

## **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

For the full list of excipients, see section 6.1

## **3 PHARMACEUTICAL FORM**

Solvent for parenteral use.

A clear, colourless sterile solvent.

## **4 CLINICAL PARTICULARS**

### **4.1 Target Species**

As required.

### **4.2 Indications for use, specifying the 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.

### **4.3 Contraindications**

None.

### **4.4 Special warnings for each target species**

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

### **4.5 Special precautions for use**

Special precautions for use in animals

None.

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

None.

**4.6 Adverse reactions (frequency and seriousness)**

None.

**4.7 Use during pregnancy, lactation or lay**

Can be used during pregnancy and lactation.

**4.8 Interaction with other medicinal products and other forms of interaction**

None.

**4.9 Amounts to be administered and administration route**

For parenteral use.

Refer to recommendations of veterinary medicinal product for which water for injections is used as solvent.

**4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

Not applicable.

**4.11 Withdrawal period(s)**

Zero days.

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

**5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Not applicable.

Pharmacotherapeutic group: non-therapeutic products; solvents and diluting agents, incl. irrigating solutions.

ATCvet code: QV07AB

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

None.

## **6.2 Incompatibilities**

None known.

## **6.3 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.

## **6.4 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.

## **6.5 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.

## **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

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

**7 MARKETING AUTHORISATION HOLDER**

SP Veterinaria, S.A.  
Ctra. Reus - Vinyols Km 4, 1  
Riudoms 43330  
Spain

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA10790/013/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 15<sup>th</sup> September 2017

**10 DATE OF REVISION OF THE TEXT**