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

Tendease 50,000 IU/100 g gel for horses

Date: 18 February 2013

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0148/001/DC
Name, strength and pharmaceutical form	Tendease 50,000 IU/100 g gel for horses
Applicant	Eurovet Animal Health BV Handelsweg 25 5531 AE Bladel The Netherlands
Active substance(s)	Heparin sodium,Hydroxyethyl salicylate, Levomenthol

ATC Vetcode	QM02AC99
Target species	Horses
Indication for use	Cutaneous use

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(1) of Directive 2001/82/EC as amended.
Date of completion of the original Decentralised procedure	28.11.2012
Date product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	BE, NL, UK

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.

The safety and efficacy aspects of this product are identical to Tensolvet 50000 I.E./100g. The initial application for Tensolvet 50000 I.E./100g was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains the active substances heparin sodium (50000 IU/100 g), hydroxyethyl salicylate (5.00 g/100 g) and levomenthol (0.50 g/100 g), the colouring agent copper complexes of chlorophyllin (E 141ii) and the excipients macrogolglycerol cocoate, propylene glycol, carbomer 980, trolamine, isopropyl alcohol, and purified water.

The container/closure system consists of a polyethylene bottle and a polypropylene/ HDPE cap with a tilting lid. The particulars of the containers and controls performed are provided and conform to the regulation.

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 from 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 heparin sodium, hydroxyethyl salicylate and levomenthol. They are established substances described in the European Pharmacopoeia. The active substances are 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.

For heparin sodium and levomenthol reference is made to EDQM certificates of suitability (CEP). For hydroxyethyl salicylate an Active Substance Master File (ASMF) has been provided.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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

E. Control on intermediate products

There are no intermediate products.

F. 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.

G. Stability

Stability data on the active substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substances 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 a stability of 6 months after broaching is based on the demonstration of stability for batches broached and stored under the approved conditions during this period.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, and the Applicant has demonstrated that the product meets all relevant criteria for a generic, results of safety and residue tests are not required.

The pharmacological-toxicological aspects of this product are identical to the reference product.

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

III.A Safety Testing

Pharmacological Studies

No data provided due to generic application.

Toxicological Studies

No data provided due to generic application.

Observations in Humans

No data provided due to generic application.

User Safety

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

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The product is not expected to pose a risk for the environment when used according to SPC and product information.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because the product is identical to the reference product, and the withdrawal period is the same as for the reference product.

MRLs

The veterinary medicinal product is intended for topical use in a food-producing target species (horse).

The active compounds of Tendease 50,000 IU/100 g gel for horses (heparin sodium, levomenthol, hydroxyethyl salicylate) were evaluated and classified according to Council Regulation (EEC) No 2377/90, as replaced by Regulation (EC) No 470/2009 of the European Parliament and of the Council by 6 May 2009. The results were published in Commission Regulation (EU) No 37/2010 of 22 December 2009. No MRLs are required for these substances.

The following excipients of Tendease 50,000 IU/100 g gel for horses are listed in Annex 1, Allowed Substances, of Regulation (EU) No 37/2010 for all food-producing species:

- Macrogolglycerol cocoates
- Propylene glycol
- Isopropyl alcohol

No MRLs are required for these excipients.

The excipients purified water, carbomer and triethanolamine are considered as not falling under the scope of Regulation (EC) No 470/2009, copper complexes of chlorophylls and chlorophyllins (E 141) are an EU-authorised food colour.

Withdrawal Periods

The same withdrawal period as authorised for the reference product has been set for Tendease 50,000 IU/100 g gel for horses:
Meat and offal: 0 days
Do not use in mares whose milk is intended for human consumption.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, where the applicant refers to the own product Tensolvet 50000 I.E./100g and confirms that Tensolvet and Tendease are identical, bioequivalence with the reference product can be taken for granted, and new efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

As the composition of Tendease and the reference product Tensolvet 50000 is qualitatively and quantitatively identical and the product is intended for use in the same species, for the same indications and at the same dose and treatment regimen as the reference product, Tendease can be considered a generic of Tensolvet 50000. No new target species tolerance data but periodic safety update reports (from May 2003 to May 2011) for the reference product Tensolvet 50000

have been presented. No pharmacovigilance events were reported during this period.

The wording in the product literature of both products is essentially the same, and accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

As the product Tendease 50000 has been justified to be a generic of the reference product Tensolvet 50000, and Tendease shall be used for the treatment of the same indications in horses at the same dose and treatment regimen as Tensolvet, no new clinical studies have been submitted. The reference product has been authorized at a time when no assessment report has been required. Therefore, no such information can be provided.

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.

Quality changes

Summary of change **(Application number)**	**Section updated in Module 3**	**Approval date**

Submission of an updated Ph. Eur. certificate of suitability for an active substance and deletion of a Ph. Eur. certificate of suitability for an active substance Change from a combined label-leaflet to a "separate label and booklet-leaflet" for BE / NL and adaption of the SPC/PIL texts to the newest QRD template (DE/V/0148/IB/002/G)	N/A	03/05/2017
Addition of a manufacturer responsible for all manufacturing steps, including bulk manufacturing, primary and secondary packaging, batch testing and batch release Deletion of the approved manufacturer responsible for batch release (DE/V/0148/II/008/G)	N/A	17/02/2021

Safety/efficacy changes

Summary of change **(Type; application number)**	**Section updated in Module 3**	**Approval date**
<Example: Addition of target species - pigs>	<IIIA>	
(MS/V/XXX/X/II/XX)	<IIIB> <IV>	