Veterinêre medisyne
Slegs vir dieregebruik

SKEDULERINGSTATUS: S4

Hexasol HB Inspuiting

SAMESTELLING
Elke mℓ bevat oksitetrasikliendihidraat ekwivalent aan oksitetrasiklien 300 mg/mℓ en fluniksienmeglumien ekwivalent aan fluniksien 20 mg/mℓ.
Natriumformaldehiedsulfoksilaat 0,4 % word ten tye van vervaardiging as antioksidant bygevoeg.

FARMAKOLOGIESE KLASSIFIKASIE
C.17.1.11 Antibakteriese kombinasies

FARMAKOLOGIESE WERKING
Die tetrasikliene is 'n familie van wye-spektrum bakteriostatiese antibiotika wat proteïensintese in vatbare mikroörganismes inhibeer. Die tetrasikliene, insluitende oksitetrasiklien, is aktief teen teenoor vele sensitiewe Gram-positiewe en Gram-negatiewe bakterieë. Milkoplasma, chlamydia, rikettsia en sommige protosoa is ook vatbaar. Deur aan die reseptore van die bakteriese ribosoom te bind inhibeer oksitetrasiklien proteïensintese. Die werking op proteïensintese is relatief spesifiek vir bakterieselle en 'n soortgelyke werking vind nie teen kliniese dosisse in soogdierselle plaas nie. Oksitetrasiklien is derhalwe selektief toksies vir bakterieselle.
Fluniksienmeglumien is 'n potente nie-narkotiese, nie-steroïed pynstiller met anti-inflammatoriese, anti-endotoksiese en koorswerende eienskappe.
Fluniksienmeglumien tree op as 'n omkeerbare inhibeerder van siklo-oksigenase, 'n belangrike ensiem in die aragidoonsuurkaskadebaan, wat verantwoordelik is vir die omskakeling van aragidoonsuur na sikliese endoperoksiede. Gevolglik word die sintese van eikosanoïede, belangrike medieerders van die inflammatoriese proses betrokke by sentrale koors, pyn en weefselinflamasie geïnhibeer. Deur sy werking op die aragidoonsuurkaskade, inhibeer fluniksien ook die produksie van tromboksaan, 'n plaatjie pro-aggregeerder en vasokonstriktor, wat gedurende bloedstolling vrygestel word. Fluniksien oefen sy koorswerende effek uit deur die sintese van prostaglandien E_2 in die hipotalamus te inhibeer. Deur inhibering van die aragidoonsuurkaskade, verskaf fluniksien ook 'n anti-endotoksiese effek deur onderdrukking van eikosanoïedformasie, om sodoende hul betrokkenheid in endotoksiese siektetoestande te voorkom. *In vitro* antibakteriese sensitiwiteit beteken nie noodwendig *in vivo* aktiwiteit nie.

INDIKASIES
Hexasol HB Inspuiting word aangedui vir die behandeling van respiratoriese infeksies en verwante koors in beeste wat veroorsaak word deur oksitetrasiklien sensitiewe organismes.

KONTRA-INDIKASIES
Die gebruik word teenaangedui in diere wat aan hart-, lewer- of niersiektes ly, of waar daar 'n moontlikheid van gastroïntestinale ulserasie of bloeding bestaan, of waar daar hipersensitiwiteit teen die middel bestaan.
Moenie ander NSAIM saam of binne 24 uur na mekaar toedien nie.
Die veiligheid van gebruik in dragtigheid is nie vasgestel nie.

WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS
Vermy intra-arteriële inspuiting.
Diere moet nie gedurende behandeling vir menslike gebruik geslag word nie.
Beeste mag slegs na 21 dae na die laaste dosis vir menslike gebruik geslag word.
Nie vir gebruik in beeste wat melk vir menslike gebruik produseer nie.
Die gebruik in enige dier wat jonger as 6 weke oud is of in ou diere mag bykomende risikos oplewer. Indien die gebruik onvermydelik is mag die dosis moontlik verminder moet word en word sorgvuldige kliniese bestuur vereis.
Weens die potensiële risiko van 'n toename in niertoksisiteit, moet die gebruik in gedehidreerde, hipovolumiese of hipotensiewe diere vermy word.

