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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E 1519)	0.01 ml
Azorubine (E 122)	0.025 mg
Macrogol 300	
Dimethylacetamide	
Saccharin Sodium	
Purified water	

Red, clear solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs

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 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 3.8.
- Do not use in animals suffering from dehydration or hypovolaemia.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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. Personal protective equipment consisting of protective clothing, gloves, goggles and mask should be worn 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 immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Loose stool*

*Transient, can persist for up to 8 days after withdrawal of the treatment. This does not have any effect on the general condition of pigs, 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 section ”Contact details” of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Fertility:
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 in breeding animals.

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

To ensure a correct dosage, bodyweight should be determined as accurately as possible. 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.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$\frac{\text{0.1 ml veterinary medicinal product/kg body weight / day}}{\text{Total water intake (litres) of animals to be treated on the previous day}}$	x	average body weight of individual animals (kg)	x	number of animals to be treated	= ml of veterinary medicinal product per litre of drinking water

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 (5ºC/20ºC) 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 to be treated.

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

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.

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 days

4. PHARMACOLOGICAL INFORMATION

4.1. ATC vet code: QN02BE01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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: 2 years

Shelf-life after first opening the immediate packaging: 3 months

Shelf-life after dilution according to directions: 24 hours

5.3 Special precautions for storage

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

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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 AUTHORISATION HOLDER

SP Veterinaria, S.A.

Ctra. Reus-Vinyols, Km 4.1

43330 Riudoms

Spain

7. MARKETING AUTHORISATION NUMBER

Vm 36967/3000

8. DATE OF FIRST AUTHORISATION

23 July 2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

March 2024

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).

Approved: 13 May 2024