ANNEX III

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Securitainer, Composite can, bucket

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release , if different

Marketing authorisation holder:
Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer The Netherlands

Manufacturer responsible for the batch release:
Dopharma B.V.
Zalmweg 24
4941 VX Raamsdonksveer The Netherlands

2. Name of the veterinary medicinal product

Phenoxypen WSP, 325 mg/g powder for oral solution for chickens

3. Statement of the active substance (s) and other ingredients

Per gram

Active substance:

Phenoxymethylpenicillin	293 mg
equivalent to potassium phenoxymethylpenicillin	325 mg

White to off-white powder

4. Pharmaceutical form

Powder for oral solution.

5. Package size

250 gram, 1 kg, 2.5 kg or 5 kg.

6. Indication(s)

Prevention of mortality at a group level from necrotic enteritis in chickens caused by *Clostridium perfringens* susceptible to phenoxymethylpenicillin.

7. Contraindications

Do not use in case of hypersensitivity to the active substance.

8. Adverse reactions

Although no adverse reactions have been seen after the administration of the product, penicillins may cause vomiting, diarrhoea and alter gut flora with selecting resistant bacteria.

If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

9. Target species

Chickens

10. Dosage for each species, route(s) and method of administration

13.5 – 20 mg phenoxymethylpenicillin per kg of body weight per day,
corresponding with 46 – 68 mg of the product per kg of body weight per day, for 5 days

This product is administered to the chickens after dissolution in drinking water.

The following calculation should be made to determine the quantity in gram of the product to be added in
1000 litres of water:

$$\frac{\text{mg product/ kg body weight/day} \times \text{mean body weight of individual animals (kg)} \times \text{number of animals}}{\text{total water consumption of the house (litres) at the previous day}}$$

= mg product/l = g product/1000 l water

In dispensing the weight of the product to be used, the use of calibrated weighing equipment is recommended.

11. Advice on correct administration

Taking into account that sick animals may drink less, it is recommended to start therapy with the higher dose, to compensate for a possible lower intake of medicated water.
To ensure correct dosage, the body weight of the animals should be determined as accurately as possible to avoid underdosing.
The maximal solubility is 250 g of the product per litre of drinking water.
No other source of drinking water should be available during the medication period.
In cases of altered drinking water consumption in poultry the concentration should be adjusted so that the recommended dosage is achieved.
Only sufficient medicated drinking water should be prepared to cover daily requirements
Medicated drinking water should be refreshed or replaced every 12 hours.

12. Withdrawal period(s)

Withdrawal period(s):
Meat and offal: 2 days.
Eggs: zero days.

13. Special storage precautions

Store below 25ºC.
Do not refrigerate or freeze.
Protect from frost.
Store in the original package.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after exp.

14. Special warning(s)

Special warnings for each target species
The administration of the product may lead to an increase in medicated water consumption.

Special precautions for use in animals
Use of the product should be based on susceptibility testing of the bacteria isolated from chickens that have already died on the farm.
The product should not be used to compensate for poor hygiene and management of the chicken houses.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Phenoxymethylpenicillin may cause hypersensitivity reactions after injection, inhalation, oral ingestion, skin or eye contact. Hypersensitivity to phenoxymethylpenicillin may lead to cross-sensitivity to other penicillins and cephalosporins, and vice versa. Allergic reactions caused by these substances can sometimes be serious.
In case of accidental ingestion or serious symptoms of hypersensitivity reactions such as skin rash following exposure, swelling of the face, lips or eyes or difficulty with breathing, seek medical advice immediately and show the package leaflet to the physician.
People with known hypersensitivity to penicillins or cephalosporins should avoid contact with the product. In case of development of hypersensitivity symptoms following exposure to the product, all further contact with the product (and other medicines containing other penicillins or cephalosporins) should be avoided.
Handle this product with great care to avoid exposure, taking all recommended precautions. Wear protective clothing, impervious gloves and either a disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator conforming to European Standard EN140 with a filter to EN 143 when mixing and handling the product. Wash hands immediately after handling the product.

Pregnancy, lactation or lay
Studies in laboratory animals and humans have not produced any evidence of effects on reproductive function or foetal development.

Interactions with other medicinal products and other forms of interaction
Do not use the product in combination with bacteriostatic antibiotics.
Do not mix the product with other veterinary medicinal products.

Overdose (symptoms, emergency procedures, antidotes)
Phenoxymethylpenicillin has a high therapeutic index. The administration of the medicated drinking water at two and five times the recommended therapeutic dose for twice the recommended duration of treatment did not reveal any adverse effects. In some individuals, administration of five times the recommended therapeutic dose for twice the recommended duration of treatment led to an increase in water consumption, a decrease in feed intake and watery faeces.

Incompatibilities
Contact of penicillin containing solutions with metals and the use of metal systems for their administration is known to adversely influence penicillin stability. Therefore such systems should be avoided and they should not be used for the storage of solutions.

15. 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 product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon to dispose of medicinal products no longer required. These measures should help to protect the environment.

16. Date on which the label was last approved

July 2020

<17. Other information>

List of pack sizes:
- Securitainer: 250 g, 1000 g
- Composite can: 1 kg
- Bucket: 1 kg, 2.5 kg, 5 kg.

Not all pack sizes may be marketed.

18. The words “For animal treatment only” and conditions or restrictions regarding supply and use, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

19. The words “Keep out of the sight and reach of children”

Keep out of the sight and reach of children.

20. Expiry date

Exp <<EXP month/year>>

Shelf life after first opening the container: 3 months
Shelf life after dilution according to directions: 12 hours.

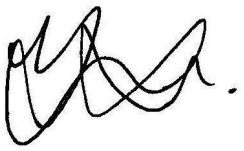
Once opened, use by:

21. Marketing authorisation number(s)

Vm 28365/4000

22. Manufacturer's batch number

Batch <<partijnummer>>



Approved: 07 July 2020