SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRACETAM 10 % premix for Medicated Feeding Stuff for Pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains

Active substance :
- Paracetamol ……...100 mg

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

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (weaned pigs).

4.2 Indications for use, specifying the target species

Pigs (weaned pigs) :
Symptomatic treatment for reduction of pyrexia, in the context of acute infectious respiratory diseases, in combination with appropriate anti-infective therapy.

4.3 Contraindications

- Do not use in animals with known hypersensitivity to paracetamol.
- Do not use the product if there are animals with hepatic or renal impairment, or hypovolaemic animals.

And see the section 4.8.

4.4 Special warnings for each target species

Animals with reduced appetite and/or disturbed general condition have to be treated parenterally.

4.5 Special precautions for use

Special precautions for use in animals

The product is a premix that must not be given to pigs before it has been mixed with solid feed at the minimum rate of 5 kg/ton.

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

Persons with known hypersensitivity to paracetamol should avoid any contact with the medicated feed. In order to avoid contact with skin, mucous membranes and/or eyes use gloves, CE-approved anti-dust mask and protecting spectacles when handling the medicated feed. In case of contact with skin and/or eyes rinse generously with clean water. Seek medical advice if, following exposure, signs such as skin rash or persistent eye irritation develop.

4.6 Adverse reactions (frequency and seriousness)

No side effects have been seen following administration of the medicinal product at the therapeutic dose.

4.7 Use during pregnancy, lactation or lay

The safety has been shown in studies with pregnant and lactating sows when using the product in 3 times of the recommended dose.

4.8 Interactions with other medicinal products and other forms of interaction

Concurrent administration of nephrotoxic drugs should be avoided.

No interactions described with commonly used antibiotics. Concomitant treatment should be considered case by case.
The safety of the co-administration of the product and feed supplemented with vitamine E or polyinsatured fatty acids has not been established. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

4.9 Amounts to be administered and administration route

The daily dose is 30 mg per kg b.w. for 5 consecutive days to be administered in feed:
The dose can be administered in dry feed supplied in two meals.

The product may be administered in pellets as well as non-pelleted feed.

For the preparation of medicated feed:

30 mg Paracetamol per kg b.w. daily corresponds to 300 mg “Pracetam 10 % Premix” per kg b.w. daily.

For the preparation of the medicated feed the body weight of the animals to be treated and their actual daily intake of feed should be taken into due account. To provide the required

amount of active substance per kg medicated feed the premix has to be incorporated into the feed according to the following formula:

$$\frac{\text{300 mg “Pracetam 10 %” per kg b.w. daily} \times \text{average body weight (kg) of the animals to be treated}}{\text{average daily feed intake per animal (kg) per kg feed}} = \text{mg “Pracetam 10 %”}$$

The mixing should be performed in an (authorised) feedingstuff manufacture with adequate mixing apparatus.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse effects have been demonstrated in pigs administered up to 10x the recommended dose.
Acetylcysteine can be used in case of accidental overdosage

4.11 Withdrawal period

Meat and offal: 1 day.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: other analgesics and antipyretics
ATCvet code: QN02BE01

5.1 Pharmacodynamic properties

Paracetamol, or acetaminophen is a para amino-phenol 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, has no gastrointestinal side-effects and has no effect on platelet-aggregation.

5.2 Pharmacokinetic particulars

Absorption and distribution: After a single oral administration of PRACETAM in feed, at 15 mg/kg, the bioavailability is 76 %, the peak of paracetamol concentration (cmax), 3.6 µg/ml, is reached 2.4 hours after the administration.

Metabolism: Paracetamol is metabolised mostly in the liver. The two major metabolic pathways are glucuronide conjugation and sulphate conjugation. A minor pathway catalysed by CYP (cytochrome P450) leads to the formation of the intermediary reagent, N-acetyl benzoquinoneimine which, is rapidly detoxified by reduced glutathione and removed in urine after conjugation with cystein and mercapturic acid.

Elimination: Paracetamol is essentially eliminated through urine (70 % of a single dose is eliminated via urine within 24 hours) under the form of paracetamol glucuronide (80 %). The other forms of elimination are cystein (10 %), unchanged paracetamol and sulphate.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Corn gluten feed

6.2 Incompatibilities

None known.

6.3 Shelf-life

- Shelf-life of the veterinary medicinal product as packaged for sale : 2 years
- Shelf-life after incorporation into feed : 5 months.

6.4 Special precaution for storage

- Store in a dry place
- Keep in the original container

6.5 Nature and composition of immediate packaging

- Low density polyethylene-paper-paper bag.

Bags of 10 and 25 kg
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 material 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
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HP10 0HH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 15052/5035

9. DATE OF FIRST AUTHORISATION

22 March 2005

10. DATE OF REVISION OF THE TEXT

October 2022

PROHIBITION OF SALE, SUPPLY AND/OR USE

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

Approved 11 October 2022