[Version 9,03/2022]

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Securitainer and bucket

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxylin 50% WSP, powder for oral solution in pre-ruminant calves, pigs and chickens
~~Doxycycline hyclate~~

2. STATEMENT OF ACTIVE SUBSTANCES

Doxycycline hyclate 500 mg/g
(equivalent to doxycycline 433 mg/g)

3. PACKAGE SIZE

1 kg, 2.5 kg, 5 kg.

heeft opmaak toegepast: Markeren

4. TARGET SPECIES

Pre-ruminant calves, pigs and chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use, after dissolution in drinking water/milk replacer.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal:
Calves: 7 days
Pigs: 8 days
Chickens: 5 days
Not ~~permitted~~ for use in ~~laying~~ birds producing eggs for human consumption.
Not ~~permitted~~ authorised for use in ~~cattle~~ animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use by…

9. SPECIAL STORAGE PRECAUTIONS

Store below 25ºC.
Do not refrigerate or freeze.
Protect from frost.

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

Dopharma Research B.V.

14. MARKETING AUTHORISATION NUMBERS

~~*To be completed nationally*~~

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Doxylin 50% WSP, powder for oral solution in pre-ruminant calves, pigs and chicken

2. Composition

Doxycycline hyclate 500 mg/g
(equivalent to doxycycline 433 mg/g)

Slightly yellowish powder.

3. Target species

Pre-ruminant calves, pigs, chickens

4. Indications for use

~~T~~For the treatment of the following specified infections of the respiratory tract and the alimentary tract caused by micro-organisms susceptible to doxycycline.
Pre-ruminant calves:
- Bronchopneumonia and pleuropneumonia caused by *Pasteurella spp*., *Streptococcus spp*., *Arcanobacterium pyogenes*, *Histophilus somni* and *Mycoplasma spp*..
Pigs:
- Atrophic rhinitis caused by *Pasteurella multocida* and *Bordetella bronchiseptica*;
- Bronchopneumonia caused by *Pasteurella multocida*, *Streptococcus suis* and *Mycoplasma hyorhinis*;
- Pleuropneumonia caused by *Actinobacillus pleuropneumoniae*.
Chickens:
- Infections of the respiratory tract caused by *Mycoplasma spp*., *Escherichia coli*, *Haemophilus paragallinarum* and *Bordetella avium*;
- Enteritis caused by *Clostridium perfringens* and *Clostridium colinum.*

5. Contraindications

Do not use in case of hypersensitivity to tetracyclines or any of the excipients.
Do not administer to animals with severe liver- or kidney insufficiency.

6. Special warnings

Special warnings:
A high resistance rate of E. coli, isolated from chickens, against tetracyclines has been documented. Therefore, the product should be used for the treatment of infections caused by E. coli only after susceptibility testing has been carried out. Resistance to tetracyclines has also been reported in pig respiratory pathogens (A. pleuropneumoniae, S. suis) and calf pathogens (Pasteurella spp) in some EU countries.
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 for safe use in the target species:
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target
pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial
policies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
During the handling of the veterinary medicinal product, skin contact and inhalation has to be avoided, taking into account the risk of sensitization and contact dermatitis. For that purpose wear gloves and a dust mask.

Pregnancy and lactation:
Due to deposit of doxycycline in young bone tissue, use of the veterinary medicinal product should be limited during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Do not use in conjunction with bactericidal antibiotics, such as penicillins and cephalosporins. Tetracyclines can chelate cations (e.g. Mg, Mn, Fe and Al) and this may lead to decreased bioavailability.

Overdose:
In calves acute, sometimes fatal myocardial degeneration can occur following single or multiple dosages. Since mostly this is caused by overdosage, it is important to measure the dosage accurately.

~~Special restrictions for use and special conditions for use:~~
~~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.~~

~~A high resistance rate of E. coli, isolated from chickens, against tetracyclines has been documented. Therefore the product should be used for the treatment of infections caused by E. coli only after susceptibility testing has been carried out. Resistance to tetracyclines has also been reported in pig respiratory pathogens (A. pleuropneumoniae, S. suis) and calf pathogens (Pasteurella spp) in some EU countries.~~

~~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.~~

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

7. Adverse events

None known.

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 using the contact details at the end of this leaflet, or via your national reporting system.

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

Pre-ruminant calves:	10 mg doxycycline hyclate / kg body weight / day, corresponding to 20 mg of veterinary medicinal product per kg body weight, for 3-5 consecutive days, divided over 2 administrations.

Pigs:	10 mg doxycycline hyclate / kg body weight / day, corresponding to 20 mg of veterinary medicinal product per kg body weight, for 3-5 consecutive days.
Chickens:	25 mg doxycycline hyclate / kg body weight / day, corresponding to 50 mg of veterinary medicinal product per kg body weight, for 3-5 consecutive days.

To be administered orally through the milk-replacer and/or the drinking water.

9. Advice on correct administration

For the administration through the drinking water, the exact daily amount of veterinary medicinal product should be calculated, based on the recommended dose, and the number and weight of the animals to be treated, according to the following formula:

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

Tabel met opmaak

To ensure a correct dosage body weight should be determined as accurately as possible.
The upintake of medicated water is dependants on the clinical conditions of the animals. In order to obtain the correct dosage, the concentration in drinking water may have to be adjusted accordingly.
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 - approximately 100 grams of veterinary medicinal 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.
The medicated milk replacer should be used immediately.

10. Withdrawal periods

Meat and offal:
Calves: 7 days
Pigs: 8 days
Chickens: 5 days
Not for use in birds producing eggs for human consumption.
Not authorised for use in animals producing milk for human consumption.
~~Not permitted for use in laying birds producing eggs for human consumption.~~
~~Not permitted for use in cattle producing milk for human consumption.~~

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 25ºC.
Do not refrigerate or freeze.
Protect from frost.

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

Shelf life after first opening the container: 3 months.
Shelf life after reconstitution in drinking water: 24 hours.
Shelf life after reconstitution in milk replacer: use immediately.

12. Special precautions for disposal

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.
~~Any unused product or waste material should be disposed of in accordance with national requirements.~~

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

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14. Marketing authorisation numbers and pack sizes

~~*To be completed nationally*~~

Securitainer: 1 kg
Bucket: 1 kg, 2.5 kg, 5 kg
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

~~*To be completed nationally*~~

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Dopharma Research B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer
~~The Netherlands~~
Tel +31-162-4582000
pharmacovigilance@dopharma.com

heeft opmaak toegepast: Nederlands (standaard)

heeft opmaak toegepast: Nederlands (standaard)

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

17. Other information

~~*To be completed nationally*~~