SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Paracetamol 200 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

In pigs:
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 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 4.8
- Do not use in animal 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.

4.5 Special precautions for use

i). Special precautions for use in animals
A decrease of hyperthermia is expected 12-24 hours after onset of treatment depending on the water-medicated intake.

ii). 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.

Special precautions for the protection of the environment:
Not applicable.

iii). Other precautions
None

4.6 Adverse reactions (frequency and seriousness)

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 section “Contact details” of the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

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.

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

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.

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.

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 day.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other Analgesics and Antipyretics
ATCvet code: QN02BE01

5.1 Pharmacodynamic properties

Paracetamol or acetaminophen or N-acetyl-p-aminophenol is a paraminophenol derivative with analgesic and antipyretic properties.

5.2 Pharmacokinetic particulars

Absorption: 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.

Metabolism: 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.

Elimination: 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.

Environmental properties

None known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 300.

6.2 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.

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

6.4 Special precautions for storage

Store below 25°C
Do not Freeze

6.5 Nature and composition of immediate packaging

- 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 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

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

8. MARKETING AUTHORISATION NUMBER

Vm 15052/5049

9. DATE OF FIRST AUTHORISATION

14 May 2010

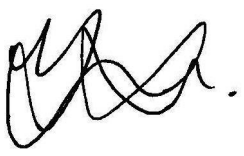
10. DATE OF REVISION OF THE TEXT

November 2023

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

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription



Approved: 18 March 2024