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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Sterilised Water for Injections BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Ingredient</u>

Water for injections 100 %

3. PHARMACEUTICAL FORM

Solvent for parenteral use.

4. CLINICAL PARTICULARS

4.1 Target species

Not applicable.

4.2 Indications for use, specifying the target species

As a sterile solvent for dissolving or diluting medicaments for parenteral administration.

4.3 Contraindications

None known.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals

Observe aseptic precautions.

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

None.

iii. Other precautions

None.

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4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not contraindicated.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dosage: as required.

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

Not applicable.

4.11 Withdrawal periods

Food producing species – zero days.

5. PHARMACOLOGICAL PARTICULARS

Pharmacotherapeutic group: Solvents and diluting agents including irrigating solutions

ATC Vet Code: QV07AB

5.1 Pharmacodynamic properties

Solvent for parenteral use.

5.2 Pharmacokinetic properties

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

None known.

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6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

6.4 Special precautions for storage

Do not store above 25°C

This product does not contain an antimicrobial preservative.

Any product remaining in the vial following withdrawal of the required volume should be discarded.

6.5 Nature and contents of immediate packaging

100 ml Type I clear glass vial with a chlorobutyl rubber closure and aluminium seal.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

Dechra Regulatory B.V. Handelsweg 25 5531 AE Bladel The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 50406/5031

9. DATE OF FIRST AUTHORISATION

25 October 1994

10. DATE OF REVISION OF THE TEXT

April 2025

Gavin Hall

Approved: 08 April 2025