Reviewed: March 2017 AN: 01588/2016

### MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

# 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sterilised water for injections BP

- 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS
- 4. PHARMACEUTICAL FORM

Solution for injection.

5. PACKAGE SIZE

100 ml

#### 6. INDICATION

A sterile diluent for the preparation of products for parenteral administration.

#### 7. CONTRAINDICATIONS

None known.

- 8. ADVERSE REACTIONS
- 9. TARGET SPECIES

Not applicable.

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### 10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage: as required.

#### 11. WITHDRAWAL PERIOD

zero days.

#### 12. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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.

#### 13. SPECIAL WARNINGS

Special warning for each target species:

None.

Observe aseptic precautions.

User warnings:

None.

Interaction with other medicinal products and other forms of interaction:

None known.

#### 14. EXPIRY DATE

EXP: month/year

# 15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

#### 16. DATE ON WHICH THE LABEL WAS LAST APPROVED

XX/XX/XX

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# 17. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on a veterinary prescription.

POM-V

Prescription Only Medicine – Veterinarian

#### 18. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

#### 19. MARKETING AUTHORISATION NUMBER

Vm 10434/4030

#### 20. MANUFACTURER'S BATCH NUMBER

Lot: {number}

#### 21. OTHER INFORMATION

Local representative:

Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom.

Approved: 22/03/2017