ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maycetam 400 mg/ml solution for use in drinking water (BG, FR, DK, ES, PL, PT, RO)
Maycetam 400 mg/ml solution for use in drinking water for pigs (DE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Paracetamol ..... 400 mg

Excipients:
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 known 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 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.
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 should avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

In rare cases, at therapeutic doses, transient soft faeces can occur and 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.
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)

4.7 Use during pregnancy, lactation or lay

Studies in rats have not detected any teratogenic or foetotoxic effects at therapeutic doses. The administration of the product to sows up to three times the recommended dose, during pregnancy or lactation, did not result in adverse effects. As such the product may be administered 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 Amounts to be administered and administration route

In drinking water use
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.
The quantity in ml of veterinary medicinal product to be added per litre of water should be calculated as follows:

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

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

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

Recommendation for dissolution:

The maximum solubility of the product in (soft/hard) water at (5ºC/20ºC) is 30 mL /L.

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. For stock solutions and when using a proportioner, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust flow rate setting of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.

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. Acetylcysteine can be used in case of accidental overdose.

4.11 Withdrawal period(s)

Meat and offal: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other Analgesics and Antipyretics.
ATCvet 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 cystein 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 suphate. 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 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.

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: 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.

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

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.U
Via Augusta, 302
08017 Barcelona (Spain)

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Bottle and can of high density polyethylene

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:
Laboratorios Maymó, S.A.U
Via Augusta, 302
08017 Barcelona (Spain)

2. Name of the veterinary medicinal product

Maycetam 400 mg/ml solution for use in drinking water (BG, FR, DK, ES, PL, PT, RO)
Maycetam 400 mg/ml solution for use in drinking water for pigs (DE)

Paracetamol

3. Statement of the active substance (s) and other ingredients

Each ml contains:

Active substance:
Paracetamol ..... 400 mg

4. Pharmaceutical form

Solution for use in drinking water.
Clear viscous pink solution

5. Package size

1 L
5 L

6. Indication(s)

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

7. Contraindications

Do not use in known 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

8. Adverse reactions

In rare cases, at therapeutic doses, transient soft faeces can occur and 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.

<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 label 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}.>*[For MRP/DCP only]*

9. Target species

Pigs.

10. Dosage for each species, route(s) and method of administration

In drinking water use

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.
The quantity in ml of veterinary medicinal product to be added per litre of water should be calculated as follows:

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

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

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

11. Advice on correct administration

Recommendation for dissolution:

The maximum solubility of the product in (soft/hard) water at (5ºC/20ºC) is 30 mL /L.

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. For stock solutions and when using a proportioner, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust flow rate setting of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.

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

12. Withdrawal period(s)

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

13. 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.

14. Special warning(s)

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 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.

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 should avoid contact with the veterinary medicinal product.

Pregnancy and lactation:
Studies in rats have not detected any teratogenic or foetotoxic effects at therapeutic doses. The administration of the product to sows up to three times the recommended dose, during pregnancy or lactation, did not result in adverse effects. As such the product may be administered 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.
Acetylcysteine can be used in case of accidental overdose.

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.

15. Special precautions for the disposal of unused product or waste materials, if any
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

16. Date on which the label was last approved

17. Other information

Package size : 1l bottle and 5 l can
Not all pack size may be marketed.

18. The words "For animal treatment only" and conditions or restrictions regarding supply and use, if applicable

For animal treatment only. <To be supplied only on veterinary prescription.>

19. The words “Keep out of the sight and reach of children”

Keep out of the sight and reach of children.

20. Expiry date

EXP {month/year}
Once opened use by…

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

21. Marketing authorisation number(s)

22. Manufacturer’s batch number

Lot{number}