ANNEX III

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
COMBINED LABEL AND LEAFLET

Securitainer and 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, NL

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

2. Name of the veterinary medicinal product

Doxylin CT WSP, 500 mg/g, powder for use in drinking water for chickens and turkeys
Doxycycline (as doxycycline hyclate)

3. Statement of the active substance and other ingredients

Doxycycline	433.3 mg/g
(as doxycycline hyclate	500.0 mg/g)

Yellow, crystalline powder

4. Pharmaceutical form

Powder for use in drinking water.

5. Package size

1 kg, 2.5 kg, 5 kg.

6. Indications

Treatment of clinical respiratory infections associated with *Mycoplasma gallisepticum* susceptible to doxycycline.

7. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use when tetracycline resistance has been detected in the herd/flock due to the potential for cross resistance.
Do not use in animals with hepatic dysfunction.

8. Adverse reactions

As for all tetracyclines, on rare (more than 1 but less than 10 animals in 10 000 animals treated) occasions allergic reactions and photosensitivity may occur. If suspected adverse reactions occur, treatment should be discontinued.
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

Chicken (broiler, broiler breeder) and turkey (broiler, breeder).

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

To be administered in drinking water.

Chickens: 20 mg doxycycline per kg of body weight daily (equivalent to 46 mg product per kg of body weight), administered in the drinking water for 5 consecutive days.
Turkeys: 25 mg doxycycline per kg of body weight daily (equivalent to 58 mg product per kg of body weight), administered in the drinking water for 5 consecutive days.

11. Advice on correct administration

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

$$\frac{\text{..... mg product per kg body weight per day} \times \text{mean body weight (kg) of animals to be treated}}{\text{mean daily water consumption (litre per animal)}} = \text{.... mg product per litre of drinking water}$$

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
The uptake of medicated water is dependent on the clinical conditions of the animals. In order to obtain the correct dosage, the concentration in drinking water may have to be adjusted. The use of suitably calibrated weighing equipment is recommended if part packs are used. The daily amount is to be added to the drinking water such that all medication will be consumed in 24 hours. Medicated drinking water should be freshly prepared every 24 hours. It is recommended to prepare a concentrated pre-solution - not exceeding 100 grams product per litre drinking water - and to dilute this further to therapeutic concentrations, if required. Alternatively; the concentrated solution can be used in a proportional water medicator.
It should be ensured that all animals intended for treatment should have free access to the drinking facilities. At the end of treatment, the watering equipment should be cleaned adequately to avoid the uptake of remaining quantities in sub-therapeutic doses. The medicated water should be the only source of drinking water, throughout the treatment period. The medicated water must not be made or stored in a metal container. Solubility of the product is pH dependent and it will precipitate if it is mixed in an alkaline solution.

. In order to ensure a complete and permanent dissolution of the veterinary medicinal product in each water quality, a minimum concentration is required. The minimum concentration in drinking water is 200 mg veterinary medicinal product per litre. Animals requiring a lower concentration should not be treated with the product.

12. Withdrawal period(s)

Withdrawal periods:
Chickens: meat and offal: 5 days.
Turkeys: meat and offal: 12 days.
Not authorised for use in birds producing eggs for human consumption.

13. Special storage precautions

Store below 25ºC.
Store in tightly closed, original container, in order to protect from light.
Medicated drinking water should be protected from light.
Do not use this veterinary medicinal product after the expiry date which stated on the label after EXP.

14. Special warning(s)

Special warnings for each target species
The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of drinking water, animals should be treated parenterally.

Special precautions for use in animals
Due to variability (time, geographical) in susceptibility of bacteria for doxycycline, bacteriological sampling and susceptibility testing of micro-organisms from diseased animals on farm are highly recommended.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to doxycycline and may decrease effectiveness of treatment with tetracyclines due to the potential for cross resistance.
Use of the product should take into account official and local antimicrobial policies.
Avoid administration in oxidized drinking equipment.
As eradication of the target pathogens may not be achieved, medication should therefore be combined with good management practices, e.g. good hygiene, proper ventilation, no overstocking.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
During preparation and administration direct contact of the product with the skin, eyes and mucous membranes and inhalation of dust particles should be avoided.
People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.
Wear protective gloves (e.g. rubber or latex), glasses and an appropriate dust mask (e.g. disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143) when reconstituting or administering the solution. Wash exposed skin after preparation of medicated drinking water. In case of accidental eye contact, rinse with plenty of fresh water. Do not smoke, eat or drink when handling the product.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Inflammation of the face, lips or eyes or respiratory difficulties are the most serious signs which require urgent medical attention.

Pregnancy, lactation or lay
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effects.

Interaction with other medicinal products and other forms of interaction
Do not administer concurrently with feed overloaded with polyvalent cations such as Ca^{2+}, Mg^{2+}, Zn^{2+} and Fe^{3+} because the formation of doxycycline complexes with these cations is possible. Do not administer together with antacids, kaolin and iron preparations as tetracyclines are bacteriostatic antimicrobials, do not administer in conjunction with bactericidal antibiotics like beta-lactams. It is advised that the interval between administration of other products containing polyvalent cations should be 1-2 hours because they limit the absorption of tetracycline.
Doxycycline increases the action of anticoagulants.

Incompatabilities
Do not mix with other veterinary medicinal products.

15. Special precautions for the disposal of unused products 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.

16. Date on which the label was last approved

April 2020

17. Other information

List of pack sizes:
- Securitainer: 1 kg.
- Bucket: 1, 2.5, 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 << >>

Shelf-life after first opening the container: 3 months
Once opened, use by …
Once dissolved in drinking water, use within 24 hours.

21. Marketing authorisation number

Vm 28365/4006

22. Manufacturer's batch number

Batch << >>

LEAFLET

(All information is included in the label/outer package)

Approved 08 June 2020