ANNEX III

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

HDPE bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pracetam 200 mg/ml solution for use in drinking water for pigs

2. COMPOSITION

Each ml contains:

Active substance:
Paracetamol ..... 200 mg

Excipients:
Macrogol 300

Clear viscous solution, slightly pinkish to pinkish.
Colour may intensify over time.

3. PACKAGE SIZE

- 1-litre
- 2-litre
- 5-litre
- 10-litre

4. TARGET SPECIES

Pig.

5. INDICATIONS FOR USE

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

6. CONTRAINDICATIONS

- Do not use in cases of hypersensitivity to the active substance or to the excipient,
- 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.

7. SPECIAL WARNINGS

Special Warnings
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 safe use in the target species
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
Personal protective equipment consisting of protective clothing, gloves and a mask and goggles should be worn when handling the veterinary medicinal product. If the veterinary medicinal 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 the veterinary medicinal product and to wash the hands after use. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to paracetamol should avoid contact with the veterinary medicinal product.

Pregnancy and lactation
Studies in laboratory animals have not detected any teratogenic nor foetotoxic effects at therapeutic doses. The administration of the veterinary medicinal product up to three times the recommended dose, during pregnancy or lactation, did not result in adverse effects. Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Concurrent administration of nephrotoxic drugs should be avoided.

Overdose
After administration of 5-fold 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.

Major incompatibilities
The veterinary medicinal 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.

8. ADVERSE EVENTS

Pig

Rare (1 to 10 animals / 10,000 animals treated):
Soft stool[1]

[1]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 resolves without any specific treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details indicated in section "Contact details", or via your national reporting system.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

In drinking water use.

30 mg of paracetamol per kg body weight per day, for 5 days, orally, administered in the drinking water, equivalent to 1.5 ml of oral solution per 10 kg body weight per day for 5 days.

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of paracetamol may need to be adjusted accordingly.

10. ADVICE ON CORRECT ADMINISTRATION

Recommendation for dissolution:
The veterinary medicinal product easily dissolved in ambient temperature water (20°C to 25°C).
When using the veterinary medicinal 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.

11. WITHDRAWAL PERIODS

Meat and offal: zero day.

12. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and the reach of children.
Store below 25°C.
Do not Freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the bottle.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

(MA)

Pack sizes :

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

Not all pack size may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

{ MM/YYYY}
Detailed information on this veterinary medicinal product is available in the Union Product Database.
(https://medicines.health.europa.eu/veterinary)

17. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
(Name and address to be completed nationally)
Tel: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale
Zone Industrielle Très le Bois
22603 Loudéac
France

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp. {MM/YYYY}
Shelf life after dilution according to directions:: 24 hours.
Once opened, use within 1 year, by ___/___/___

21. BATCH NUMBER

Lot {number}