUMBER

Lot {number}

22. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Approved 15 May 2024

Gavin Hall