ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

LABEL FOR BOX FOR 12 X 1 LITRE BOTTLE AND 4 X 5 LITRES BARREL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Paracetamol 300.00 mg

3. PACKAGE SIZE

12 x 1 l
4 x 5 l

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.
Once diluted use within 24 hours.

Once opened, use by….

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

SP VETERINARIA, S.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 36967/3000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL FOR 1 LITRE BOTTLE AND 5 LITRES BARREL (BOX FOR 12 X 1 LITRE BOTTLE AND 4 X 5 LITRES BARREL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PIRESOL 300 mg/ml solution for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Paracetamol 300.00 mg

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

In drinking water use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: zero days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.
Once diluted use within 24 hours.
Once opened, use by….

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

SP VETERINARIA, S.A.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL FOR 1 LITRE BOTTLE AND 5 LITRES BARREL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains :
Paracetamol 300.00 mg

3. PACKAGE SIZE

1 l

5 l

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.
Once diluted use within 24 hours.

Once opened, use by….

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

SP VETERINARIA, S.A.

14. MARKETING AUTHORISATION NUMBERS

Vm 36967/3000

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains :

Active substance :

Paracetamol	300.00 mg

Excipients :

Benzyl alcohol (E1519)	0.01 ml
Azorubine (E 122)	0.025 mg

Red, clear solution

3. Target species

Pigs

4. Indications for use

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

5. 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 “Special warnings”, subsection “Interaction with other medicinal products and other forms of interaction”.

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

6. Special warnings

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.

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.

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.

Interaction with other medicinal products and other forms of interaction:

Concurrent administration of nephrotoxic drugs should be avoided.

Overdose (symptoms, emergency procedures, 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-acetylcysteinehas been used as antidote in case of accidental overdose.

Excessive overdoses can cause hepatotoxicity.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

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:

$\frac{\text{0.1 ml veterinary medicinal product/ kg body weight / day} \times \text{average body weight of individual animals (kg)} \times \text{number of animals to be treated}}{\text{Total water intake (litres) of animals to be treated on the previous day}}$	= 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. The maximum solubility of the product 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.

10. Withdrawal periods

Meat and offal: zero days

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

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

Shelf-life after dilution according to directions: 24 hours

12. Special precautions for disposal

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 applicable national collection systems._These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 36967/3000

1 litre bottle
5 litres barrel
12 x 1 litre bottle
4 x 5 litres barrel
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

August 2023

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

S.P. VETERINARIA, S.A.

Ctra Reus Vinyols km 4.1

Tel. +34 977 850 170

Riudoms (43330)

Spain

Local representative and contact details to report suspected adverse reactions:

Vetsonic (UK) Ltd

Riccal Drive

York Road Business Park

Malton

North Yorkshire

YO17 6YE.

Tel. +44(0)1653 695333

Approved 15 August 2023