INTERAKSIES
Moenie ander nie-steroïed anti-inflammatoriese middels (NSAIM) saam of binne 24 uur na mekaar toedien nie. Sommige NSAIM is sterk aan plasmaproteïene gebind en kompeteer met ander hoogsgebonde middels wat tot toksiese effekte mag lei.
Die medetoediening van potensieel nefrotoksiese middels behoort vermy te word.

DOSIS EN GEBRUIKSAANWYSINGS
Moenie die aanbevole dosis of behandelingsperiode oorskry nie.
Hexasol HB word aangedui vir intramuskulêre of onderhuidse toediening in beeste.
Die aanbevole dosis is 1 mℓ per 10 kg liggaamsmassa (ekwivalent aan 2 mg/kg fluniksien en 30 mg/kg oksitetrasiklien).
Die periode tussen die onttrekking van die eerste en die finale dosis moet nie onnodig uitgerek word nie en moet binne 28 dae nadat die flessie oopgemaak is, gebruik word.
Moenie meer as 15 mℓ op enige enkel spuitplek toedien nie.

NEWE-EFFEKTE
Newe-effekte sluit gastroïntestinale irritasie, ulserasie en, in gedehidreerde of hipovolumiese pasiënte, die potensiaal vir nierbeskadiging in. Die verlengde gebruik van hoër as die aanbevole dosisse mag gastroïntestinale ulserasie veroorsaak en mag tot lewensbedreigende plasmaproeteïenverspillende enteropatie lei. Nefrotoksisiteit in die vorm van papillêre nekrose, beenmurg-onderdrukking wat tot bloeddiskrasieë lei, en vertraagde lewerfunksie mag voorkom.
Ataksie, vinnige asemhaling, spierswakheid en sentrale senuweestelseleffekte (histerie) mag na intra-arteriële toediening voorkom.
Langwerkende tetrasiklienoplossing mag weefselreaksies veroorsaak.
Intramuskulêre inspuitings mag tydelike ongemak veroorsaak wat na een of twee minute sal verdwyn.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Oordosering word geassosieer met gastroïntestinale toksisiteit.
Wanneer 'n oordosering plaasgevind het, moet die medikasie onmiddellik onttrek word. Die behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE
'n Helder, donker amberkleurige oplossing, vry van sigbare deeltjies.

AANBIEDING
Hexasol HB word in 50 mℓ, 100 mℓ, 250 mℓ and 500 mℓ amberkleurige glasflessies verskaf vir veelvuldige dosisgebruik.

BERGINGSAANWYSINGS
Bewaar teen of benede 25 °C. Beskerm teen lig. Hou buite bereik van kinders, oningeligte persone en diere.
Nadat die oplossing die eerste keer oopgemaak is, bly dit vir 28 dae stabiel.

REGISTRASIENOMMER
99/21.1/9

NAAM EN BESIGHEIDSADRES VAN DIE REGISTRASIESERTIFIKAAT HOUER
Biotech Laboratories (Edms) Bpk
Grond Vloer, Blok K Wes, Central Park,
400 16de Straat, Midrand, Gauteng, 1685.

BEMARK DEUR:
Biotech Laboratories (Edms) Bpk
Tel: (011) 848 3050
Faks: (011) 848 3065
Epos: info@biotechlabs.co.za
www.biotechlabs.co.za

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET
01 Oktober 2010

UITVOER REGISTRASIE INLIGTING NAMIBIË:
NS 2 Hexasol Injection: V05/17.1.10/1171

Veterinary Medicine
For Animal Use Only

SCHEDULING STATUS: S4

Hexasol HB Injection

COMPOSITION
Each mℓ contains oxytetracycline dihydrate equivalent to oxytetracycline 300 mg/mℓ and flunixin meglumine equivalent to flunixin 20 mg/mℓ. Sodium formaldehyde sulphoxylate 0,4 % is added at the time of manufacture as an antioxidant.

