B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

ORNICURE 150 mg/g, powder for use in drinking water for racing pigeons and ornamental birds (all CMS except FR)
ORNICURE, powder for use in drinking water for racing pigeons and ornamental birds (FR)

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

Marketing authorisation holder: Oropharma nv, Kapellestraat 70, BE-9800 Deinze, Belgium.
Manufacturer responsible for batch release: Laboratoria Smeets nv, Industriepark Terbekenhof, Fotografielaan 42, BE-2610 Wilrijk, Belgium.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ORNICURE 150 mg/g, powder for use in drinking water for racing pigeons and ornamental birds (all CMS except FR)
ORNICURE, powder for use in drinking water for racing pigeons and ornamental birds (FR)

Doxycycline hyclate

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

Per 1 gram

Active substance: Doxycycline hyclate 150.0 mg, corresponding to 130.0 mg of doxycycline.
Other ingredients: citric acid, sodium dihydrogen citrate, lactose monohydrate.

The product is a fine, light yellow to yellow powder.

4. INDICATION(S)

Treatment of infections caused by micro-organisms:

- Racing pigeons: treatment of infections caused by *Chlamydophila psittaci, Pasteurella multocida, Mycoplasma spp.*
- Ornamental birds: treatment of infections caused by *Chlamydophila psittaci*

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance, to other tetracyclines or to any of the excipients.

6. ADVERSE REACTIONS

As for all tetracyclines, on rare occasions allergic reactions and sensitivity to sunlight may occur.
Intestinal flora may be affected if treatment is prolonged (more than 10 days), and this may result in digestive disturbance. If suspected adverse reactions occur, treatment should be stopped.
A slight weight loss may occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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

Pigeons (racing pigeons) and ornamental birds, particularly Psittaciformes (e.g. African grey parrots, Goffin's cockatoos, cockatiels)

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

In drinking water use.

Racing pigeons:

- Treatment of infections due to *Chlamydophyla psittaci*:
  46 mg doxycycline hyclate/day/kg bodyweight for at least 30 days
- Treatment of infections due to other pathogens (*Pasteurella multocida, Mycoplasma spp)*: 20 mg doxycycline hyclate/day/kg bodyweight for 5 days

The medicated drinking water can also be administered directly into the crop.

Ornamental birds, particularly Psittaciformes (e.g. African grey parrots, Goffin's cockatoos, cockatiels):

For the treatment of infections due to *Chlamydophyla psittaci*, the drinking water should be medicated in:

African grey parrots:
at a dose of 800 mg doxycycline hyclate/day/L drinking water ad libitum for 42 days or 54 mg doxycycline hyclate/day/kg bodyweight;

Goffin’s cockatoos:
at a dose of 400 mg doxycycline hyclate/day/L drinking water ad libitum for 42 days or 24 mg doxycycline hyclate/day/kg bodyweight;

Cockatiels:
at a dose of 400 mg doxycycline hyclate/day/L drinking water ad libitum (or 40 mg doxycycline hyclate/day/kg bodyweight via feeding tube into the crop) for 30 days.

Owing to physiological and pharmacokinetic differences between the wide range of species for which this product is indicated, the dose rates above are for guidance only. Depending upon the species of animal and the infection to be treated, alternative doses may be appropriate using an evidence-based approach. However, any change in dosing regimen should be based on a benefit:risk assessment by the responsible veterinarian, as tolerance at higher doses has not been investigated.

The exact daily amount of the product can be calculated using the following formula as guidance:

$$\frac{\text{... mg product/kg bodyweight/day*} \times \text{mean bodyweight (kg) of birds to be treated}}{\text{Mean daily water uptake (L) per bird}} = \text{... mg product per L drinking water}$$

* 10 mg doxycycline hyclate/kg bodyweight is equivalent to 67 mg product/kg bodyweight.

To ensure a correct dosage, the body weight should be determined as accurately as possible.

The uptake of medicated drinking water depends on the clinical condition of the birds. To obtain the correct dosage the concentration in the drinking water may have to be adjusted accordingly.
The medicated drinking water is a clear, colourless to yellow solution.

The maximal solubility of the product in soft/hard water at 20°C is around 390 g/L and in soft/hard water at 5°C around 190 g/L.
Warning: The solubility of the product depends on the pH-value; in hard alkaline water the product can precipitate. Water with a hardness of > 19.2°d and a pH-value of > 8.1 is not suitable for dissolving this product.

9. ADVICE ON CORRECT ADMINISTRATION

It is recommended to use suitably calibrated weighing equipment if only parts of the packs are used.
Add the daily amount to the drinking water such that all medication will be consumed in 24 hours.
Replace the medicated drinking water every 24 hours.

