<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

CARTON BOX: 10 X 100 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxyval 500 mg/g powder for use in drinking water for pigs and chickens
Sogedoxy 500 mg/g powder for use in drinking water for pigs and chickens (CZ)
Doxyval Vet (DK)
Doxyval 433 mg/g powder for use in drinking water for pigs and chickens (FR)

Doxycycline hyclate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 g of powder contains 500 mg of doxycycline hyclate
(equivalent to 433 mg doxycycline base)

3. PHARMACEUTICAL FORM

Yellow to pale yellow powder for use in drinking water.

4. PACKAGE SIZE

10 x 100 g

5. TARGET SPECIES

Pigs and chickens (broiler, pullet, breeder).

6. INDICATION(S)

Read the label before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administration: orally with the drinking water.
Read the label before use.

8. WITHDRAWAL PERIOD

Pigs:
- Meat and offal: 4 days

Chickens:
- Meat and offal: 3 days, following a dose rate of 10 mg/kg body weight for 4 days.
- Meat and offal: 9 days, following a dose rate of 20 mg/kg body weight for 4 days.
- Eggs: Not authorised for use in laying birds producing eggs for human consumption. Do not use within 4 weeks of onset of the laying period

9. SPECIAL WARNING(S), IF NECESSARY

Read the label before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging: 1 year.
Shelf-life after dilution in drinking water: 24 hours.

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions

12. 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.

13. 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.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4095

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

<PARTICULARS TO APPEAR ON THE INMEDIATE PACKAGE>

LABEL/LEAFLET: BAG of 100 g, 1 kg AND 2.5 kg

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

Marketing authorisation holder:
To be completed nationally

Manufacturer for the batch release
DIVASA-FARMAVIC S.A.
Ctra. Sant Hipòlit, km 71
08503 Gurb-Vic
Barcelona (Spain)

Or
Ceva Santé Animale
200 Avenue de Mayenne – Zone Industrielle des Touches
53000 Laval
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxyval 500 mg/g powder for use in drinking water for pigs and chickens
Sogedoxy 500 mg/g powder for use in drinking water for pigs and chickens (CZ)
Doxyval Vet (DK)
Doxyval 433 mg/g powder for use in drinking water for pigs and chickens (FR)

Doxycycline hyclate

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 g of powder contains 500 mg of doxycycline hyclate (equivalent to 433 mg doxycycline base)

4. INDICATIONS

Pigs: For the treatment of the clinical signs associated with porcine respiratory disease caused by *Actinobacillus pleuropneumoniae, Pasteurella multocida*, and *Mycoplasma hyopneumoniae* susceptible to doxycycline.

Chickens: Where clinical disease is present in the flock, to reduce mortality, morbidity, and clinical signs and to reduce lesions due to Pasteurellosis caused by *Pasteurella multocida* or to reduce morbidity and lesions in respiratory infections caused by *Ornithobacterium rhinotracheale (ORT)*.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to any of excipients.
Do not use in animals with an impaired liver function.

6. ADVERSE REACTIONS

Tetracyclines may - in very rare cases (less than 1 animal in 10,000 animals, including isolated report) - induce photosensitivity and allergic reactions. If suspected adverse reactions occur, treatment should be discontinued. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon

7. TARGET SPECIES

Pigs and chickens (broiler, pullet, breeder).

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

Administration orally with the drinking water.

The recommended dose in pigs is:
12.5 mg doxycycline hyclate (25 mg product) per kg body weight per day for 4 consecutive days. If no improvement in clinical signs is seen within this time, the diagnosis should be reviewed and treatment changed. In case of severe infections the medication period may be prolonged for a maximum of 8 consecutive days as determined by the attending veterinary surgeon.

