

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

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

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 Louverné
France
Or
Ceva Santé Animale
Zone Industrielle Très le Bois
22603 Loudéac
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:

Paracetamol 200 mg

4. INDICATION(S)

In pigs :

Symptomatic treatment of fever in the context of respiratory diseases in combination with an appropriate anti infective therapy, if necessary.

5. 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 Drug interactions
- Do not use in animal suffering from dehydration or hypovolaemia

6. ADVERSE REACTIONS

In rare cases, 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 resolve without any specific treatment
If you notice any serious effects or effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs.

8. METHOD AND ROUTE(S) OF ADMINISTRATION

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 10 kg 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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

Meat and offal: zero day.

11. SPECIAL STORAGE CONDITIONS

Keep out of the sight and the reach of children

Store below 25 °C

Do not Freeze

Do not use after the expiry date stated on the bottle

Shelf life after first opening the immediate packaging: 1 year.

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

12. SPECIAL WARNING(S)

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.

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.

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 Paracetam 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.

Drug interactions and other forms of interaction

Concurrent administration of nephrotoxic drugs should be avoided.

Overdose (symptoms, emergency procedures, antidotes)

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.

Use during pregnancy, lactation or laying

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.

Incompatibilities

Pracetam 200 mg/ml has been proved to be physically-chemically compatible with the actives substances Amoxicillin, sulfadiazine/Trimethoprim, Doxycycline, Tylosine, Tetracycline, Colistin.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS OFR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

For animal treatment only

PACKAGE SIZE

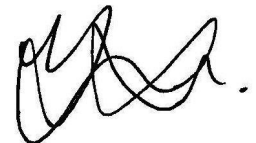
- 1-litre bottle :
- 2-litre bottle :
- 5-litre bottle :
- 10-litre jar :

Not all pack size may be marketed

Lot:

Expiry:

Date of discard:



Approved: 12 October 2022