PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hexasol LA Solution for Injection for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Hexasol LA is a clear dark amber solution for parenteral administration containing 300 mg oxytetracycline as oxytetracycline dihydrate and 20 mg flunixin, as flunixin meglumine, per ml. 4 mg Sodium Formaldehyde Sulphoxylate is also included as a chemical preservative.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50 ml and 100 multi-dose vials.

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For use in Cattle.
Oxytetracycline is a member of the tetracycline family of broad-spectrum antibiotics that inhibit protein synthesis in susceptible microorganisms.
Flunixin meglumine is a relatively potent non-narcotic, non-steroidal analgesic with anti-inflammatory, anti-endotoxic and anti-pyretic properties.
Hexasol LA is specifically formulated to provide initial anti-inflammatory activity for 24-36 hours and sustained anti-bacterial activity for 5-6 days following a single administration.
Hexasol LA is indicated primarily for the treatment of bovine respiratory disease associated with *Mannheimia haemolytica*, where an anti-inflammatory and anti-pyretic effect is required.
In addition a wide range of organisms including *Pasteurella* spp, *Arcanobacterium pyogenes, Staphylococcus aureus* and certain mycoplasmas are known to be sensitive *in vitro* to oxytetracycline.
Hexasol LA may, therefore, be of use in the treatment of disease in cattle caused by such organisms where both anti-inflammatory and anti-pyretic effect is required.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For deep intramuscular injection to cattle.
The recommended dosage is 1 ml per 10 kg bodyweight (equivalent to 30 mg/kg oxytetracycline and 2 mg/kg flunixin) on a single occasion.
Maximum volume per injection site: 15ml. If concurrent treatment is administered, use a separate injection site.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 35 days from the last treatment.
Not for use in cattle producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Avoid intra-arterial injection.
Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding or where there is hypersensitivity to the product.
Use in any animals less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided, animals may require a reduced dosage and careful clinical management.
Avoid use in dehydrated, hypovolemic or hypotensive animals as there is a potential risk of increased renal toxicity.
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.
Do not administer other NSAIDs concurrently or within 24 hours of each other. Concurrent use of potentially nephrotoxic drugs should be avoided.
Although Hexasol LA is well tolerated, occasionally a local reaction of a transient nature may be observed.
The use of tetracyclines during the period of tooth and bone development, including late pregnancy, may lead to discolouration.
If concurrent treatment is administered, use a separate injection site.
Do not exceed the stated dose or duration of treatment.
It is preferable that prostaglandin-inhibiting drugs are not administrated to animals undergoing general anaesthesia until fully recovered.

Operator Warnings
See package leaflet for operator warnings.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Store upright only. Keep the container in the outer carton.
Do not store above 25°C.
Store out of reach of children.
Following withdrawal of the first dose, use the product within 28 days.
When the container is broached (opened) for the first time, the date on which any product remaining in the container should be discarded should be calculated. A statement of the in-use shelf-life of the product is given on this package leaflet. This discard date should be written on the space provided on the label.

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

Dispose of any used 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

Manufacturer:
Norbrook Laboratories Limited
Newry, Co. Down, Northern Ireland

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm: 02000/4152

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

FURTHER INFORMATION:
Clinically beneficial anti-inflammatory activity has been demonstrated following the single administration of flunixin in Hexasol LA. However, additional NSAID therapy may be administered after 24 hours if desired.
Following intramuscular injection of Hexasol LA at the recommended dose rate effective oxytetracycline blood levels persist for 5-6 days.

LOGO

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hexasol LA Solution for Injection for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
300 mg oxytetracycline, as oxytetracycline dihydrate and 20 mg flunixin, as flunixin meglumine, 4 mg Sodium Formaldehyde Sulphoxylate is also included as a chemical preservative.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml and 100 ml vials

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Hexasol LA is indicated for the treatment of bovine respiratory disease associated with *Mannheimia haemolytica,* where an anti-inflammatory and anti-pyretic effect is required.
In addition, a wide range of organisms including *Pasteurella* spp, *Arcanobacterium pyogenes, Staphylococcus aureus* and certain mycoplasmas are known to be sensitive *in vitro* to oxytetracycline.
Hexasol LA may, therefore, be of use in the treatment of disease in cattle caused by such organisms where both an anti-inflammatory and anti-pyretic effect is required.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For deep intramuscular injection to cattle.
CATTLE: The recommended dose rate is 1 ml per 10 kg bodyweight equivalent to 30 mg/kg oxytetracycline and 2 mg/kg flunixin.
Additional NSAID therapy may be administered after 24 hours if required.

