DRAFT CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Devomycin 250 mg/ml Solution for Injection.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A clear pale yellow sterile aqueous solution containing Streptomycin Sulphate 250 mg per ml along with 1.0 mg/ml Chlorocresol and 1.0 mg/ml Sodium Metabisulphite

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

Horses
Cattle
Sheep
Dogs
Cats

6. INDICATION(S)

Devomycin is active against a wide range of Gram-negative organisms and some Gram-positive pathogens. It is indicated in the treatment of infections caused by organisms sensitive to streptomycin, in particular *E. coli*, *Klebsiella* spp. and some species of *Proteus, Pasteurella* and *Salmonella*.
Use of the product should be based on susceptibility testing of bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

For intramuscular injection only.
The injection site should be massaged after administration.
Care should be taken in computing the dose to avoid overdosage.

Horses, cattle and sheep: 10 mg Streptomycin / kg bodyweight (1 ml / 25 kg bodyweight) for up to 3 days.
For cattle, the maximum dose volume to be administered at a single site is 10 ml and for sheep 5 ml.
Dogs and cats: 25 mg Streptomycin / kg bodyweight (1 ml / 10 kg bodyweight).

8. WITHDRAWAL PERIOD

Cattle
Meat and Offal – 16 days
Milk – 48 hours

Sheep
Meat and Offal – 18 days
Do not use in sheep producing milk intended for human consumption.

Horses
Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

Excessive and prolonged administration can lead to interference with balance and hearing. In extreme cases damage can be permanent.
Cats are the most susceptible animals.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

When the container is broached for the first time, using the in-shelf-life which is specified on the package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

User Warnings:

Do not handle this product if you are sensitised (allergic) to aminoglycoside antibiotics.

Care should be taken to avoid accidental self-injection. In case of accidental injection seek medical advice.

In case of accidental contact with skin or eyes, wash the affected area with plenty of

water immediately.

Wash hands after use.

10. EXPIRY DATE

D.O.M.:
Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 ºC
Keep out of the reach and sight of children.
For Animal Treatment Only
Protect from light
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.
Keep container in outer carton.

12. 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

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 by veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT 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
Northern Ireland BT35 6JP

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

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4018

17. MANUFACTURER'S BATCH NUMBER

Bn:

Package Quantities:
Multidose vials of 50 ml and 100 ml.
Not all package sizes may be presented.

DRAFT INSERT TEXT

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

Devomycin 250 mg/ml Solution for Injection.

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

A clear pale yellow sterile aqueous solution containing Streptomycin Sulphate 250 mg per ml along with 1.0 mg/ml Chlorocresol and 1.0 mg/ml Sodium Metabisulphite

4. INDICATION(S)

Devomycin is active against a wide range of Gram-negative organisms and some Gram-positive pathogens. It is indicated in the treatment of infections caused by organisms sensitive to streptomycin, in particular *E. coli*, *Klebsiella* spp. and some species of *Proteus, Pasteurella* and *Salmonella*.
Use of the product should be based on susceptibility testing of bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

5. CONTRAINDICATIONS

Contraindicated in cases of known hypersensitivity to the active ingredients.
Take particular care when treating animals suffering from renal damage.

6. ADVERSE REACTIONS

Excessive and prolonged administration can lead to interference with balance and hearing. In extreme cases damage can be permanent. Cats are the most susceptible animals.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses
Cattle
Sheep
Dogs
Cats

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

Horses, cattle and sheep: 10 mg Streptomycin / kg bodyweight (1 ml / 25 kg bodyweight) for up to 3 days.
For cattle, the maximum dose volume to be administered at a single site is 10 ml and for sheep 5 ml.
Dogs and cats: 25 mg Streptomycin / kg bodyweight (1 ml / 10 kg bodyweight).

9. ADVICE ON CORRECT ADMINISTRATION

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.
For intramuscular injection only.
The injection site should be massaged after administration.
Care should be taken in computing the dose to avoid overdosage.

10. WITHDRAWAL PERIOD

Cattle
Meat and Offal – 16 days
Milk – 48 hours

Sheep
Meat and Offal – 18 days
Do not use in sheep producing milk intended for human consumption.

Horses
Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.

The horse must have been declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 ºC
Keep out of the reach and sight of children.
For Animal Treatment Only
Protect from light
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.
Keep container in outer carton.

12. SPECIAL WARNINGS

When the container is broached for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.
Concurrent use with other potentially nephrotoxic drugs, such as diuretics, should be avoided.

User Warnings:
Do not handle this product if you are sensitised (allergic) to aminoglycoside antibiotics.

Care should be taken to avoid accidental self-injection. In case of accidental injection seek medical advice.

In case of accidental contact with skin or eyes, wash the affected area with plenty of water immediately.

Wash hands after use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2012

15. OTHER INFORMATION

Legal category:

POM-V

To be supplied only by veterinary prescription.

Product licence number:
Vm 02000/4018

Package Quantities:
Multidose vials of 50 ml and 100 ml.
Not all package sizes may be presented.

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

DRAFT LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Devomycin 250 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
250 mg Streptomycin Sulphate 1.0 mg Chlorocresol and 1.0 mg of Sodium Metabisulphite

3. PHARMACEUTICAL FORM

Solution for injection.
A clear pale yellow sterile aqueous antibiotic solution.

4. PACKAGE SIZE

50 ml / 100ml

5. TARGET SPECIES

Horses
Cattle
Sheep
Dogs
Cats

6. INDICATION(S)

Devomycin Injection is active against a wide range of Gram-negative organisms and some Gram-positive pathogens. Devomycin Injection is indicated in the treatment of infections caused by organisms sensitive to Streptomycin including *E.coli*, *Klebsiella spp*. and some species of *Proteus*, *Pasteurella* and *Salmonella*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular injection only.
The injection site should be massaged after administration.

Horses, cattle and sheep : 10 mg Streptomycin / kg bodyweight (1 ml / 25 kg bodyweight) for up to 3 days.
For cattle, the maximum dose volume to be administered at a single site is 10 ml and for sheep 5 ml.

Dogs and cats: 25 mg Streptomycin / kg bodyweight (1 ml / 10 kg bodyweight).

8. WITHDRAWAL PERIOD

Cattle
Meat and Offal – 16 days
Milk – 48 hours

Sheep
Meat and Offal – 18 days
Do not use in sheep producing milk intended for human consumption.

Horses
Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings:
Do not handle this product if you are sensitised (allergic) to aminoglycoside antibiotics.

Care should be taken to avoid accidental self-injection. In case of accidental injection seek medical advice.

In case of accidental contact with skin or eyes, wash the affected area with plenty of water immediately.

Wash hands after use.

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25º C
Protect from light.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.
Keep container in outer carton.

12. 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.

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 by veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Distributed by:
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Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

ManA.: 2000
Vm.: 02000/4018

17. MANUFACTURER'S BATCH NUMBER

Bn.:
D.O.M.:

Discard Date: _____