"פורמט עלון זה נקבע ע"י משרד הבריאות ותוכנו נבדק ואושר מרץ 2012"

לשימוש וטרינרי בלבד

עפ מרשם רופא וטרינרי

Hexasol Veterinary

Solution for injection, IM

PRESENTATION:
Hexasol Veterinary is a clear dark amber solution for parenteral administration containing 300 mg oxytetracycline as dihydrate Ph.Eur and 20 mg flunixin, as flunixin meglumine USP, per ml.

INDICATION:
Hexasol veterinary may be of use in the treatment of disease caused by microorganisms sensitive to oxytetracycline where anti-inflammatory, anti-pyretic, and anti-bacterial effect is required.

USES:
For use in cattle. Oxytetracycline is a member of the tetracycline family of broad spectrum antibiotics that inhibit protein synthesis in susceptible micro-organisms.
Flunixin meglumine is a relatively potent non- narcotic, non-steroidal analgesic with anti-inflammatory, anti-endotoxic and anti-pyretic properties.
Hexasol Veterinary has anti-inflammatory activity and anti-bacterial activity.
Hexasol Veterinary is indicated primarily for the treatment of bovine respiratory disease associated with *Pasteurella haemolytica* where an anti-inflammatory and anti-pyretic effect is required.
In addition a wide range of organisms including *Pasteurella spp. Corynebacterium pyogenes, Staphylococcus aureus* and certain mycoplasmas are known to be sensitive *in vitro* to oxytetracycline.
Hexasol Veterinary may therefore be of use in the treatment of disease caused by such organisms where both an anti-inflammatory and anti-pyretic effect is required.

DOSAGE AND 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.

CONTRA-INDICATIONS, WARNINGS, ETC:
Avoid intra-arterial injection.
Use is contra-indicated 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, hypovolaemic 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 Veterinary 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.

Client Artwork Approval - Proof 3 - Norbrook Designer: Eamon McAllister (6/11/2015)

Customer..... Comex
Country..... Jerusalem
Product ..... Hexasol Veterinary
Volume ..... Insert
Resource Code ..... (405)007472
Revision Level I04
Pharma Code..... 1018
Barcode..... n/a
Dimensions ..... 148 x 210mm
Keyline (Die) Ref. ..... A5, Double-sided

COLOURS USED:
■ PMS Black

PLEASE READ THIS IMPORTANT INFORMATION: Please ensure this proof matches your artwork requirements. Please check all aspects of the proof i.e. text, fonts, spelling, colours, size, construction, copy position, barcodes, pharma codes, orientation of graphics etc. Mark clearly any amendments which you identify. Receiving the signed approval of this proof will authorise Norbrook Laboratories to proceed with your order. Norbrook Laboratories will not be liable for the costs of an order produced where any amendments required were not identified on the signed proof. Please return the signed approval at your earliest convenience to enable us to proceed with the order and meet your requested delivery date.

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CUSTOMER APPROVAL (PLEASE SIGN)
Signature: _____
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29/10/15 Proof2: Add additional Hewbrew text (heading) / pg2: spelling
6/11/15 Proof3: Apply recommended corrections as indicated by proofreader.

DISPOSAL: Unused product and containers should be disposed of in accordance with any guidance from the appropriate waste regulatory authority.

WITHDRAWAL PERIODS:
Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 21 days from the last treatment.
Not for use in cattle producing milk for human consumption.

PHARMACEUTICAL PRECAUTIONS:
Store upright only
Keep the container in the outer carton.
Store below 25ºC. Protect from light.
Store out of reach of children.
Following first opening, use the product within 28 days.

EXCIPIENTS
Magnesium oxide light
Glycerol formal
Polyethylene glycol 200
Sodium formaldehyde sulphoxylate
Ethanolamine
Water for injection

LEGAL CATEGORY: POM

PACKAGE QUANTITIES:
50 ml and 100 ml multi-dose vials.

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

MANUFACTURED BY:
Norbrook Laboratories Limited, Northern Ireland

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