8. WITHDRAWAL PERIOD

Cattle must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 35 days from the last treatment.
Not for use in cattle producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not mix this product with other medicaments prior to administration. Maximum injection site volume; 15ml. Do not exceed the stated dose or duration of treatment.

For full information read Package Leaflet before use.

Operator Warnings:
See package leaflet for operator warnings.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Store upright only. Keep the container in the outer carton.
Do not store above 25°C.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material safely. Avoid the introduction of contamination.

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

Manufacturer:
Norbrook Laboratories Limited
Newry, Co. Down, Northern Ireland

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm: 02000/4152

17. MANUFACTURER’S BATCH NUMBER

B.N.:
DOM:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>
{Base vial label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hexasol LA Solution for Injection for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
300 mg oxytetracycline, as oxytetracycline dihydrate and 20 mg flunixin, as flunixin meglumine, 4 mg Sodium Formaldehyde Sulphoxylate is also included as a chemical preservative.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

250 ml and 500 ml vials

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Hexasol LA is indicated for the treatment of bovine respiratory disease associated with *Mannheimia haemolytica,* where an anti-inflammatory and anti-pyretic effect is required.
In addition, a wide range of organisms including *Pasteurella* spp, *Arcanobacterium pyogenes, Staphylococcus aureus* and certain mycoplasmas are known to be sensitive *in vitro* to oxytetracycline.
Hexasol LA may, therefore, be of use in the treatment of disease in cattle caused by such organisms where both an anti-inflammatory and anti-pyretic effect is required.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For deep intramuscular injection to cattle.
CATTLE: The recommended dose rate is 1 ml per 10 kg bodyweight equivalent to 30 mg/kg oxytetracycline and 2 mg/kg flunixin.
Additional NSAID therapy may be administered after 24 hours if required.

8. WITHDRAWAL PERIOD

Cattle must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 35 days from the last treatment.
Not for use in cattle producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not mix this product with other medicaments prior to administration.
Maximum injection site volume; 15ml. Do not exceed the stated dose or duration of treatment.

For full information read expanding label before use.

Operator Warnings:
See expanding label for operator warnings.

10. EXPIRY DATE

EXP:
Once opened use by:___/___/___

11. SPECIAL STORAGE CONDITIONS

Store upright only. Keep the container in the outer carton.
Do not store above 25°C.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material safety. Avoid the introduction of contamination.

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

Manufacturer:
Norbrook Laboratories Limited
Newry, Co. Down, Northern Ireland

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4152

17. MANUFACTURER’S BATCH NUMBER

B.N.:
DOM:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Expanding Label for protective sleeve – Page 1

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hexasol LA Solution for Injection for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
300 mg oxytetracycline, as oxytetracycline dihydrate and 20 mg flunixin, as flunixin meglumine, 4 mg Sodium Formaldehyde Sulphoxylate is also included as a chemical preservative.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

250 ml and 500 ml vials

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Hexasol LA is indicated for the treatment of bovine respiratory disease associated with *Mannheimia haemolytica,* where an anti-inflammatory and anti-pyretic effect is required.
In addition, a wide range of organisms including *Pasteurella* spp, *Arcanobacterium pyogenes, Staphylococcus aureus* and certain mycoplasmas are known to be sensitive *in vitro* to oxytetracycline.
Hexasol LA may, therefore, be of use in the treatment of disease in cattle caused by such organisms where both an anti-inflammatory and anti-pyretic effect is required.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For deep intramuscular injection to cattle.

CATTLE: The recommended dose rate is 1 ml per 10 kg bodyweight equivalent to 30 mg/kg oxytetracycline and 2 mg/kg flunixin.

Additional NSAID therapy may be administered after 24 hours if required

8. WITHDRAWAL PERIOD

Cattle must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 35 days from the last treatment.
Not for use in cattle producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not mix this product with other medicaments prior to administration.
Maximum injection site volume; 15ml. Do not exceed the stated dose or duration of treatment.

For full information read expanding label before use.

Operator Warnings:
See expanding label for operator warnings.

10. EXPIRY DATE

EXP:
Once opened use by:___/___/___

11. SPECIAL STORAGE CONDITIONS

Store upright only. Keep the container in the outer carton.
Do not store above 25°C.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material safety. Avoid the introduction of contamination.

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

Manufacturer:
Norbrook Laboratories Limited
Newry, Co. Down, Northern Ireland

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4152

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Expanding Label for protective sleeve – Page 2

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hexasol LA Solution for Injection for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Hexasol LA is a clear dark amber solution for parenteral administration containing 300 mg oxytetracycline as oxytetracycline dihydrate and 20 mg flunixin, as flunixin meglumine, per ml. Sodium formaldehyde sulphoxylate is also included as a chemical preservative.

