Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
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(Germany)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Soliphen 120 mg tablets

Date: 22 December 2021

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0305/003/DX/001
Name, strength and pharmaceutical form	Soliphen, 120 mg, tablet for dogs
Applicant	Dômes Pharma 3 Rue Andre Citroën 63430 Pont-Du-Chateau France
Active substance(s)	Phenobarbital
ATC Vetcode	QN03AA02
Target species	Dogs
Indication for use	Prevention of seizures due to generalised epilepsy in dogs

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of the original Decentralised procedure	22 December 2021
Date product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	AT, BE, ES, FR, IT, LU, NL, PT, UK(NI)

I. SCIENTIFIC OVERVIEW

This is an extension application to Soliphen 60 mg tablets for dogs to add the strength 120 mg tablet.
The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the products can be safely used in the target species; the reactions observed are indicated in the SPC.
The products are safe for the user, and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of the product was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The tablet contains 120 mg phenobarbital as active substance and the excipients cellulose microcrystalline, pregelatinised starch, lactose monohydrate, colloidal hydrated silica, pig liver flavour, dried yeast from *Saccharomyces* and magnesium stearate.

The container/closure system consists of a PVC/aluminium thermosealed blister.

The choice of the formulation is justified. 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 data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is phenobarbital, an established active substance described in the European Pharmacopoeia. 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 substance 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 products have been provided in accordance with applicable European guidelines, demonstrating the stability of the products throughout its shelf life when stored under the approved conditions.

G. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacological and toxicological studies are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline and warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in non-food animals.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 of Directive 2001/82/EC, as amended, and bioequivalence with the reference product Epiphen® 60 mg Tablets (Vetoquinol UK Ltd, authorised in the UK 11 April 1996) has been demonstrated in accordance with section 7.2 of the Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMEA/CVMP/016/00-Rev. 3), efficacy studies are not required. The efficacy claim for the product is equivalent to that of the reference product. The product literature has been updated as requested by the RMS and CMSs.

IV.A Pre-Clinical Studies

Pharmacology

This is an extension application to Soliphen 60 mg tablets for dogs, for which bioequivalence with the reference product has been accepted previously.
As similarity of *in vitro* dissolution has been demonstrated for Soliphen 60 mg and 120 mg, respectively, bioequivalence to the reference product can be assumed for the 120 mg strengths. Thus, data on pharmacodynamics and pharmacokinetics are not required.

Tolerance in the Target Species of Animals

Due to the nature of the application and since bioequivalence of the candidate and the reference product is accepted, studies on target animal tolerance are not required. The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

The application is made in accordance with Article 13 of Directive 2001/82/EC, as amended and pharmaceutical equivalence of the candidate and reference products are accepted. Therefore, the applicant is not required to submit results of clinical studies.

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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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 on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

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.