cSUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

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 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 veterinary medicinal 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
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.
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.
The product may be harmful if ingested. In the case of accidental ingestion, seek medical advice.
Do not eat, drink or smoke while handling this product.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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)

4.7 Use during pregnancy, lactation or lay

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.

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

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.

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.

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.
N-acetylcysteine can be used in case of accidental overdose.
Excessive overdoses can cause hepatotoxicity.

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-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.

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: 3 years.
Shelf life after first opening the immediate packaging: 3 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.

6.5 Nature and composition of immediate packaging

- High density polyethylene bottle
- High density polyethylene screwcap
- Polyethylene – Polyethylene – Polyethylene – seal (500 ml bottle)
- Polyethylene-aluminium-wax-paper-low density polyethylene seal (1-l bottle)
- Polyethylene-PET-aluminium-wax-cardboard seal (2.5-l and 5-l bottles)
- Polypropylene screwcap (1-l and 5-l bottle)
- PVC 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

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 Sante Animale
8 rue de Logrono
33500 Libourne
France

8. MARKETING AUTHORISATION NUMBER

Vm 14966/5091

9. DATE OF FIRST AUTHORISATION

06 September 2016

10. DATE OF REVISION OF THE TEXT

November 2025

Gavin Hall
Approved: 19 November 2025