1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UISCE-JECT 100 % v/v, solvent for parenteral use

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Water for Injections 100% v/v

A clear, colourless sterile solvent.

3. CLINICAL INFORMATION

3.1 Target species

As required.

3.2 Indications for use for each target species

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.

3.3 Contraindications

None.

3.4 Special warnings

Use only as a solvent for a veterinary medicinal product for which sterile water is authorised for use for preparation, reconstitution or dilution.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse reactions

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Parenteral use.

Refer to recommendations of the veterinary medicinal product for which this veterinary medicinal product is used as solvent.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.
The withdrawal period of the veterinary medicinal product for which this veterinary medicinal product is used as solvent should be referred to.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QV07AB

4.2 Pharmacodynamics

Not applicable.

4.3 Pharmacokinetics

Not applicable.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

Shelf life after first opening the immediate packaging: use immediately.

5.3. Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions. Any solution remaining in the vial following withdrawal of the required dose should be discarded. This product does not contain an antimicrobial preservative.

5.4 Nature and composition of immediate packaging

100 ml polypropylene vials with grey bromobutyl rubber stoppers and aluminium flip-off seals.

Pack sizes:
Box with 1 vial of 100 ml
Box with 10 vials of 100 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

There are no special precautions for disposal of any unused veterinary medicinal product. The disposal advice of the veterinary medicinal product for which this veterinary medicinal product is used as solvent should be followed.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Duggan Veterinary Supplies Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10400/003/001

8. DATE OF FIRST AUTHORISATION

15 September 2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

20 December 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).