PHARMACOLOGICAL CLASSIFICATION
C.17.1.11 Antibacterial combinations

PHARMACOLOGICAL ACTION
The tetracyclines are a family of broad-spectrum bacteriostatic antibiotics that inhibit protein synthesis in susceptible microorganisms. The tetracyclines, including oxytetracycline are active against many gram-positive and gram-negative bacteria. Mycoplasma, chlamydia, rickettsia and some protozoa are also susceptible. By binding to receptors of the bacterial ribosome, oxytetracycline inhibits protein synthesis.
The action on protein synthesis is relatively specific for bacterial cells and similar actions on mammalian cells do not occur at clinical dose rates. Oxytetracycline is therefore selectively toxic for bacterial cells.
Flunixin meglumine is a potent non-narcotic, non-steroid analgesic with anti-inflammatory, anti-endotoxic and anti-pyretic properties.
Flunixin meglumine acts as a reversible inhibitor of cyclo-oxgenase an important enzyme in the arachidonic acid cascade pathway, which is responsible for converting arachidonic acid to cyclic endoperoxides. Consequently, synthesis of eicosanoids, important mediators of the inflammatory process involved in central pyresis, pain perception and tissue inflammation is inhibited. Through its effects on the arachidonic acid cascade, flunixin also inhibits the product of thromboxane, a potent platelet pro-aggregator and vasoconstrictor, which is released during blood clotting. Flunixin exerts its antipyretic effect by inhibiting prostaglandin E2 synthesis in the hypothalamus. By inhibiting the arachidonic acid cascade pathway, flunixin also produces an anti-endotoxic effect by suppressing eicosanoid formation and therefore preventing their involvement in endotoxin disease states. *In vitro* antibacterial sensitivity does not necessarily imply *in vivo* activity.

INDICATIONS
Hexasol HB Injection is indicated for the treatment of respiratory infections, and the associated pyresis, caused by oxytetracycline-sensitive organisms, in cattle.

CONTRAINDICATIONS
Use is contraindicated in animals suffering from cardiac, hepatic, or renal disease, where there is a possibility of gastro-intestinal ulceration or bleeding or where there is hypersensitivity to the product.
Do not administer other NSAIDs concurrently or within 24 hours of each other.
Safety in pregnancy has not been established.

WARNINGS AND SPECIAL PRECAUTIONS
Avoid intra-arterial injection.
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.
Use in any animal 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 dose and careful clinical management.
Avoid use in dehydrated, hypovolaemic or hypotensive animals, as there is a potential risk of increased renal toxicity.

INTERACTIONS
Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound medicines which can lead to toxic effects. Concurrent administration of potentially nephrotoxic medicines should be avoided.

DOSAGE AND DIRECTIONS FOR USE
Do not exceed the stated dose or the duration of treatment.
Hexasol HB is indicated for intramuscular or subcutaneous administration to cattle.
The recommended dose rate is 1 mℓ per 10 kg bodymass (equivalent to 2 mg/kg flunixin and 30 mg/kg oxytetracycline).
The period of time between the withdrawal of the first and final doses should not be unduly prolonged, and used within 28 days after broaching of the vial.
Do not administer more than 15 mℓ at any one injection site.

SIDE EFFECTS
Untoward effects include gastrointestinal irritation, ulceration and, in dehydrated or hypovolaemic animals, potential for renal damage. Prolonged use or higher than recommended dose rates may cause gastro-intestinal ulceration and may lead to a life-threatening plasma protein enteropathy. Nephrotoxicity in the form of papillary necrosis, bone-marrow suppression resulting in blood dyscrasias and impaired hepatic function may occur. Ataxia, rapid breathing, muscle weakness and Central Nervous System effects (hysteria) may occur after intra-arterial administration.
Long-acting tetracycline solutions may cause tissue reactions.
Intra-muscular injections may cause temporary discomfort that will abate after one or two minutes.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Overdosage is associated with gastrointestinal toxicity.
When overdosage has occurred withdraw the medication immediately. Treatment is symptomatic and supportive.

IDENTIFICATION
A clear, dark amber solution free from visible particles.

PRESENTATION
Hexasol HB is supplied in 50 mℓ, 100 mℓ, 250 mℓ and 500 mℓ amber glass vials for multiple dose use.

STORAGE INSTRUCTIONS
Store at or below 25 °C. Protect from light.
Keep out of reach of children, uninformed persons and animals.
After broaching the first time the solution will be stable for 28 days.

REGISTRATION NUMBER 99/21.1/9

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Biotech Laboratories (Edms) Bpk., Ground Floor, Block K West, Central Park, 400 16th Road, Midrand, Gauteng, 1685

MARKETED BY:
Biotech Laboratories (Edms) Bpk
Tel: (011) 848 3050
Fax: (011) 848 3065
Email: info@biotechlabs.co.za
www.biotechlabs.co.za

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