PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> 50 ML / 100 ML / 250 ML / 500 ML CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ultrapen LA 30% Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

300 mg procaine benzylpenicillin and 0.07 mg each of butylhydroxyanisole and butylhydroxytoluene (antioxidants) in a long acting oily base as a suspension for injection.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml, 100 ml, 250 ml, 500 ml

5. TARGET SPECIES

Cattle and Pigs

6. INDICATION(S)

For the treatment of infections caused by, or associated with, organisms sensitive to penicillin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular or subcutaneous administration to non-lactating cattle. For intramuscular administration only to pigs and lactating cattle.
Recommended dose rate is 20 mg procaine penicillin per kg bodyweight, equivalent to 1 ml per 15 kg bodyweight. If signs persist at 72 hours repeat the dose.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.
Subcutaneous Administration:
Cattle may be slaughtered for human consumption only after 13 days from the last treatment.
Intramuscular Administration:
Cattle may be slaughtered for human consumption only after 23 days from the last treatment.

Pigs may be slaughtered for human consumption only after 10 days from the last treatment.
Milk for human consumption must not be taken during treatment.
Milk for human consumption may only be taken from treated cows after 132 hours from the last administration.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings: Penicillins may occasionally cause severe allergic reactions. See carton for full user warnings.

Shake vial before use.

Contraindicated in known cases of hypersensitivity to penicillins. Do not inject intravenously or by intrathecal route. This product does not contain an antimicrobial preservative. Use a dry, sterile needle and syringe. Swab the septum before removing each dose.

Further Information: See Carton Text.

10. EXPIRY DATE

Following withdrawal of the first dose the product should be used within 28 days.
Discard unused material. Keep container in outer carton.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Protect from light.

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 *[Distribution category]*

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
Station Works
Newry
Co. Down
BT35 6JP
United Kingdom

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co Down
United Kingdom

16. MARKETING AUTHORISATION NUMBER

ManA 2000
Vm 02000/4133

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM.:
EXP:

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> 50 ML / 100 ML / 250 ML / 500 ML LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ultrapen LA 30% Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

300 mg procaine benzylpenicillin and 0.07 mg each of butylhydroxyanisole and butylhydroxytoluene (antioxidants) in a long acting oily base as a suspension for injection.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml/ 100 ml/ 250 ml/ 500 ml

5. TARGET SPECIES

Cattle and Pigs

6. INDICATION(S)

Ultrapen LA is specifically formulated to provide sustained antibacterial activity following a single administration.

Ultrapen LA is indicated for use in cattle and pigs in the treatment of infections caused by, or associated with, organisms sensitive to penicillin including:

Trueperella pyogenes, Erysipelothrix rhusiopathiae, Mannheimia haemolytica, Pasteurella multocida and *Streptococcus* spp.

Ultrapen LA may be used in the treatment and control of a wide range of common systemic, respiratory, urinary and local infections caused by penicillin-susceptible organisms including:

Erysipelas; navel/joint-ill; respiratory tract infections including pneumonia and atrophic rhinitis; meningitis; septicaemia; urogenital tract infections and the control of secondary bacterial invaders in diseases primarily of viral origin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

CATTLE: Ultrapen LA may be administered by either the subcutaneous or intramuscular route of administration to non-lactating cattle and by the intramuscular route only to lactating cattle.

PIGS: Ultrapen LA may be administered by the intramuscular route of administration only.

The recommended dose rate is 20 mg procaine penicillin per kg bodyweight, equivalent to 1 ml per 15 kg bodyweight. If signs persist at 72 hours repeat the dose.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.
Subcutaneous Administration:
Cattle may be slaughtered for human consumption only after 13 days from the last treatment.
Intramuscular Administration:
Cattle may be slaughtered for human consumption only after 23 days from the last treatment.
Pigs may be slaughtered for human consumption only after 10 days from the last treatment.
Milk for human consumption must not be taken during treatment.
Milk for human consumption may only be taken from treated cows after 132 hours from the last administration.

9. SPECIAL WARNING(S), IF NECESSARY

Contraindicated in known cases of hypersensitivity to penicillin.

Do not inject intravenously or by intrathecal route.

Not to be used on very small herbivores such as guinea pigs, gerbils and hamsters.

Although Ultrapen LA is well tolerated, occasionally a slight local reaction of a transient nature may be observed.

Occasionally in suckling and fattening pigs administration of such products may cause a transient pyrexia, vomiting, shivering, listlessness and incoordination. Additionally in pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

Shake the vial before use.

This product does not contain an antimicrobial Preservative.

Use a dry, sterile needle and syringe. Swab the septum before removing each dose.

Wash hands after use.
Avoid the introduction of contamination during use.

After absorption, benzylpenicillin poorly penetrates biological membranes (e.g., blood-brain barrier) since it is ionised and poorly lipid soluble. Use of the product for treatment of meningitis or CNS infections due to e.g., *Streptococcus suis* or *Listeria monocytogenes* may not be efficacious. Furthermore, benzylpenicillin penetrates mammalian cells poorly, hence this product may have little effect in treating intracellular pathogens e.g., *Listeria monocytogenes*.

Elevated MIC values or bi-modal distribution profiles suggesting acquired resistance have been reported for the following bacteria:
- *Glaesserella parasuis*, *Staphylococcus* spp. causing MMA/PPDS, *Streptococcus* spp. and *S. suis* in pigs;
- *Fusobacterium necrophorum* causing metritis and *Mannheimia haemolytica*, as well as *Bacteroides* spp., *Staphylococcus chromogenes*, *Actinobacillus lignieresii* and *Trueperella pyogenes* in cattle;

Use of the veterinary medicinal product may result in a lack of clinical efficacy when treating infections caused by these bacteria.

Operator Warnings

Take care to avoid accidental injection. Wash hands after use.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

Handle this product with great care to avoid exposure, taking all recommended precautions.

If you develop symptoms following exposure such as a skin rash you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

10. EXPIRY DATE

DOM:
EXP:

Once broached, use by:

Following withdrawal of the first dose the product should be used within 28 days. Discard unused material safely.

Keep container in outer carton.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Protect from light.

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.

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Approved 18 June 2024
Gavin Hall