LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Somulose, 400 mg/25 mg/ml, Avlivningsvätska för djur
Secobarbital Sodium

Applicant: Dechra Limited

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MODULE 1

PRODUCT SUMMARY

Asp no	**2014-0114**
Name, strength and pharmaceutical form	**Somulose, 400 mg/25 mg/ml, Avlivningsvätska för djur**
Applicant	**Dechra Limited** **Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2 RW**
Active substance(s)	**Secobarbital Sodium** **Cinchocaine Hydrochloride**
ATC Vetcode	**QN51AA52**
Target species	**Dogs, cats, horses and cattle.**
Indication for use	***"For euthanasia in dogs, cats, horses and cattle only."***

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Medical Products Agency's website (http://www.lakemedelsverket.se/english/).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Hybrid application, 13(3), in accordance with Directive 2001/82/EC
Date of completion of the original national	2014-12-22
Date product first authorised	2015-01-09

I. SCIENTIFIC OVERVIEW

The veterinary medicinal product that is the subject of this application is SOMULOSE AVLIVNINGSVÄTSKA FÖR DJUR. SOMULOSE AVLIVNINGSVÄTSKA FÖR DJUR is a clear, slightly straw coloured viscous solution for the euthanasia in dogs, cats, horses and cattle only. The active ingredients of the product are secobarbital sodium & cinchocaine hydrochloride.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains secobarbital sodium 400 mg/ml, cinchocaine hydrochloride 25 mg/ml and the excipients propylene glycol, ethanol and water for injections.

The container/closure system consists of 25 ml and 50 ml amber glass multidose vials with red chlorobutyl rubber stoppers.

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.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substances are secobarbital sodium and cinchocaine hydrochloride. The active substances are manufactured in accordance with the principles of good manufacturing practice.

The active substances specifications are considered adequate to control the quality of the materials. Batch analytical data demonstrating compliance with these specifications have been provided.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on intermediate products (pharmaceuticals)

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<s> 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.

The claim of 60-days stability after broaching is based on the demonstration of stability for a batch broached and stored 60 days at +25°C.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

The pharmaceutical aspects of this product are identical to the reference product.

Warnings and precautions as listed on the product literature are adequate to ensure safety of the product to users / the environment / consumers.

V. CLINICAL ASSESSMENT (EFFICACY)

The applicant has submitted this application in accordance with Article 13(3) of Directive 2001/82/EC, as amended, and the product has been demonstrated to be ‘a hybrid generic’ on the basis that the product is to be intravenously administered as a solution and contains the same active substances and excipients as the veterinary medicinal product currently approved in the UK and Ireland for use in the target species. The stated reason for submitting this hybrid application rather than a generic application is the fact that the pharmaceutical form for this product will be different in Sweden.

The applicant claims exemption from the requirement of performing bioequivalence studies. According to the Guideline on the conduct of bioequivalence studies for veterinary medicinal

products (EMA/CVMP/016/00-Rev.2), no bioequivalence study is necessary for a solution that is to be administered intravenously if it has the same active substance as the currently approved product and provided that there are no excipients that interact with the active substance (e g complex formulation). The excipients in the applied formulation are not considered to be excipients that may interact with the active substance. The composition of the applied product is identical to the approved formulation of the reference product. Thus, the absence of bioequivalence studies is acceptable.

As this is a hybrid generic application according to Article 13, and bioequivalence with a reference product can be concluded, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

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 Medical Products Agency's website (http://www.lakemedelsverket.se/english/).

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