Veterinary Medicines Directorate

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Veterinary Medicines Directorate
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Hypertonic 72 mg/ml Solution for Infusion(BE, FR, NL, UK)
Hypertonic 72 mg/ml solution for infusion for cattle, calves, horses, dogs and cats (DE)

Date Created: November 2017

PuAR correct as of 18/03/19 when RMS was transferred to BE.
Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0639/001/DC
Name, strength and pharmaceutical form	Hypertonic 72 mg/ml Solution for Infusion
Applicant	Dechra Limited
Active substance	Sodium chloride
ATC Vetcode	QB05BB01
Target species	Cattle, calves, horses, dogs and cats
Indication for use	In all target species: As adjunctive therapy in the treatment of circulatory shock (hypovolaemic or endotoxaemic).

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

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 conclusion of the decentralised procedure	18 October 2017.
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	Belgium, France, Germany, The Netherlands

I. SCIENTIFIC OVERVIEW

This was an application for a generic product, Hypertonic 72 mg/ml Solution for Infusion, submitted in accordance with Article 13 (1) of Directive 2001/82/EC as amended. The reference product is Hypertonic 7.2% w/v Solution for Injection, previously Vetivex 20. The reference product has been authorised in the UK since December 1998.

The product is indicated for use in cattle, calves, horses, dogs and cats, as an adjunctive therapy in the treatment of circulatory shock, (hypovolaemic or endotoxaemic).

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, any reactions observed are indicated in the SPC.[1] The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy [2] of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains 72 mg/ml sodium chloride (approximate ionic content in millimoles per litre: sodium 1232 mmol/L, chloride 1232 mmol/L) and water for injections.

The container/closure system consists of a polyvinylchloride infusion bag overwrapped with polypropylene. Pack sizes: Individual fluid bags of 500 ml, 3000 ml and 5000 ml, each supplied with a package leaflet, or boxes containing 20 x 500 ml, 4 x 3000 ml or 2 x 5000 ml. Individual units of the product may be supplied but each must be accompanied by a package leaflet.

The particulars of the containers and controls performed are provided and conform to the regulation. The choice of the formulation and the absence of preservative are justified.

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

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of the dissolution of sodium chloride, making up the solution to volume, cooling, mixing, filtering and filling into bags. The filled bags are terminally sterilised by autoclaving under Ph. Eur. conditions.

II.C. Control of Starting Materials

The active substance is sodium chloride, an established active substance described in the European Pharmacopoeia (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.

An acceptable Certificate of Suitability were provided.

Water for injections match the requirements specified in the Ph. Eur. Packaging was suitably defined and approved.

II.C.4. Substances of Biological Origin

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

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.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. Control tests on the finished product include those for: fill volume, pack appearance, assay and identification of the active substance, acidity, visible particles, sub-visible particles, the presence of endotoxins and sterility.

II.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. The certificate of Suitability cites a retest period of 36 months when suitably stored.

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 for stability as cited on the SPC is based on data from 24 months storage.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

This veterinary medicinal product does not contain an antimicrobial preservative. It is intended for single use only and unused contents should be discarded.

Do not store above 25°C.

Do not freeze.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

This was an application for a generic product. Therefore, no toxicological or pharmacological data, other than that required to support the User Risk Assessment were required. An Environmental Safety Assessment was also required. Due to the nature of the active substance, there are no pharmacological or toxicological issues to address. The substance meets the criteria for 'well established use'. The product is additionally qualitatively and quantitatively the same as the reference product.

User Safety

A user risk assessment was provided in compliance with the relevant guideline. Sodium chloride is the key salt within the body, maintaining the osmotic tension of blood and tissues. The most likely route of exposure for humans is dermal. The product is to be used in an environment where it will be handled only by veterinarians or other suitably trained staff.

No specific user warnings are listed on the SPC. The warning 'keep out of the reach and sigh of children is included in the packaging. The following applicant's user recommendations are cited on the SPC:

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:

The product will be used to treat a small number and as such environmental exposure will be low. A Phase II ERA was not required. The SPC and product literature carry a suitable warning for disposal of the product.

III.B.2 Residues documentation

Residue Studies

No residue depletion studies were conducted, sodium chloride does not require a maximum residue limit to be defined, and water for injection does not fall within the scope of Regulation (EC) 470/2009 with regard to residues of veterinary medicinal product of animal origin.

Withdrawal Periods

Meat and offal: Zero days.

Milk: Zero hours.

IV CLINICAL DOCUMENTATION

Due to the nature of the application, whereby bioequivalence with the reference product was accepted under 7.1a of the bioequivalence guideline (EMA/CVMP/016/00-Rev.2), no data were required for this section.

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 benefit/risk profile of the product(s) 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 on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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