

PART I B: SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1- NAME OF THE VETERINARY MEDICINAL PRODUCT

PRACETAM 10 % Premix for pigs

2- QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance :

- Paracetamol 100 mg

Excipients :

- Corn gluten feed..... to 1.00 g

3- PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4- PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: other analgesics and antipyretics

ATCvet code: QN02BE01

4.1 Pharmacodynamic properties

Paracetamol, or acetaminophen is a para amino-phenol derivatives 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.

4.2 Pharmacokinetic properties

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 (c_{max}), 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.

5- CLINICAL PARTICULARS

5.1- Target species

Pigs (weaned pigs).

5.2- Indications for use

Symptomatic treatment for reduction of pyrexia, in the context of acute infectious respiratory diseases, in combination with appropriate anti-infective therapy.

5.3 – 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.
- Concurrent administration of nephrotoxic drugs should be avoided.

5.4- Undesirable effects

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

5.5- Special precautions for use

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.

5.6- Use during pregnancy and lactation

Studies in laboratory animals have not identified teratogenic or foetotoxic effects in the doses used therapeutically. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

5.7- Interactions with other medicinal products and other forms of interaction

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 polyinsaturated fatty acids has not been established. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

5.8- Posology and method of administration

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:

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

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

5.9- Overdose (symptoms, emergency procedures, antidotes)

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

5.10- Special warnings for each target species

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

5.11- Withdrawal period

Meat and offal: 1 day.

5.12- 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.

6- PHARMACEUTICAL PARTICULARS

6.1- Major incompatibilities

None known.

6.2- Shelf-life

- Premix : 18 months
- Medicated feeding stuff : 5 months.

6.3- Special precaution for storage

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

6.4- Nature and contents of container

Nature of immediate packaging:

- Low density polyethylene-paper-paper bag.

Model(s) destined for sale and identification numbers :

- Bag of 10 kg :
- Bag of 25 kg :

6.5- Special precautions for the disposal of unused product or waste material, if any

Any unused product or waste material should be disposed of in accordance with national requirements.

7- NAME OR CORPORATE NAME AND ADDRESS OR REGISTERED PLACE OF BUSINESS OF THE MARKETING AUTHORISATION HOLDER

SOGEVAL
200 Route de Mayenne – BP 2227
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FRANCE

PROHIBITION OF SALE,SUPPLY AND/OR USE

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

. MARKETING AUTHORISATION NUMBER(S) Vm20749/4003

. DATE OF FIRST AUTHORISATION : 18 April 2005

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.CONDITIONS OF SUPPLY MFS (Medicated Feeding Stuff)