Veterinary Medicine

For Animal Use Only

SCHEDULING STATUS S3

PROPRIETARY NAME AND DOSAGE FORM

Pyroflam NS Injection

COMPOSITION

Each ml contains flunixin meglumine 50 mg.
Phenol as preservative: 0,5 % m/v.

PHARMACOLOGICAL CLASSIFICATION

C 1.8 Analgesic antipyretics.

PHARMACOLOGICAL ACTION

Flunixin meglumine is a non-narcotic, non-steroidal analgesic with anti-inflammatory, anti-endotoxic and antipyretic properties.
Flunixin meglumine acts as a reversible inhibitor of cyclo-oxygenase an important enzyme in the arachidonic acid cascade 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 production of thromboxane, a platelet pro-aggregator and vasoconstrictor which is released during blood clotting. Flunixin exerts its antipyretic effect by inhibiting prostaglandin E_2 synthesis in the hypothalamus. By inhibiting the arachidonic acid cascade, flunixin also produces an anti-endotoxic effect by suppressing eicosanoid formation and therefore preventing their involvement in endotoxin disease states.

INDICATIONS

Horses: Pyroflam NS is indicated for the alleviation of inflammation and pain associated with musculoskeletal disorders and for the alleviation of visceral pain associated with colic.
Cattle: Pyroflam NS is indicated for the control of acute inflammation associated with respiratory disease.

CONTRAINDICATIONS

Do not administer to pregnant mares and to foals younger than 72 hours.
Use is contraindicated in animals suffering from cardiac, hepatic, or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding, where there is evidence of a blood dyscrasia or hypersensitivity to the product

WARNINGS AND SPECIAL PRECAUTIONS

Animals must not be slaughtered for human consumption within 10 days after administration.
Milk for human consumption may only be taken from treated cows 24 hours after administration of Pyroflam NS. Avoid intra-arterial injection.
Do not use in cats.
Young animals (less than 30 days of age) are more susceptible to toxicity due to a deficiency in the enzyme glucoronyl transferase, an important conjugation mechanism.
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 any dehydrated, hypovolaemic or hypotensive animal.
It is preferable that flunixin is not administered to animals undergoing general anaesthesia until fully recovered.

INTERACTIONS

Monitor medicine compatibility closely where adjunctive therapy is required. 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

Pyroflam NS is indicated for intravenous administration to cattle or horses.
Do not mix Pyroflam NS with other medication prior to administration.
Do not exceed the recommended dose or the duration of treatment.
Following withdrawal of the first dose from the vial, use the product within 28 days.
Discard unused product.

Horses:
For the use in colic the recommended dose rate is 1,1 mg flunixin/kg bodyweight equivalent to 1 ml per 45 kg bodyweight. Treatment may be repeated once or twice if colic recurs.
For use in musculoskeletal disorders, the recommended dose rate is 1,1 mg flunixin/kg bodyweight equivalent to 1 ml per 45 kg, once daily for up to 5 days according to clinical response.

Cattle:
The recommended dose rate is 2,2 mg flunixin/kg bodyweight equivalent to 2 ml per 45 kg bodyweight. Repeat as necessary at 24-hour intervals for up to 5 consecutive days.
The cause of the underlying inflammatory condition or colic should be determined and receive appropriate concomitant therapy.

SIDE EFFECTS

Untoward effects include gastrointestinal ulceration and, in dehydrated or hypovolaemic animals, potential for renal damage. Prolonged use, or higher than recommended dose rates, may lead to a life-threatening plasma protein enteropathy due to gastrointestinal ulceration. Nephrotoxicity in the form of papillary necrosis, bone-marrow suppression resulting in blood dyscrasias and impaired hepatic function may occur.
Intra-arterial administration of flunixin may result in ataxia, rapid breathing, muscle weakness and central nervous system effects.
Isolated reports of local reactions following intramuscular injection in the horse, particularly in the neck have been reported. These include sweating, swelling, induration and stiffness.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See "Side effects".

IDENTIFICATION

A clear, colourless solution free of visible particles.

PRESENTATION

Pyroflam NS is supplied in 50 ml, 100 ml and 250 ml clear glass vials.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Protect from light. Keep out of reach of children, uninformed persons and animals.

REGISTRATION NUMBER

99/2.6/4

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DATE OF PUBLICATION OF THE PACKAGE INSERT

22 October 2008

Namibia: V06/2.6/1172

02245708

TRIAL

Veterinêre medisyne

Slegs vir dieregebruik

SKEDULERINGSTATUS S3

EIENDOMSNAAM EN DOSEERVORM

Pyroflam NS Inspuiting

SAMESTELLING

Elke ml bevat fluniksienmeglumien ekwivalent aan 50 mg fluniksien.
Fenol as preserveermiddel: 0,5 % m/v.

FARMAKOLOGIESE KLASSIFIKASIE

C1.8 Pynstillend, koorswerende middels.

FARMAKOLOGIESE WERKING

Fluniksien is 'n 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 aragidoonsuurkaskade wat verantwoordelik is vir die omskakeling van aragidoonsuur na endoperoksiede. Gevolglik word die sintese van eikosanoïede, belangrike medieerders van die inflammatoriese proses betrokke in sentrale pirese, pynpersepsie en weefselinflammasie, geïnhibeer. Deur sy werking op die aragidoonsuur-kaskade 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 inhibisie van die aragidoonsuurkaskade, verskaf fluniksien ook 'n anti-endotoksiese effek deur onderdrukking van eikosanoïedformasie, om sodoende hul betrokkenheid in endotoksiese siektetoestande te voorkom.

