FEDERAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

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(Reference Member State)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Ornicure 150 mg/g powder for use in drinking water
Date created: July 2017

MODULE 1

PRODUCT SUMMARY

EU Procedure number	BE/V/0030/001/DC
Name, strength and pharmaceutical form	Ornicure 150 mg/g powder for use in drinking water
Applicant	Oropharma n.v. Kapellestraat 70 9800 Deinze Belgium
Active substance(s)	doxycycline hyclate
ATC Vetcode	QJ01 AA 02
Target species	Racing pigeons and ornamental birds, particularly Psittaciformes (e.g. African grey parrots, Goffin's cockatoos, cockatiels)
Indication for use	Treatment of infections caused by micro-organisms susceptible to doxycycline: Racing pigeons: *Chlamydophila psittaci, Pasteurella multocida, Mycoplasma spp.* Ornamental birds: *Chlamydophila psittaci*

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MODULE 2

The Summary of Product Characteristics (SPC) for this product is available in the VMRI Product Index on the Heads of Veterinary Medicines Agencies website (http://mri.medagencies.org/veterinary/).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended
Date of completion of the original decentralised procedure	25/05/2016
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	Germany, France, the Netherlands, Poland, Portugal and United Kingdom

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released onto the market. It has been shown that the product can be safely used in the target species; the rare reactions observed are indicated in the SPC. The product is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
As Ornicure 150 mg/g is a generic, the efficacy is considered identical to that of the reference product.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 150 mg/g doxycycline hyclate as active substance and the excipients anhydrous citric acid, anhydrous sodium dihydrogen citrate and lactose monohydrate.

The container/closure systems are:

Carton box with 8 single-use aluminium foil sachets, containing 4 g powder each. Each sachet contains 600 mg of doxycycline hyclate.

- Box: carton
- Sachets: Paper-PE-Alu-PE

Polypropylene jar with screw cap containing a bag of 200 g powder.

- Jar: PP
- Scew cap: HDPE
- Bag: Paper-PE-Alu-PE

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

The product is manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post-authorisation.

C. Control of Starting Materials

The active substance is doxycycline hyclate, an established active substance described in the Ph. Eur. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

Scientific data and/or certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D. Control on intermediate products

Not applicable

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

Conclusions on the shelf life for this product, are:

- shelf life of the veterinary medicinal product as packaged for sale of 3 years
- shelf life after first opening of the 4 g sachet: use immediately
- shelf life after first opening of the 200 g bag: 1 month
- shelf life after dilution or reconstitution according to directions: 24 hours

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

As this is a generic application according to Article 13(1) of Directive 2001/82/EC as amended, and Ornicure 150 mg/g may be considered bioequivalent with a reference product, the results of pharmacological tests are not required.

In accordance with point 7.1.C of the Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2) the principle of exemption from bioequivalence studies for Ornicure 150 mg/g and its reference product was applied.

Toxicological Studies

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, and as bioequivalence with a reference product has been established, the results of toxicological studies are not required.

User Safety

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, and bioequivalence with a reference product has been established, full user safety data are not required.

The candidate product contains anhydrous citric acid and anhydrous sodium dihydrogen citrate as acidifying agents, and lactose monohydrate as a filler. All ingredients have a high solubility in water.

The risk for the user with the candidate product concerning anhydrous citric acid is not higher than the one related to the reference product.

As the qualitative composition of the test product differs by the presence of anhydrous sodium dihydrogen citrate, a user safety risk assessment was done based on material safety data sheet for anhydrous sodium dihydrogen citrate.

The modified section 4.5 is adequate and justified concerning the presence of anhydrous citric acid and anhydrous sodium dihydrogen citrate:

“Avoid direct contact with skin and inhalation during the preparation and administration to prevent sensitisation and contact dermatitis. It is recommended to wear impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (disposable half-mask respirator conforming to European Standard EN 149 (FFP2) or a nondisposable respirator to European Standard EN 140 with a 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. Do not smoke, eat or drink while handling the product".

Environmental Risk Assessment

Phase I

The environmental risk assessment can stop in Phase I because following the decision tree as described in the VICH GL6 (CVMP/VICH/592/98-FINAL) it was concluded that no further phase II should be assessed as the product should be strictly used in non-food producing animals.

Conclusion

Based on the available information the product is not expected to pose an unacceptable risk for the environment when used according to the recommended use.

III.B Residues documentation

Not applicable as the product is not authorised for use in birds intended for human consumption and not for use in birds producing eggs for human consumption.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

As this is a generic application according to Article 13(1) of Directive 2001/82/EC as amended, and bioequivalence with a reference product has been established, the results of pharmacological studies are not required.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, and bioequivalence with a reference product has been established, the results of tolerance studies are not required. However, for each target species tolerance to the active substance at the recommended posology was supported by bibliographic references.

Resistance

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, and bioequivalence with a reference product has been established, resistance data are not required. However, resistance was documented based on a bibliographic review of the target pathogens.

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IV.B Clinical Studies

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, and bioequivalence with a reference product has been established the results of clinical studies are not required. However on the basis of the bibliographic references available, posology has been specified for racing pigeon and the minor species covered by the term ornamental birds.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the overall risk / benefit profile of the product is favourable.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available in the VMRI (http://mri.medagencies.org/veterinary/).

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

None