

SUMMARY OF PRODUCT CHARACTERISTICS

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 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

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE