

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Water For Injection 100% v/v Solvent for Parenteral Use.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Water for Injections 100% v/v

Excipients:

For 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 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 veterinary medicinal product to 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 Interaction with other medicinal products and other forms of interaction

None

4.9 Amounts 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 period

Meat - Zero days Milk – Zero hours

5. PHARMACOLOGICAL 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.

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

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 product or waste materials derived from the use of such products

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
Newry
Co. Down, BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4122

9. DATE OF FIRST AUTHORISATION

17th May 1994

10. DATE OF REVISION OF THE TEXT

November 2008.