ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1 – NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 - QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients:

Qualitative composition of excipients and other constituents
Macrogol 300

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

3. CLINICAL INFORMATION

3.1 Target species

Pig.

3.2 Indications for use for each target species

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

3.3 Contraindications

- Do not use in cases of hypersensitivity to the active substance or to the excipient of the veterinary medicinal product,
- Do not use in animal with severe hepatic impairment,
- Do not use in animal with severe renal impairment. See also section 3.8,
- Do not use in animal suffering from dehydration or hypovolaemia.

3.4 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.

3.5 Special precautions for the target species

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..

Special precautions for the protection of the environment
Not applicable.

3.6 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. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative, or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration of nephrotoxic drugs should be avoided.

3.9 Administration routes and dosage

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..

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures, and antidotes)

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.

3.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: zero day.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QN02BE01

4.2 Pharmacodynamics

Paracetamol or acetaminophen or N-acetyl-p-aminophenol is a paraminophenol derivative with analgesic and antipyretic properties.

4.3 Pharmacokinetics

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 (CYP), 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 5 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 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.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 1 year.

Shelf life after dilution according to directions: 24 hours.

5.3 Special precautions for storage

Store below 25 C.
Do not Freeze.

5.4 Nature and composition of immediate packaging

High density polyethylene bottle with high density polyethylene screwcap and either polyethylene-aluminium-wax-paper-low density polyethylene seal (1 L bottle) or polyethylene-PET-aluminium-wax-cardboard seal (2 L bottle, 5 L bottle, or 10 L bottle).
High density polyethylene bottle with polypropylene screwcap and polyethylene seal (1 L bottle or 5 L bottle).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTORISATION HOLDER

7. MARKETING AUTHORISATION NUMBERS

8. DATE OF FIRST AUTHORISATION:

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARCTERISTICS:

{mm/yyyy}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database.
(https://medicines.health.europa.eu/veterinary).