INDIKASIES

Perde: Pyroflam NS word aangedui vir die verligting van inflammasie en pyn geassosieer met muskuloskeletale afwykings en vir die verligting van viserale pyn geassosieer met koliek.
Beeste: Pyroflam NS word aangedui vir die beheer van akute inflammasie geassosieer met respiratoriese siektes.

KONTRA-INDIKASIES

Moenie aan dragtige merries of vullens jonger as 72 uur toedien nie.
Die gebruik word teenaangedui in diere wat aan hart-, lewer-, of niersiektes ly, waar daar die moontlikheid van gastroïntestinale bloeding, of bewyse van bloeddiskrasieë of hipersensitiwiteit teen die produk bestaan.

WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS

Diere moet nie binne 10 dae na toediening vir menslike gebruik geslag word nie.
Melk vir menslike gebruik mag slegs na 24 uur na die laaste toediening van Pyroflam NS geneem word. Vermy intra-arteriële toediening.
Moenie in katte gebruik nie.
Weens 'n tekort aan die ensiem glukoronieltransferase, 'n belangrike konjugasiemeganisme, is jong diere (jonger as 30 dae) meer vatbaar vir toksisiteit. Die gebruik in enige dier jonger as 6 weke oud of in ou diere mag 'n bykomende risiko behels. Indien die gebruik daarvan nie in sulke diere vermy kan word nie, moet die dosis moontlik verminder en sorgvuldige kliniese bestuur toegepas word. Vermy die gebruik daarvan in enige gedehidreerde, hipovolumiese of hipotensiewe dier. Verkieslik moet fluniksien nie toegedien word aan diere wat algemene narkose ondergaan nie, tensy hulle ten volle herstel het.

INTERAKSIES

Middelversoenbaarheid moet noukeurig gemonitor word wanneer bykomende terapie benodig word.
Moenie ander nie-steroïed anti-inflammatoriese middels (NSAIM) saam of binne 24 uur na mekaar toedien nie. Sommige NSAIM mag hoogs gebind wees aan plasmaproteïene en kompeteer met ander hoogs gebinde middels en sodoende tot toksisiteit lei.
Die gelyktydige toediening van potensieel nefrotoksiese middels moet vermy word.

DOSIS EN GEBRUIKSAANWYSINGS

Pyroflam NS word aangedui vir intraveneuse toediening in beeste en perde. Moenie Pyroflam NS voor toediening met ander medikasies meng nie. Moenie die aanbevole dosis oorskry of die tydperk van behandeling verleng nie. Na onttrekking van die eerste dosis van die ampuul moet die produk binne 28 dae gebruik word. Gooi ongebruikte produk weg.

Perde:
Vir gebruik in koliek is die aanbevole dosis 1,1 mg fluniksien/kg liggaamsmassa, ekwivalent aan 1 ml per 45 kg liggaamsmassa. Behandeling mag 1 of twee keer herhaal word indien koliek weer voorkom.
Vir die gebruik in musculoskeletale afwykings is die aanbevole dosis 1,1 mg fluniksien/kg liggaamsmassa, ekwivalent aan 1 ml per 45 kg liggaamsmassa, een keer per dag vir tot solank as 5 dae volgens kliniese respons.

Beeste:
Die aanbevole dosis is 2,2 mg fluniksien/kg liggaamsmassa, ekwivalent aan 2 ml per 45 kg liggaamsmassa. Herhaal wanneer nodig met tussenposes van 24 uur vir tot solank as 5 opeenvolgende dae.
Die oorsaak van die onderliggende inflammatoriese kondisie moet vasgestel word en behoort die toepaslike meegaande terapie te ontvang.

NEWE-EFFEKTE

Newe-effekte sluit gastroïntestinale ulserasie, en in gedehidreerde of hipovolumiese pasiënte, die potensiaal vir nierbeskadiging in. Die verlengde gebruik of die gebruik van hoër as aanbevole dosisse mag tot 'n lewensbedreigende plasmaproteïenenteropatie weens gastroïntestinale ulserasie lei.
Nefrotoksisiteit in die vorm van papillêre nekrose, beenmurgonderdrukking wat tot bloeddiskrasieë lei, en vertraagde lewerfunksie mag voorkom.
Die intra-arteriële toediening van fluniksien mag tot ataksie, vinnige asemhaling, spierswakheid en sentrale senuweestelseleffekte lei.
Geïsoleerde gevalle van lokale reaksies na intramuskulêre inspuiting in perde, veral in die nekarea, is aangemeld. Dit sluit sweet, swelling, verharding en styfheid in.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien "Newe-effekte".

IDENTIFIKASIE

'n Helder, kleurlose oplossing sonder sigbare partikels.

AANBIEDING

Pyroflam NS word aangebied in helder glas flesse van 50 ml, 100 ml en 250 ml.

BERGINGSAANWYSINGS

Bewaar teen of benede 25°C.
Beskerm teen lig. Hou buite bereik van kinders, oningeligte persone en diere.

REGISTRASIENOMMER

99/2.6/4

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DATUM VAN PUBLIKASIE VAN DIE VOUBILJET

22 Oktober 2008

Namibië: V06/2.6/1172