The recommended dose in chickens is:
10 mg doxycycline hyclate (20 mg product) per kg body weight per day for 3-4 consecutive days in case of infections caused by *P. multocida* and
20 mg doxycycline hyclate (40 mg product) per kg body weight per day for 3-4 consecutive days in case of infections caused by *O. rhinotracheale.*

Based on the dose to be used, and the number and weight of the animals to be treated, the exact daily amount of product can be calculated. The following formula can be used to calculate the concentration of the product in drinking water:

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

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage body weight should be determined as accurately as possible. The uptake of medicated drinking water depends on the clinical condition of the pigs/chickens. In order to obtain the correct dosage the concentration of doxycycline has 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 refreshed or replaced every 24 hours.
It is recommended to prepare a concentrated pre-solution - approximately 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. Solubility of the product is pH dependent and it may precipitate if it is mixed in hard alkaline drinking water. Use at minimum concentrations of 200 mg powder per litre drinking water in areas with hard alkaline drinking water (hardness above 10.2 °d and pH more than 8.1). During the treatment period animals should not have access to other water sources than the medicated water.

10. WITHDRAWAL PERIOD(S)

Pigs:
- Meat and offal: 4 days
Chickens:
- Meat and offal: 3 days, following a dose rate of 10 mg/kg body weight for 4 days.
- Meat and offal: 9 days, following a dose rate of 20 mg/kg body weight for 4 days.
- Eggs: Not authorised for use in laying birds producing eggs for human consumption. Do not use within 4 weeks of onset of the laying period

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 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: 1 year.
Shelf-life after dilution or reconstitution according to directions: 24 hours after dilution in drinking water.

12. SPECIAL WARNINGS

Special precautions for use in animals
Due to likely variability (time, geographical) in susceptibility of bacteria for doxycycline, especially susceptibility of *A. pleuropneumoniae* and *O. rhinotracheale* may differ from country to country and even farm to farm, bacteriological sampling and susceptibility testing are recommended. Use of the product should be based on culture and sensitivity of micro-organisms from diseased cases on farm. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
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

If you know you are allergic to the tetracycline class of antibiotics, special care should be taken when handling this product or the medicated solution.

During preparation and administration of the medicated drinking water, skin contact with the product and inhalation of dust particles should be avoided. Wear impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (e.g. disposable half-mask respirator conforming to European Standard EN149) when applying the product.

In the event of eye or skin contact, rinse the affected area with large amounts of clean water and if irritation occurs, seek medical attention. Wash hands and contaminated skin immediately after handling the product.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show this warning to the physician. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Do not smoke, eat or drink while handling the product.

Take measures to avoid producing dust when incorporating the product into water. Avoid direct contact with skin and eyes when handling the product to prevent sensitisation and contact dermatitis.

Use during pregnancy, lactation or lay

Doxycycline has a low affinity for forming complexes with calcium and studies have demonstrated that doxycycline scarcely affects skeleton formation. No negative effects were observed in poultry after the administration of therapeutic doses of doxycycline.

In the absence of specific studies the use of the product is not recommended during pregnancy or lactation.

Interactions with other medicinal products and other forms of interactions

Do not combine with antibiotics that are bacteriocidal e.g. penicillins or cephalosporins.

Absorption of doxycycline can be decreased in the presence of high quantities of calcium, iron, magnesium or aluminium in the diet. Do not administered together with antacids, kaolin and iron preparations.

It is advised that the interval between the administration of other products containing polyvalent cations should be 1-2 hours because they limit the absorption of tetracyclines.

Doxycycline increases the action of anticoagulants.

The solubility of the product is pH dependent and will precipitate if mixed in alkaline solution.

Do not store the drinking water in metallic containers.

Overdose

Overdoses up to 1.6 times the label recommended dose resulted in no clinical signs that could be attributed to treatment. Poultry tolerate double overdoses of doxycycline (40 mg/kg body weight) without any clinical effect

Incompatibilities

Solubility of doxycycline is pH dependent. Precipitation will occur in an alkaline solution. 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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pharmaceutical form

Yellow to pale yellow powder for use in drinking water.

Pack size

Bag, 100, 1000 and 2500 g. Box 10 x 100 g
Not all pack sizes may be marketed.

For animal treatment only – to be supplied only on veterinary prescription.
Authorisation number:
EXP {month/year}
Batch {number}

19 September 2016