SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PIRETAMOL 300 mg/ml solution for use in drinking water for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

Active substance :

Paracetamol	300.00 mg

Excipients :

Benzyl alcohol (E1519)	10.467 mg
Azorubine (E122)	0.025 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for use in drinking water.
Red, clear solution.

4. CLINICAL PARTICULARS

4.1 Target species

Porcine: pigs for fattening (up to 40 kg bodyweight)

4.2 Indications for use, specifying the target species

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

Do not use in cases of hypersensitivity to paracetamol or to any of the excipients.
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

The intake of medicated water by animals may be altered as a consequence of illness. In case of insufficient water intake, animals should be treated parenterally instead.
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

Special precautions for use in animals

None.

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 to the skin and eyes. Personal protective equipment consisting of impervious gloves, mask and safety glasses should be worn when handling this product. In case of contact with skin and/or eyes, wash the affected area immediately with plenty of water. If symptoms occur, 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 require urgent medical attention.

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

4.6 Adverse reactions (frequency and seriousness)

In very rare cases an increase in blood urea levels and a decrease in blood creatinine levels may be seen.

In very rare cases somnolence, anxiety, irritability, vomiting, cutaneous rash, tachycardia, increased blood pressure, and abdominal pain may occur.

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment).
- Common (more than 1 but less than 10 animals in 100 animals).
- Uncommon (more than 1 but less than 10 animals in 1,000 animals).
- Rare (more than 1 but less than 10 animals in 10,000 animals).
- Very rare (less than 1 animal in 10,000 animals, including isolated reports).

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 investigated with commonly used antibiotics. Therefore, concomitant treatment with other products should be considered on a case-by–case basis.

Concurrent administration of nephrotoxic drugs should be avoided

4.9 Amounts to be administered and administration route

For use in drinking water.

30 mg of paracetamol per kg bodyweight per day, for 3 to 5 consecutive days by oral route, i.e. 0.1 ml of product per kg bodyweight.
To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. The uptake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of paracetamol in the drinking water should be adjusted taking into account water intake.
The quantity in ml of product to be added per litre of water should be calculated as follows:

$$\frac{0.1 \times \text{mean b.w. of individual animals (kg)} \times \text{number of animals to be treated}}{\text{Total water consumption (litres) of these animals on the previous day}}$$

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 dose proportioning pump, settings should be in the rage 3% to 5%. Do not use a setting below 3% as precipitation may occur.

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

Administration of three times the recommended dose or twice the recommended treatment duration did not result in side effects.

Excessive doses could cause hepatotoxicity.

It has been reported in both human and veterinary published literature that administration of N-acetylcysteine has been used in case of overdose of paracetamol.

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 endogenous pyrogenic agents in pigs, by acting on the thermoregulatory centre of the hypothalamus. It is a weak inhibitor of COX-1

synthesis; therefore it has limited side effects on the gastrointestinal tract or on platelet aggregation.

5.2 Pharmacokinetic particulars

- Absorption and distribution: after oral administration of the product 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. Presence of food slows down the rate of absorption of paracetamol. Plasma binding is low at therapeutic levels.
- Metabolism: Paracetamol is extensively and rapidly metabolised, mainly in the liver. The main metabolites are glucuronide and sulphate conjugates.
- Excretion: Paracetamol is rapidly excreted ($t_{1/2}$: 2.23 hrs), mainly by urine as glucuronide conjugate, and in lower amounts as cysteine, unchanged paracetamol and sulphate conjugates.

Environmental properties

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 300
Dimethylacetamide
Benzyl alcohol (E1519)
Saccharin Sodium
Azorubine (E122)
Purified water

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must 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 according to directions: 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 L barrel, sealed by induction with a green high density polyethylene screw-on cap.
Pack sizes:
1x 5L barrel
4 x 5 L barrels.

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/Capcanes, 12-bajos
Polígono Agro-Reus
43206-Reus
Tarragona
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 36167/4000

9. DATE OF FIRST AUTHORISATION

5 July 2011

10. DATE OF REVISION OF THE TEXT

May 2016

PROHIBITION OF SALE, SUPPLY AND/OR USE

Conditions of dispensation: “With veterinary prescription”


04 May 2016