

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dunlop's 100% v/v Water for Injections
Solvent for parenteral use

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Water for injections 100% v/v

Excipients

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solvent for parenteral use.
A clear colourless solution

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 medicines intended for parenteral administration where water is a component of the preparation and for reconstituting or diluting medicines for parenteral administration immediately before use.

4.3 Contraindications:

None.

4.4 Special Warnings for Each Target Species:

No special warnings

4.5 ***Special Precautions for Use:***

Special Precautions for use in animals:

None

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

None

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

None.

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

Water for Injections is safe for use during pregnancy and lactation.

4.8 ***Interactions with other medicinal products and other forms of interaction:***

None.

4.9 ***Amount to be administered and administration route:***

For parenteral use.
Dosage: as required

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

Not Applicable

4.11 ***Withdrawal periods:***

Meat – Zero days
Milk – Zero hours

5. **PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Solvents and diluting agents, incl irrigation solutions

ATCvet Code: QV07AB

5.1 ***Pharmacodynamic properties:***

Not Applicable

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.

6.4 ***Special precautions for storage:***

Do not store above 25°C

Take adequate precautions to maintain sterility.

This product does not contain an antimicrobial preservative

Any water remaining in the vial following withdrawal of the required dose should be discarded.

6.5 ***Nature and composition of immediate packaging:***

Dunlop's Water for Injection is packaged in 20ml, 50ml and 100ml clear grade I glass vials with bromobutyl bungs and aluminium seals.

Not all pack sizes may be marketed.

6.6 ***Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate:***

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. **MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited

Station Works

Camlough Road

NEWRY

Co. Down, BT35 6JP

Northern Ireland

8. **MARKETING AUTHORISATION NUMBER**

Vm 02000/4237

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

17th May 2004

10. **DATE OF REVISION OF THE TEXT**

September 2008