COMBINED LABEL/LEAFLET FOR

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Global Vet Health S.L.
C/Capçanes nº12-bajos
Polígono Agro-Reus
REUS 43206 (Spain)

Manufacturer responsible for batch release:

S.P. VETERINARIA, S.A.
Ctra. Reus-Vinyols km 4.1
RIUDOMS 43330 (Spain)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains

Active substance:
Paracetamol.....300 mg

Excipients:
Benzyl alcohol (E1519) .....10.467 mg
Azorubine (E122).....0.025 mg

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

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).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 to be added per litre of water should be calculated as follows:

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

9. ADVICE ON CORRECT ADMINISTRATION

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 range 3% to 5%. Do not use a setting below 3% as precipitation may occur.

10. WITHDRAWAL PERIOD

Meat and offal: 1 day

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Protect from light.

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 container: 3 months.
Shelf-life after dilution according to directions: 24 hours.

12. SPECIAL WARNING(S)

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.

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 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.

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.

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.

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

Administration of three times the recommended dose or for 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.

Incompatibilities

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes: 5 L barrel, 4 x 5 L barrels.
Once opened, use by …
Batch number: PL: Nr serii (Lot)
Expiry date: PL: Termin ważności (EXP)
Marketing authorisation number(s): 10477/003/001
POM 'Prescription Only Medicine'.
For animal treatment only - to be supplied only on veterinary prescription

Administration by a veterinary surgeon or under their direct responsibility.

(PL: "Wyłącznie dla zwierząt. Wydawany z przepisu lekarza – Rp.

Do podawania pod nadzorem lekarza weterynarii.")

04 May 2016