LABELLING PROJECT OF BAG

PRACETAM 10 % premix for medicated feeding stuff for pigs

Bag of 10 kg

Bag of 25 kg

1. NAME AND ADDRESS OF THE MARKETING AUTORISATION HOLDER AND OF THE MANUFACTURING AUTORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

Manufacturer responsible for batch release:
Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 Louverné
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRACETAM 10 % premix for medicated feeding stuff for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

Paracetamol ……..	100 mg
Excipient……..qsp	1,0 g

4. INDICATION

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

5. 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 INTERACTIONS

6. ADVERSE REACTIONS

No side effects have been seen following administration of the medicinal product at the therapeutic dose.
If you notice any serious effects or other effects not mentioned in this labelling, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (weaned pigs)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

9. ADVICE ON CORRECT ADMINISTRATION

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:

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

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

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.

10. WITHDRAWAL PERIOD

Meat and offal: 1 day.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children

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

Do not use after the expiry date which is stated on this label after EXP

Medicated feeding stuff: 5 months.

12. SPECIAL WARNING(S)

SPECIAL WARNINGS FOR EACH TARGET SPECIES

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

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.

USE DURING PREGNANCY AND LACTATION

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

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

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

14. DATE ON WICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

EXPIRY DATE :

BATCH NUMBER :

PACKAGE SIZE

Bags of 10
Bags of 25 kg

FOR VETERINARY USE

Approved 08 July 2022