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Oxytetracycline is a member of the tetracycline family of broad-spectrum antibiotics that inhibit protein synthesis in susceptible microorganisms.
Flunixin meglumine is a relatively potent non-narcotic, non-steroidal analgesic with anti-inflammatory, anti-endotoxic and anti-pyretic properties.
Hexasol LA is specifically formulated to provide initial anti-inflammatory activity for 24-36 hours and sustained anti-bacterial activity for 5-6 days following a single administration.
Hexasol LA is indicated primarily for the treatment of bovine respiratory disease associated with *Mannheimia haemolytica*, where an anti-inflammatory and anti-pyretic effect is required.
In addition a wide range of organisms including *Pasteurella* spp, *Arcanobacterium pyogenes, Staphylococcus aureus* and certain mycoplasmas are known to be sensitive *in vitro* to oxytetracycline.
Hexasol LA may, therefore, be of use in the treatment of disease in cattle caused by such organisms where both anti-inflammatory and anti-pyretic effect is required.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

CONTRAINDICATIONS:

Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding or where there is hypersensitivity to the product.
Avoid use in dehydrated, hypovolemic or hypotensive animals as there is a potential risk of increased renal toxicity.
Do not administer other NSAIDs concurrently or within 24 hours of each other.
Concurrent use of potentially nephrotoxic drugs should be avoided.
Do not exceed the stated dose or duration of treatment.

ADVERSE REACTIONS:

Although Hexasol LA is well tolerated, occasionally a local reaction of a transient nature may be observed.
The use of tetracyclines during the period of tooth and bone development, including late pregnancy, may lead to discolouration.
Hypersensitivity reactions (collapse) may occur very rarely. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening.
The frequency of adverse reactions is defined using the following convention:
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

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

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

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufacturer:
Norbrook Laboratories Limited
Newry, Co. Down, Northern Ireland

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4152

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Expanding Label for protective sleeve – Page 3

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hexasol LA Solution for Injection for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For deep intramuscular injection to cattle.
The recommended dosage is 1 ml per 10 kg bodyweight (equivalent to 30 mg/kg oxytetracycline and 2 mg/kg flunixin) on a single occasion.
Maximum volume per injection site: 15ml. If concurrent treatment is administered, use a separate injection site.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 35 days from the last treatment.
Not for use in cattle producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Avoid intra-arterial injection.
Use in any animals less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided, animals may require a reduced dosage and careful clinical management.
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

Although Hexasol LA is well tolerated, occasionally a local reaction of a transient nature may be observed.
The use of tetracyclines during the period of tooth and bone development, including late pregnancy, may lead to discolouration.
If concurrent treatment is administered, use a separate injection site.
It is preferable that prostaglandin-inhibiting drugs are not administrated to animals undergoing general anaesthesia until fully recovered.
Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

OPERATOR WARNINGS:
Avoid eye contact and direct contact with skin.
To avoid possible sensitisation reactions, avoid contact with skin. Gloves should be worn during application.
Wash hands after use.
In the case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice.
The product may cause reactions in sensitive individuals. If you have known hypersensitivity for non-steroidal anti-inflammatory products, do not handle the product. Reactions may be serious.
Avoid accidental self-injection.
Keep out of reach and sight of children

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

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

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

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufacturer:
Norbrook Laboratories Limited
Newry, Co. Down, Northern Ireland

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4152

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Expanding Label for protective sleeve – Page 4

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hexasol LA Solution for Injection for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

Package Quantities:
Multidose vials of 50 ml, 100 ml, 250 ml and 500 ml.
Not all pack sizes may be marketed.

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Store upright only.
Do not store above 25°C.
Following withdrawal of the first dose, use the product within 28 days.
When the container is broached for the first time, using the in-use shelf-life which is specified on this expanding label, 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.

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

Manufacturer:
Norbrook Laboratories Limited
Newry, Co. Down, Northern Ireland

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4152

17. MANUFACTURER'S BATCH NUMBER

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

LOGO

Further Information:
Clinically beneficial anti-inflammatory activity has been demonstrated following the single administration of flunixin in Hexasol LA. However, additional NSAID therapy may be administered after 24 hours if desired.
Following intramuscular injection of Hexasol LA at the recommended dose rate effective oxytetracycline blood levels persist for 5-6 days.
Flunixin is toxic to avian scavengers although foreseen low exposure leads to low risk.