No other source of drinking water should be available during the medication period. Keep racing pigeons in the pigeon loft during treatment.
Clean the water supply system appropriately after the end of the medication period to avoid intake of sub-therapeutic amounts of the active substance.

10. WITHDRAWAL PERIOD

Not authorised for use in birds intended for human consumption. Not for use in birds producing or intended to produce eggs for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions.
200 g bag: tightly reclose the bag after opening in order to protect from light.
Following reconstitution, the medicated solutions should be protected from direct sunlight.

Do not use this veterinary medicinal product after the expiry date which is stated on the label or carton after "EXP". The expiry date refers to the last day of that month.

Shelf life after first opening the 4 g sachet: use immediately. Do not store.
Shelf life after first opening the 200 g bag: 1 month.
Shelf life after dilution or reconstitution according to directions: 24 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
The uptake of medicated drinking water by animals can be altered as a consequence of illness and should be monitored carefully. In case of insufficient uptake of water, it is advised to administer doxycycline directly into the crop or to medicate parenterally.

Medication should be combined with good management practices, for example good hygiene and ventilation and, as far as applicable, appropriate stocking density.

Doxycycline (re)absorption may be reduced when birds are given grit. It is therefore recommended to suppress grit and mineral additives during the treatment in pigeons and to limit calcium to a maximum content of 0.7% in pelleted feed in parrots.

Cross-resistance has been shown between doxycycline and others tetracyclines. Use of the product should be carefully considered when susceptibility testing has shown resistance to tetracyclines because its effectiveness may be reduced.

Special precautions for use in animals:
Due to the likely variability (time, geographical) in the susceptibility of bacteria to doxycycline, bacteriological sampling and susceptibility testing of micro-organisms originating from diseased animals are strongly recommended.
Use of the product deviating from the instructions given in the package leaflet may increase the frequency of bacteria resistant to doxycycline due to the potential for cross resistance with other tetracyclines and may decrease the effectiveness of the treatment.

Use of the product should take into account official and local antimicrobial policies.
Avoid administration in oxidized drinking equipment.
The quality of the drinking water may influence the bioavailability of the product. See Section 8.

Toxic concentrations might also be reached in birds housed in hot, outdoor climates where water consumption is increased. Birds undergoing treatment should be monitored for signs of doxycycline toxicosis, including lethargy, inappetance, inactivity, and passing yellow or green urine. Doxycycline toxicosis caused hepatic damage and dysfunction that may result in high plasma AST, lactate dehydrogenase, and bile acids. Doxycycline treatment should be discontinued and general supportive care started if doxycycline toxicosis is suspected.

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

This product may cause contact dermatitis and/or hypersensitivity reactions if contact is made with the skin or eyes (powder and solution), or if the powder is inhaled. People with a possible hypersensitivity to tetracyclines should avoid contact with this veterinary medicinal product.

Take measures to avoid producing dust or inhalation of dust particles when incorporating the product into water. Avoid direct contact with skin and eyes when handling and administering the product.

Wear impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (disposable half-mask respirator conforming to European Standard EN 149 (FFP) or a non-disposable respirator to European Standard EN 140 with filter to EN 143) during the preparation and the administration of the solution.

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.

In case of accidental ingestion, seek medical attention.

Lay:
The safety of the veterinary medicinal product has not been established during the reproduction period, i.e., the time period from mating until the end of feeding the progeny. During this time period the use of the product is not recommended.

Interaction with other medicinal products and other forms of interaction:
Concurrent administration of doxycycline with any divalent cations (e.g. Ca, FE, Mg, Al, divalent ions of antacids) should be avoided as this may lead to decreased bioavailability.
Doxycycline may enhance the effect of anticoagulants.
Do not administer together with kaolin, iron preparations and antacids.
Do not use in conjunction with bactericidal antibiotics, such as penicillins, cephalosporins and beta-lactam antibiotics due to antagonism of the mode of action.

Overdose (symptoms, emergency procedures, antidotes):
Gastrointestinal effects. Ornamental birds and racing pigeons can regurgitate after administration of high dosages.

In Goffin's cockatoos at a dose of 30 mg doxycycline hyclate/kg bodyweight/day for 42 consecutive days changes in plasma biochemical analyses suggest mild hepatic damage which disappears 7 days after the end of the treatment.

Major 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 or pharmacist 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

To be completed nationally

15. OTHER INFORMATION

Pack sizes: 8 x 4 g and 200 g.
Not all pack sizes may be marketed.