IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

UISCE-JECT

PRODUCT SUMMARY

Name, strength and pharmaceutical form	UISCE-JECT, 100 % v/v, solvent for parenteral use
Active substance(s)	Water for Injections
Applicant	SP Veterinaria, S.A. Ctra. Reus - Vinyols Km 4, 1 Riudoms 43330 Spain
Legal basis of application	Article 13 (1) a generic application
Date of Authorisation	15th September 2017
Target species	As required
Indication for use	For use as a sterile solvent for the preparation of veterinary medicinal products intended for parenteral administration where water is a component of the preparation and for reconstituting or diluting veterinary medicinal products for parenteral administration immediately before use.
ATCvet code	QV07AB

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

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 product is safe for the target species, 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 product is indicated for use as a sterile solvent for the preparation of veterinary medicinal products intended for parenteral administration where water is a component of the preparation and for reconstituting or diluting veterinary medicinal products for parenteral administration immediately before use.

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

II. QUALITY ASPECTS

A.Qualitative and Quantitative Particulars

The product contains 100 % v/v water for injections and no excipients. The container/closure system is a 100 ml polypropylene vial with a grey bromobutyl rubber stopper and aluminium flip-off seal.

The 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 for the manufacturing process has been presented in accordance with the relevant European guidelines.

C.Control of Starting Materials

The active substance is water for injections which is 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 has been provided.

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.

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.

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

F.Stability

The active substance is fully tested to ensure compliance with its specification immediately prior to its use in manufacture of the product.

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

G.Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, results of safety tests are not required.

Given that this product contains only sterile water for injections, there are no specific warnings and precautions required to be listed on the product literature. The product literature cross-refers, where appropriate, to the warnings and precautions of the veterinary medicinal product for which water for injections is required to be used as solvent.

IV. CLINICAL ASSESSMENT

There are no efficacy claims for this product. This product is indicated for use as a sterile solvent for the preparation of veterinary medicinal products intended for parenteral administration where water is a component of the preparation and for reconstituting or diluting veterinary medicinal products for parenteral administration immediately before use.

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 indications for use are acceptable and the quality and safety of the product for the target species, humans and the environment is acceptable.

VI. 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 HPRA website.

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.

Changes:
None.