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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRACETAM 200 MG/ML SOLUTION FOR USE IN DRINKING WATER FOR PIGS

2. COMPOSITION

Each ml contains:

Active substance:
Paracetamol ……. 200 mg

Excipients:
Macrogol 300

Solution for use in-drinking water.
Clear viscous solution, slightly pinkish to pinkish.
Colour may intensify over time.

3. PACKAGE SIZE

- 1-litre bottle :
- 2-litre bottle :
- 5-litre bottle :
- 10-litre jar :

Not all pack size may be marketed

4. TARGET SPECIES

Pigs.

5. INDICATIONS FOR USE

In pigs :
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 animals with known hypersensitivity to paracetamol and to any other ingredients of the product,
- Do not use in animal with severe hepatic impairment,
- Do not use in animal with severe renal impairment. See also section Drug interactions
- Do not use in animal suffering from dehydration or hypovolaemia

7. SPECIAL WARNINGS

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.

Special precautions for safe use in the target species

A decrease of hyperthermia is expected 12-24 hours after onset of treatment depending on the water-medicated intake.

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

Wear appropriate protective clothing, gloves and a mask and goggles to protect the face and eyes. If the product comes in contact with the skin or eyes, flush immediately with a large amount of water. If symptoms persist, seek medical advice. To rule out any risk of ingestion it is recommended not to eat, or drink while using Pracetam and to wash the hands after use. In the case of ingestion of the product, consult a doctor. Do not handle the product if you are hypersensitive to the paracetamol.

Pregnancy and lactation

Studies in laboratory animals have not detected any teratogenic nor foetotoxic effects at therapeutic doses. The administration of the product up to three times the recommended dose, during pregnancy or lactation, didn't result in adverse effects. So 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

After administration of 5-fold 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.

Major incompatibilities

Pracetam 200 mg/ml 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

Porcine

Rare (1 to 10 animals / 10,000 animals treated):
Diarrhoea[1]

[1]At therapeutic doses, transient soft faeces can occur and can persist up to 8 days after the withdrawal of administration. It does not have any effect on 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 its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

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

In drinking water use

30 mg of paracetamol per kg body weight and per day, for 5 days, orally, administered in the drinking water, equivalent to 1.5 ml of oral solution per 10kg body weight and 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.

10. ADVICE ON CORRECT ADMINISTRATION

Recommendation for dissolution:

The product easily dissolved in ambient temperature water (20°C to 25°C). When using the product through water proportioner, adjust the proportioner from 5% to 3%. Do not settle proportioners under 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 day.

12. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and the reach of children
Store below 25°C
Do not Freeze

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

Shelf life after first opening the immediate packaging: 1 year.
Shelf life of the veterinary medicinal after dilution in the drinking water: 24 hours

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 or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V To be supplied only on veterinary prescription

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 15052/5049

Pack sizes :

- High density polyethylene bottle
- High density polyethylene screwcap
- Polyethylene-aluminium-wax-paper-low density polyethylene seal (1-l bottle)
- Polyethylene-PET-aluminium-wax-cardboard seal (2-l, 5-l and 10-l bottles)
- Polypropylene screwcap (1-l and 5-l bottle)
- Polyethylene seal (for polypropylene screwcap of 1-l and 5-l bottle)

Not all pack size may be marketed

16. DATE ON WHICH THE LABEL WAS LAST REVISED

November 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

17. CONTACT DETAILS

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
Zone Industrielle Très le Bois
22603 Loudéac
France

18. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

19. EXPIRY DATE

EXP: {month/year}

20. BATCH NUMBER