

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
20 ml / 50 ml and 100 ml Cartons

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

WATER FOR INJECTIONS 100% v/v Solvent for parenteral use.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Water for Injections 100% v/v

3. PHARMACEUTICAL FORM

Solvent for parenteral use.

4. PACKAGE SIZE

20 ml/50 ml/100 ml

5. TARGET SPECIES

As required

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For parenteral use.
Dosage: as required.

8. WITHDRAWAL PERIOD

Meat - Zero days Milk – Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

None

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

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.

Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF

For Animal Treatment Only.

POM-V

To be supplied only by veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4122

17. MANUFACTURER’S BATCH NUMBER

Bn.:
D.O.M.:

Distributed by:

Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

50 ml and 100 ml Glass Vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

WATER FOR INJECTIONS 100% v/v Solvent for parenteral use.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

The product contains 100% v/v Water for Injections

3. PHARMACEUTICAL FORM

Solvent for parenteral use.

4. PACKAGE SIZE

50ml/100ml

5. TARGET SPECIES

As required.

6. INDICATION(S)

Water for Injections is intended 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For parenteral use.

Dosage: as required

8. WITHDRAWAL PERIOD

Meat - Zero days Milk – Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

No special warnings.

10. EXPIRY DATE

Exp: dd/mm/yyyy

11. SPECIAL STORAGE CONDITIONS

Take adequate precautions to maintain sterility.

Any solution remaining in the vial following withdrawal of the required dose should be discarded. Do not store above 25°C. This product does not contain an antimicrobial preservative. Keep container in outer carton

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V

To be supplied only on veterinary prescription

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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Station Works
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Co. Down, BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

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NN18 9EX
United Kingdom

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

20 ml Glass Vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

WATER FOR INJECTIONS 100% v/v Solvent for parenteral use.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

The product contains 100% v/v Water for Injections

3. PHARMACEUTICAL FORM

Solvent for parenteral use.

4. PACKAGE SIZE

20ml

5. TARGET SPECIES

As required.

6. INDICATION(S)

N/A

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For parenteral use.
Dosage: as required

8. WITHDRAWAL PERIOD

Meat - Zero days Milk – Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

No special warnings.

10. EXPIRY DATE

Exp: dd/mm/yyyy

11. SPECIAL STORAGE CONDITIONS

Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

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15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
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Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA: 2000
Vm: 02000/4122

17. MANUFACTURER’S BATCH NUMBER

B.N.:
DOM:

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1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET

50 and 100 ml Glass Vials

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

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

WATER FOR INJECTIONS 100% v/v Solvent for parenteral use.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

The product contains 100% v/v Water for Injections

4. PHARMACEUTICAL FORM

Solvent for parenteral use.

5. PACKAGE SIZE

50ml/100ml

6. INDICATION(S)

Water for Injections is intended 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.

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

As required

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

For parenteral use.
Dosage: as required

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Meat - Zero days Milk – Zero hours

13. SPECIAL STORAGE PRECAUTIONS

Take adequate precautions to maintain sterility.
Any solution remaining in the vial following withdrawal of the required dose should be discarded. Do not store above 25°C. This product does not contain an antimicrobial preservative. Keep container in outer carton.

14. SPECIAL WARNING(S)

No special warnings.

15. EXPIRY DATE

Exp: dd/mm/yyyy

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

POM-V

To be supplied only on veterinary prescription.

**19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN**

20. MARKETING AUTHORISATION NUMBER(S)

ManA: 2000
Vm: 02000/4122

21. MANUFACTURER'S BATCH NUMBER

BN:

DOM:

Distributed by:

Norbrook Laboratories (GB) Limited

1 Saxon Way East

Oakley Hay Industrial Estate

Corby

Northamptonshire

NN18 9EX

United Kingdom

22. OTHER INFORMATION

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET

20 ml Glass Vials

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

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

WATER FOR INJECTIONS 100% v/v Solvent for parenteral use.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

The product contains 100% v/v Water for Injections

4. PHARMACEUTICAL FORM

Solvent for parenteral use.

5. PACKAGE SIZE

20 ml

6. INDICATION(S)

N/A

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

As required

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

For parenteral use.
Dosage: as required

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Meat - Zero days Milk – Zero hours

13. SPECIAL STORAGE PRECAUTIONS

Keep container in outer carton.

14. SPECIAL WARNING(S)

No special warnings.

15. EXPIRY DATE

Exp: dd/mm/yyyy

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

POM-V

To be supplied only on veterinary prescription.

19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

20. MARKETING AUTHORISATION NUMBER(S)

ManA: 2000
Vm: 02000/4122

21. MANUFACTURER’S BATCH NUMBER

BN:
DOM:

Distributed by:

Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

22. OTHER INFORMATION

Approved: 25/07/2017

A handwritten signature in black ink, appearing to read 'J. King', positioned below the approval date.