PACKAGE LEAFLET FOR:

Hexasol LA Solution for Injection for Cattle

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, Camlough Road, Newry, Co. Down, BT35 6JP, United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hexasol LA Solution for Injection for Cattle

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

Hexasol LA is a clear dark amber solution for parenteral administration containing 300 mg oxytetracycline as oxytetracycline dihydrate and 20 mg flunixin, as flunixin meglumine, per ml. Sodium formaldehyde sulphoxylate is also included as a chemical preservative.

4. INDICATION(S)

Oxytetracycline is a member of the tetracycline family of broad-spectrum antibiotics that inhibit protein synthesis in susceptible microorganisms.
Flunixin meglumine is a relatively potent non-narcotic, non-steroidal analgesic with anti-inflammatory, anti-endotoxic and anti-pyretic properties.
Hexasol LA is specifically formulated to provide initial anti-inflammatory activity for 24-36 hours and sustained anti-bacterial activity for 5-6 days following a single administration.
Hexasol LA is indicated primarily for the treatment of bovine respiratory disease associated with *Mannheimia haemolytica*, where an anti-inflammatory and anti-pyretic effect is required.

In addition a wide range of organisms including *Pasteurella* spp, *Arcanobacterium pyogenes, Staphylococcus aureus* and certain mycoplasmas are known to be sensitive *in vitro* to oxytetracycline.
Hexasol LA may, therefore, be of use in the treatment of disease in cattle caused by such organisms where both anti-inflammatory and anti-pyretic effect is required.

5. CONTRAINDICATIONS

Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding or where there is hypersensitivity to the product.

Avoid use in dehydrated, hypovolemic or hypotensive animals as there is a potential risk of increased renal toxicity.
Do not administer other NSAIDs concurrently or within 24 hours of each other. Concurrent use of potentially nephrotoxic drugs should be avoided.
Do not exceed the stated dose or duration of treatment

6. ADVERSE REACTIONS

Although Hexasol LA is well tolerated, occasionally a local reaction of a transient nature may be observed.
The use of tetracyclines during the period of tooth and bone development, including late pregnancy, may lead to discolouration.
Hypersensitivity reactions (collapse) may occur very rarely. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening.
The frequency of adverse reactions is defined using the following convention:
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

For deep intramuscular injection to cattle.
The recommended dosage is 1 ml per 10 kg bodyweight (equivalent to 30 mg/kg oxytetracycline and 2 mg/kg flunixin) on a single occasion.

9. ADVICE ON CORRECT ADMINISTRATION

Maximum volume per injection site: 15ml. If concurrent treatment is administered, use a separate injection site.

10. WITHDRAWAL PERIOD(S)

Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 35 days from the last treatment.
Not for use in cattle producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Store upright only. Keep the container in the outer carton.
Do not store above 25°C.
Following withdrawal of the first dose, use the product within 28 days.
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.

12. SPECIAL WARNING(S)

Avoid intra-arterial injection.
Use in any animals less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided, animals may require a reduced dosage and careful clinical management.
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.
If concurrent treatment is administered, use a separate injection site.
It is preferable that prostaglandin-inhibiting drugs are not administrated to animals undergoing general anaesthesia until fully recovered.
Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

OPERATOR WARNINGS:
Avoid eye contact and direct contact with skin.
To avoid possible sensitisation reactions, avoid contact with skin. Gloves should be worn during application.
Wash hands after use.
In the case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice.
The product may cause reactions in sensitive individuals. If you have known hypersensitivity for non-steroidal anti-inflammatory products, do not handle the product. Reactions may be serious.
Avoid accidental self-injection.
Keep out of reach and sight of children

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

March 2023

15. OTHER INFORMATION

DISTRIBUTED BY:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

Package Quantities:
Multidose vials of 50 ml, 100 ml, 250 ml and 500 ml.
Not all pack sizes may be marketed.

Further Information:
Clinically beneficial anti-inflammatory activity has been demonstrated following the single administration of flunixin in Hexasol LA. However, additional NSAID therapy may be administered after 24 hours if desired.

Following intramuscular injection of Hexasol LA at the recommended dose rate effective oxytetracycline blood levels persist for 5-6 days.

Flunixin is toxic to avian scavengers although foreseen low exposure leads to low risk.

BN:
D.O.M:
Exp:

ManA 2000
Vm 02000/4152

POM-V To be supplied only on veterinary prescription

FOR ANIMAL TREATMENT ONLY
UK AUTHORISED VETERINARY MEDICINAL PRODUCT

LOGO