ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRACETAM 200 MG/G POWDER FOR USE IN DRINKING WATER FOR PIGS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:
Active substance:
Paracetamol ..... 200 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for use in drinking water
White powder

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (weaned pigs)

4.2 Indications for use, specifying the target species

In pigs :

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

4.3 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 4.8
- Do not use in animal suffering from dehydration or hypovolemia

4.4 Special warnings for each target species

Animals with reduced water intake and/or disturbed general condition have to be treated parenterally.
In case of combined viral and bacterial etiology of the disease, an appropriate anti infective therapy should be given concomitantly.

4.5 Special precautions for use

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 the product 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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in mice and rats have not produced any evidence of a teratogenic, foetotoxic effects. No adverse effects were observed after administration to pregnant or lactating sows of doses up to three times the recommended dose. The product can be safely used during pregnancy or lactation..

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration of nephrotoxic drugs should be avoided.

4.9 Amounts to be administered and administration route

Oral route
30 mg of paracetamol per kg body weight and per day, as long as the pigs are suffering from pyrexia for a maximum duration treatment of 5 days.
The product will be orally administered continuously in the drinking water, equivalent to 1.5 g of oral powder per 10 kg body weight.
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.

Recommendation for dissolution: pour Pracetam 20% oral powder in water preferably warm (30°C to 35°C). Shake five minutes this preparation to homogenize the medicated solution. Then adjust the quantity of water depending upon the concentration required and shake again until the solution is homogeneous.

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

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.

4.11 Withdrawal period(s)

Meat and offal: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: other analgesics and antipyretics
ATCvet code: QN02BE01

5.1 Pharmacodynamic properties

Paracetamol or acetaminophen or N-acetyl-para-aminophenol is a paraminophenol derivative with analgesic and antipyretic properties. Its antipyretic effect maybe explained by its ability to inhibit brain cyclo-oxygenases. Paracetamol is only a weak inhibitor of COX-1 synthesis and, thus, no gastro-intestinal side effects and has no effect on platelet-aggregation.

5.2 Pharmacokinetic particulars

Absorption: Paracetamol is rapidly and almost completely absorbed after oral administration (bioavailability of about 90% after administration in the drinking water). Peak concentrations are reached in a little less than 2 hours after ingestion.

Metabolism: Paracetamol is mainly metabolised in the liver. The two major metabolic pathways are conjugation to glucuronate and conjugation to sulphate. The latter route is rapidly saturable at dosages higher than therapeutic doses. A minor pathway, catalysed by cytochrome P450, leads to the formation of the intermediary reagent, N-acetyl-benzoquinoneimine which, under normal conditions of use, is rapidly detoxified by reduced glutathione and removed in urine after conjugation with cystein and mercapturic acid. On the contrary, after massive intoxication, the quantity of this toxic metabolite is increased.

Elimination: Paracetamol is mainly eliminated in the urine. In the pig, 63% of the ingested dose is eliminated by the kidneys in 24 hours mainly conjugated to glucuronate and suphate. Less than 5% is eliminated in unchanged form. The elimination half-life is approximately 4 hours.

Environmental properties
None know.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate.

6.2 Incompatibilities

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

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 3 months

Shelf life after dilution in the drinking water according to directions: 24 hours.

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

- Bag polyester / Aluminium / Polyamide / Polyethylene of 1kg, 5kg and 10kg

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 materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

VETERINARY USE

ANNEX III

LABELLING AND PACKAGE LEAFLET

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

PRACETAM 200 MG/G POWDER 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:

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 200 MG/G POWDER FOR USE IN DRINKING WATER FOR PIGS

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

Each gram 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 hypovolemia

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 other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (weaned pigs).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral route
30 mg of paracetamol per kg body weight and per day, as long as the pigs are suffering from pyrexia for a maximum duration treatment of 5 days.
The product will be orally administered continuously in the drinking water, equivalent to 1.5 g of oral powder per 10 kg body weight.
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: pour Pracetam 20% oral powder in water preferably warm (30°C to 35°C). Shake five minutes this preparation to homogenize the medicated solution. Then adjust the quantity of water depending upon the concentration required and shake again until the solution is homogeneous.

10. WITHDRAWAL PERIOD

Meat and offal: zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions

Do not use after the expiry date stated on the bag

Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution in the drinking water according to directions: 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 etiology 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 Pracetam 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.

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

Overdose (symptoms, emergency procedures, antidotes), if necessary
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 lay
Laboratory studies in mice and rats have not produced any evidence of a teratogenic, foetotoxic effects. no adverse effects were observed after administration to pregnant or lactating sows of doses up to three times the recommended dose. The product can be safely used during pregnancy or lactation.

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

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

ORAL ROUTE

FOR ANIMAL TREATMENT ONLY

PACKAGE SIZE
- Bag of 1 kg:
- Bag of 5 kg:
- Bag of 10 kg:

Not all pack size may be marketed

BATCH NUMBER:

EXPIRY DATE: