B. PACKAGE LEAFLET

PACKAGE LEAFLET

ES : DOXI – 10 S.P. PREMIX
BG, PL, RO : Doxi SP 100 mg/g premix for porcine

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

S.P VETERINARIA S.A.
Ctra. Reus-Vinyols, km 4,1
43330 RIUDOMS
TARRAGONA

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ES : DOXI – 10 S.P. PREMIX
BG, PL, RO : Doxi SP 100 mg/g premix for porcine

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

Doxycycline (hyclate) .....100 mg/g

4. INDICATION(S)

Porcine (fattening pigs): treatment of porcine respiratory complex caused *by Pasteurella multocida, Bordetella bronchyseptica* and/or *Mycoplasma hyopneumoniae.*

For any infectious process a bacteriological confirmation of the diagnosis is recommended and a sensitivity test for the bacteria causing the process should be performed.

5. CONTRAINDICATIONS

Do not administer to animals with known hypersensitivity to tetracyclines.
Do not administer to animals with hepatic disturbances.
Do not use in case of known resistance to tetracyclines

6. ADVERSE REACTIONS

- As for all tetracyclines, photosensitization as well as allergic reactions may occur.
- Prolonged treatments can lead to digestive disturbances and intestinal disbiosis.

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

7. TARGET SPECIES

Porcine (fattening pigs)

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

In-feed use
13 mg of doxycycline / kg b.w. / day, during 8 days, approximately 250 g of doxycycline / tonne feed, for an estimated average consumption of 50 g of feed / kg b.w. / day, (equivalent to 2.5 kg of the product / tonne feed).

The dosage of the product to be incorporated in feed should be established according to the following formula:

130 mg the product / (kg b.w. * day) * (average body weight of animals in kg) / (average feed daily intake in kg)

Feed consumption will depend on the clinical condition of the animal. In order to obtain a correct dosage, the concentration of the antimicrobial agent should be adjusted taking into account the daily feed intake at the onset of treatment.

The product may be administered in pellets as well as non-pelleted feed. Recommended granulation conditions are: vapour during 15 minutes at a temperature not exceeding 80 ºC and pressure of 2.5 atm.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Pigs: meat and offal: 5 days

11. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.
Protect from light

12. SPECIAL WARNING(S)

Sick animals may have reduced appetite if necessary be medicated parenterally

Special precautions for use

For any infectious process a bacteriological confirmation of the diagnosis is recommended and a sensitivity test for the bacteria causing the process should be performed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals.

- People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.
- Handle the veterinary medicinal product with care to avoid dust inhalation and contact with skin and eyes during incorporation of premix into feed, as well as when administering the medicated feed to animals, by taking specific precautions:
  - Take the appropriate measures to avoid dust dissemination during the incorporation of the premix into feed.
  - Wear a dust mask (in compliance with EN140FFP1), gloves, overalls and approved safety glasses.
  - Avoid contact with skin and eyes. Rinse thoroughly with water in case of exposure.
  - Do not smoke, eat or drink when handling the veterinary medicinal product.
  - If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the present warning to the doctor. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Use during pregnancy, lactation or lay

In studies performed with experimental animals (mice and rabbit) toxic effects were not observed. The safety of the product has not been demonstrated in pregnant or lactating sows, therefore its use is not recommended in these animals.

Interactions with other medicinal products and other forms of interaction

Doxycycline absorption is diminished by the presence of high concentrations of calcium, iron, magnesium and aluminium in the diet. Do not administer along with antiacids, kaolin or iron preparations.
It is advised that the interval between the administrations of other products containing polyvalent cations should be 1-2 hours because the limit the absorption of tetracyclines.
Do not combine with bactericidal antimicrobial agents as penicillin and cephalosporins

Doxycycline increases the action of anticoagulants.

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

Not described.

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

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

MARKETING AUTHORISATION NUMBER: 1726 ESP

PRESENTATIONS: 1 KG AND 25 KG

PL: Termin ważności (EXP)

Wyłącznie dla zwierząt.
Wydawany z przepisu lekarza – Rp. Do podawania pod nadzorem lekarza weterynarii

Nr serii (Lot)

Keep out of the reach and sight of children
To be supplied only on veterinary prescription.
Administration by a veterinary surgeon or under their direct responsibility.