PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Doxyprex 100 mg/g Premix for medicated feeding stuff for pigs (after weaning)

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

Marketing authorisation holder and manufacturer responsible for batch release:
Industrial Veterinaria, S.A.
Esmeralda, 19
E-08950 Esplugues de Llobregat (Barcelona) Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxyprex 100 mg/g Premix for medicated feeding stuff for pigs (after weaning)
Doxycycline hyclate

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

Yellow granules containing 100 mg of doxycycline base as hyclate per gram of product. Semoline is employed as carrier.

4. INDICATION(S)

For the treatment and prevention of porcine respiratory disease caused by *Pasteurella multocida* and *Bordetella bronchiseptica,* susceptible to doxycycline, when the disease has been diagnosed in the herd.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to tetracyclines.
Do not use in animals with hepatic damage.

6. ADVERSE REACTIONS

Allergic reactions and photosensitivity may appear, as for all tetracyclines.
Digestive alterations by intestinal dysbiosis may appear in very long-term treatments.
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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (after weaning)

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

In feed use
The recommended dose is 10 mg of doxycycline/kg of body weight/day (equivalent to 1 g of Doxyprex/10 kg of b.w.) for 7 consecutive days. For pigs with a daily consumption of 40 g of feed/kg b.w./day this dose corresponds to 250 mg of doxycycline per kg of feed which gives a rate of incorporation of 2.5 kg/Ton.

The feed consumption will depend on the clinical condition of the animal. In order to obtain a correct dosage, the concentration of the product should be adjusted taking into account the daily feed intake at the onset of treatment.
The following calculation can be used to calculate dosage:
mg Doxyprex/kg feed = 10 mg doxycycline/kg b.w. x 10 x bodyweight (kg)/Daily feed intake (kg)

9. ADVICE ON CORRECT ADMINISTRATION

Mixing instructions:

The premix is only intended to be incorporated into granulated medicated feeding stuffs.
A horizontal ribbon mixer should be used to incorporate the product into the feeding stuff. It is recommended that one part of Doxyprex is first mixed into one part of the feeding stuff, followed by the rest of the feeding stuff and mixed well. Medicated feed may then be granulated. Pelleting conditions involve preconditioning ingredients with steam at 55-65ºC and 10% moisture. Before granulation, flour should not reach a temperature higher than 55 ºC.

10. WITHDRAWAL PERIOD

Meat and offal: 7 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 30 ºC.
After first opening, keep the pack tightly closed. Store in a dry place.

EXP {month/year} 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 incorporation into meal or pelleted feed: 3 months.

12. SPECIAL WARNING(S)

Special warnings for each target species:
The uptake of medicated feed by animals can be altered as a consequence of illness. In case of insufficient feed intake, animals should be treated parenterally.

Special precautions for use in animals:
Due to variability in susceptibility of bacteria for doxycycline, use of the product should be based on bacteriological sampling and sensitivity testing or recent experience on the farm and

take into account official and local antimicrobial policies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid handling the product if hypersensitivity to tetracyclines exists.
Care should be taken to avoid contact with the product during its incorporation to the feed as well as during the administration of the medicated feed to the animals.
Adequate measures should be taken to avoid powder dissemination during the incorporation of the product to the feed.
It is recommended to use a non-powder mask (according to the EN140FFP1 regulation), gloves, working suit and approved safety glasses.
Avoid skin and eye contact. In case of accidental contact with eyes and spillage onto skin, wash the exposed area with plenty of clean water.
Do not smoke, eat or drink while handling the product.
If symptoms appear after exposition as a skin eruption, seek medical advice and show the package leaflet to the physician. Inflammation of the face, lips and eyes or respiratory difficulty are more severe signs that require urgent medical attention.

Use during pregnancy, lactation or lay:
The use is not recommended during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Absorption of doxycycline may be diminished in the presence of high quantities of Ca, Fe, Mg or Al in the diet. Do not administer together with antacids, kaolin and iron preparations.
Do not administer in conjunction with bactericidal antibiotics like beta-lactames.
Do not administer with oxidant substances.

Overdose (symptoms, emergency procedures, antidotes):
No symptoms of intolerance to the product have been detected in the studies conducted in which a medicated feed with 600 ppm (2.4 times the recommended dose) was administered to the 20-30 kg animals during twice the recommended period.

Incompatibilities:
Do not administer with oxidant substances.
Do not mix with any other veterinary medicinal product.

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 or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.
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

{<DD/MM/YYYY>}

15. OTHER INFORMATION

To be supplied only on veterinary prescription

PACKAGE SIZE
1 kg
5 kg
20 kg
25 kg
Not all pack sizes may be marketed.

16. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

17. MARKETING AUTHORISATION NUMBER(S)

{number}

18. MANUFACTURER'S BATCH NUMBER

Batch: {number}