Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

PIRESOL 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:

Benzylalcohol (E1519)	0.01 ml
Azorubine (E 122)	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

Pigs.

4.2 Indications for use, specifying the target species

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 cases of hypersensitivity to paracetamol and 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 anti-pyretic effect of the veterinary medicinal product is expected at 12 - 24 hours after the onset of treatment.
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.

4.5 Special precautions for use

Special precautions for use in animals
Not applicable.

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

This veterinary medicinal product may cause hypersensitivity (allergy). People with known hypersensitivity to paracetamol or any of the excipients should avoid contact with the veterinary medicinal product.

This veterinary medicinal product may cause skin or eye irritation. Wear appropriate protective clothing, gloves, goggles and mask when handling the veterinary medicinal product. In case of skin or eye contact, rinse immediately with a large amount of water. If symptoms persist, seek medical advice.

This veterinary medicinal product may be harmful if ingested. Do not smoke, eat or drink while handling the veterinary medicinal product.

This veterinary medicinal product contains dimethylacetamide, which has been shown to have potential to affect fertility or development unborn child. Pregnant women and women of child-bearing age should avoid working with this product. In case of accidental contact, seek medical advice.

4.6 Adverse reactions (frequency and seriousness)

Transient soft faeces can occur in rare cases and can persist for up to 8 days after withdrawal of the treatment. This does not have any effect on the general condition of animals, and resolves without any specific treatment.

The frequency of adverse reactions is defined using the following convention:

- Very common (more than 1 in 10 animals displaying adverse reaction(s)
- 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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in the target species.

This veterinary medicinal product contains dimethylacetamide which is considered to be a reproductive toxicant in laboratory animals, therefore, the use of this product is not recommended inbreeding animals.

4.8 Interaction with other medicinal products and other forms of interactions

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 body weight per day, for 5 days, orally, administered in drinking water, equivalent to 1 ml of the veterinary medicinal product per 10 kg body weight per day for 5 days.

To avoid under-dosing and to ensure a correct dosage, bodyweight should be determined as accurately as possible. The uptake of medicated drinking water depends on the clinical condition of the animals. In order to obtain a correct dosage, the concentration of the veterinary medicinal product in the drinking water should be adjusted taking into account water intake.

The quantity in ml of veterinary medicinal product to be added per litre of water should be calculated as follows:

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

The solution should be prepared freshly every 24 hours. No other source of drinking water should be available during the medication period.

Recommendation for dissolution:
The maximum solubility of the product in (soft/hard) water at (5°C/20°C) is 100 ml /L. First add the necessary quantity of water for the preparation of the final solution in the container. Then add the product while stirring the solution. For stock solutions and when using a proportioner, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust flow rate setting of the dosing pump according to concentration of the stock solution and water intake of the animals ot be treated.

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.
It has been reported in both human and veterinary published literature that administration of N-acetylcysteine has been used as antidote in case of accidental overdose.
Excessive overdoses can cause hepatotoxicity.

4.11 Withdrawal period(s)

Meat and offal: zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other analgesics and antipyretics.
ATC vet 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 may be explained by its ability to inhibit brain cyclo-oxygenases. Paracetamol is a weak inhibitor of COX-1 synthesis and, thus, it has no gastro-intestinal side effects and has no effect on platelet-aggregation.

5.2 Pharmacokinetic particulars

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.
Paracetamol is mainly metabolised in the liver. The two major metabolic pathways are conjugation to glucuronate and conjugation to sulfate. 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 (toxic metabolite) 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.
Paracetamol is mainly eliminated in the urine. In the pig, 63% of the ingested dose is excreted by the kidneys in 24 hours mainly conjugated to glucuronate and sulfate. Less than 5% is eliminated in unchanged form. The elimination half-life is approximately 5 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E 1519)
Azorubine (E 122)
Macrogol 300
Dimethylacetamide
Saccharin Sodium
Purified water

6.2 Major 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

This veterinary medicinal product does notrequire any special storage conditions.

6.5 Nature and composition of immediate packaging

Opaque and white high density polyethylene 1 litre bottle and 5 litres barrel with a high density polyethylene screw-on cap containing a polyethylene induction seal.
Package sizes:
1 litre bottle
5 litres barrel
12 x 1 litre bottle
4 x 5 litres barrel
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

SP Veterinaria, S.A.
Ctra. Reus - Vinyols Km 4, 1
Riudoms 43330
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10790/014/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd August 2018

10 DATE OF REVISION OF THE TEXT