SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PIRETAMOL, 300 mg/ml oral solution for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

Active substance :

Paracetamol	300.00 mg

Excipients :

Benzyl alcohol (E1519)	10.467 mg
Azorubine (E-122)	0.025 mg
Excipients q.s.t.	1.00 ml

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral solution
Red, clear solution.

4. CLINICAL PARTICULARS

4.1 Target species

Porcine: growing pigs (up to 40 kg bodyweight)

4.2 Indications for use, specifying the target species

Porcine: growing pigs (up to 40 kg bodyweight): symptomatic treatment of fever appearing as a concomitant sign of respiratory diseases of viral origin in combination with an appropriate anti-infective therapy, if necessary.

4.3 Contraindications

Not to use in animals with known hypersensitivity to paracetamol and to any other ingredients of the product.
Do not use in animals with severe hepatic impairment.
Do not use in animals with severe renal impairment. See also section 4.8.
Do not use in animals suffering from dehydration or hypovolaemia.

4.4 Special warnings for each target species

Do not exceed the recommended dose.
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.
A decrease of hyperthermia is expected 12-24 hours after onset of treatment depending on the water-medicated intake.

4.5 Special precautions for use

i. Special precautions for use in animals

None.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

Take precautions to avoid accidental self-exposure to this product. This product may cause irritation of the skin and eyes. Personal protective equipment consisting of gloves, mask and goggles should be worn when handling this product. If this product does get into contact with skin and/or eyes, wash the affected area immediately with plenty of water. If symptoms persist, seek medical advice
People with known hypersensitivity to paracetamol should avoid contact with this product. Inflammation of the face, lips and eyes or respiratory difficulties are more serious signs that need urgent health care.

Do not eat, drink or smoke whilst handling this product.
Do not ingest. In case of accidental ingestion, seek medical care.

4.6 Adverse reactions (frequency and seriousness)

Sometimes an increase of blood urea levels and a drop in blood creatinine levels may be seen.
Secondary and side effects that could appear are: somnolence, anxiety, irritability, sickness, nauseas, vomiting, cutaneous rash, tachycardia, increased blood pressure, and abdominal pain.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have not detected any teratogenic nor foetotoxic effects. However, the safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species, and this product is not indicated for use in breeding animals. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

No interactions were examined with commonly used antibiotics. Concomitant treatment should be considered case by case.
Concurrent nephrotoxic drugs should be avoided

4.9 Amounts to be administered and administration route

30 mg of paracetamol per kg bodyweight per day, for 3 to 5 consecutive days by oral route, i.e. 0.1 ml of oral solution per kg bodyweight.
The uptake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration in the drinking water should be adjusted accordingly.
The quantity in ml to be added per litre of water should be calculated as follows :

$$\frac{\text{ml product/ kg b.w./day} \times \text{mean b.w. of individual animals (kg)} \times \text{number of animals to be treated}}{\text{Total water consumption (litres) of these animals at the previous day}}$$

The solution should be prepared freshly every 24 hours. No other source of drinking water should be available during the medication period. The product is easily dissolved in ambient temperature water (20°C to 25°C) When using a proportional dosing pump, adjust the proportioner from 5% to 3%. Do not settle proportioners under 3%.

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

Administering the recommended dose in triplicate and for the recommended time in duplicate to pigs, no side effects were identified.

Excessive doses could cause hepatotoxicity.

Should overdose take place, N-acetylcysteine may be administered as an antidote.

4.11 Withdrawal period(s)

Meat and offal: 1 day

5. PHARMACOLOGICAL PROPERTIES

Pharmaceutical group: Other analgesic and antipyretic.

ATCVet Code: QN02BE01

5.1 Pharmacodynamic properties

Paracetamol or acetaminophen is a derivative of para-aminophenol with analgesic and antipyretic properties. It inhibits the action of endogen pyrogen agents in pigs, in the hypothalamic centers of temperature regulation. It is a weak inhibitor of COX-1 synthesis; therefore it has not side effects at gastrointestinal level, neither on platelet aggregation.

5.2 Pharmacokinetic particulars

- Absorption and distribution: after forced oral administration of PIRETAMOL via drinking water at a dose of 30 mg/kg bw, bioavailability was 81%, reaching a maximum concentration (C_{max}) of 10.41 mg/l at 2 hours (T_{max}) later. The presence of food reduces gastric emptying times and slows intestinal paracetamol absorption. Plasma binding is low at therapeutic levels.
- Metabolism: Paracetamol is extensively and rapidly metabolized, mainly in the liver, the main metabolites being glucuronide and sulphate conjugates.
- Excretion: it is rapidly excreted ($t_{1/2}$: 2.23 h), mainly by urine as glucuronide conjugate, and in less amount as cysteine, unchanged paracetamol and sulphate conjugated.

Environmental properties

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 300
Dimethylacetamide
Benzyl alcohol (E1519)
Saccharin Sodium
Azorubine (E-122)
Purified water

6.2 Incompatibilities

None known

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 for medicated drinking water: 24 hours

6.4 Special precautions for storage

Protect from light**.**

6.5 Nature and composition of immediate packaging

Opaque and white high density polyethylene 5 litres barrel, sealed by induction and green high density polyethylene screw-on cap.
Presentation: 5 litres, 4 x 5 litres barrel.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Global Vet Health, S.L.
C/Capçanes, 12-bajos
Poligono Agro-Reus
43206-REUS Tarragona
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 36167/4000

9. DATE OF FIRST AUTHORISATION

Date: 5 July 2011

10. DATE OF REVISION OF THE TEXT

Date: June 2012

PROHIBITION OF SALE, SUPPLY AND/OR USE

Conditions of dispensation: “With veterinary prescription”