ANNEX III

LABELLING AND PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 Louverné
France
Or
Ceva Santé Animale
Zone Industrielle Très le Bois
22603 Loudéac
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pracetam 400 mg/ml solution for use in drinking water for pigs
Paracetamol

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:
Paracetamol ..... 400 mg

4. PHARMACEUTICAL FORM

Solution for use in drinking water.
Clear viscous pink solution

5. PACKAGE SIZE

- 500 ml bottle :
- 1-litre bottle :
- 2.5-litre bottle :
- 5-litre bottle :

6. INDICATION(S)

In pigs:
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 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 Drug interactions
- Do not use in animals suffering from dehydration or hypovolaemia

8. ADVERSE REACTIONS

In rare cases, 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 package leaflet 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}.

9. TARGET SPECIES

Pigs.

10. 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.

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:
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 40ml of product per litre of drinking solution.

When using the 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.

12. WITHDRAWAL PERIOD(S)

Meat and offal: zero days.

13. SPECIAL STORAGE PRECAUTIONS

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

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 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
The product can cause hypersensitive reactions (allergy). People with known hypersensitivity to paracetamol or any of the excipients should avoid contact with the product.
The product may cause skin and eye irritation. Wear appropriate protective clothing, gloves, goggles and mask when handling the product.
The product may be harmful if ingested. In cases of accidental contact with the skin or eyes, rinse immediately with a large amount of water. If symptoms persist, seek medical advice and show the leaflet to the physician.
In the case of accidental ingestion, seek medical advice.

Do not eat, drink or smoke while handling this product.
Wash hands after use.

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.

Pregancy and lactation
Laboratory studies in rats have not produced any evidence of teratogenic or foetotoxic effects at therapeutic doses. The administration of the product up to three times the recommended dose, during pregnancy or lactation, did not result in adverse effects. The product can be used during pregnancy and lactation.

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

October 2022

17. OTHER INFORMATION

- 500 ml bottle :
- 1-litre bottle :
- 2.5-litre bottle :
- 5-litre bottle :

Not all pack size may be marketed.

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

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only

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

Do not use after the expiry date stated on the bottle.
The expiry date refers to the last day of that month.

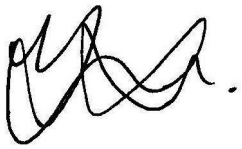
Once opened use by.....

21. MARKETING AUTHORISATION NUMBER(S)

MA n° 15052/4130

22. MANUFACTURER'S BATCH NUMBER

Lot:



Approved: 12 October 2022