VETERINÊRE MEDISYNE

SKEDULERINGSTATUS

S4

EIENDOMSNAAM EN DOSEERVORM

COLVASONE INSPUITING

SAMESTELLING
'n Steriele oplossing van Deksametasoonnatriumfosfaat 2 mg/ml met bensielalkohol 20 mg/ml as preserveermiddel.

FARMAKOLOGIESE KLASSIFIKASIE
C3.1.1 Steroïede

FARMAKOLOGIESE WERKING
Deksametasoon is 'n kortikosteroïed met anti-inflammatoriese en glukogeniese eienskappe en met min mineralokortikoïede aktiwiteite. Kortikosteroïede beïnvloed proteïen-, koolhidraat- en vetmetabolisme, elektroliet- en waterbalans en die funksionele vermoëns van die kardovaskulêre sisteem, die niere en skeletspiere, die senuwee sisteem en ander organe en weefsels.

Teiken Spesies
Perde, beeste, kalwers, varke, skape en bokke, honde en katte.

INDIKASIES
Deksametasoon is 'n sintetiese kortikosteroïed met 'n baie potente inflammatoriese werking.

COLVASONE kan gebruik word vir:
1) Intraveneuse terapie in gevalle waar nood behandeling aangedui is, veral tydens skok en sirkulasie instorting, "fog fever" (akute pulmonêre edeem en emfiseem by beeste), akute mastitis en brandwonde.
2) Asetonemie (ketose) in beeste. COLVASONE het 'n sterk glukoneogeniese werking.
3) Inflammatoriese toestande in al die spesies: COLVASONE sal inflammasie onderdruk en is aangedui vir die behandeling van artritis, laminitis, dermatitis, ens.

KONTRA-INDIKASIES
Sistemiese kortikosteroïed behandeling is gewoonlik teen aangedui by pasiënte met niersiektes, diabetes mellitus, en kongestiewe hartversaking en algemene beensiekte (osteoporose).

Kortikosteroïede word nie aanbeveel vir gebruik in dragtige diere nie. Dit is bekend dat toediening van kortikosteroïede tydens vroeë dragtigheid fetale abnormaliteite by diere kan veroorsaak. Toediening gedurende die laat dragtigheidperiode kan voortydige baring of abortasie veroorsaak.

Kortikosteroïede kan wondheling vertraag en die immuno-onderdrukkende werking kan die weerstandbiedenheid teenoor infeksies verlaag of bestaande infeksies vererger. Indien bakteriële infeksie teenwoordig is tydens steroïedbehandeling word antibakteriële geneesmiddelsdekking gewoonlik vereis. In teenwoordigheid van virus infeksies kan steroiede die verloop van die siekte of vertraag of bevorder.

Maag-dermseervorming is gerapporteer in diere wat met kortikosteroïede behandel is en steroïed kan dit ook vererger in pasiënte wat tegelykertyd met nie-steroïedale anti-inflammatoriese middels behandel word, asook in diere met rugmurgbeserings wat met kortikosteroïede behandel word.

Die gebruik van hierdie produk in perde kan aanleiding gee tot laminitis en die diere moet dus noukeuring dopgehou word tydens behandeling.

Gedurende die verloop van behandeling behoort die situasie dikwels deur goeie veeartsenykundige supervisie hersien te word.

WAARSKUWINGS EN SPESIALE VOORSORGSMAATREËLS
Wondheling mag vertraag word.

Gelydelike onttrekking word aanbeveel na 'n langdurende behandelingkurses.

Toediening gedurende die laaste stadiums van dragtigheid in beeste en skape kan voortydige baring veroorsaak. Fetale abnormaliteite is waargeneem in knaagdiere, konyne en honde, veral as die geneesmiddel tydens die vroeë stadiums van dragtigheid toegedien was.

Na parenterale toediening van COLVASONE duur die kortikosteroïedale aktiwiteit vir tot en met 12 ure.

Ontrekkingtye:
Beeste, varke, skape en bokke mag nie tydens behandeling vir menslike gebruik geslag word nie. Beeste, varke, skape en bokke kan slegs 21 dae, nadat behandeling gestaak is, vir menslike gebruik geslag word.

Melk vir menslike gebruik mag nie tydens behandeling geneem word nie. Melk vir menslike gebruik mag slegs van beeste, skape en bokke geneem word 72 uur na die laaste behandeling.

Moet nie gebruik word in perde wat vir menslike gebruik geslag word nie.

DOSIS EN GEBRUIKSAANWYSINGS
Toediening geskied binne-aars of binnespiers.

Normale aseptiese voorsorgmaatreëls moet nagekom word.

Perde en beeste:	5 tot 20 mℓ
Kalwers, varke, skape en bokke:	1 tot 5 mℓ
Honde:	0,25 tot 2 mℓ
Katte:	0,25 tot 0,5 mℓ

byvoorbeeld

Perd	500 kg	10 tot 20 mℓ
Koei	400 kg	10 tot 16 mℓ
Skaap	50 kg	2 mℓ
Vark	50 kg	2 mℓ
Hond	10 kg	0,5 tot 1 mℓ
Kat	5 kg	0,25 tot 0,5 mℓ

NEWE-EFFEKTE
Dit is bekend dat anti-inflammatoriese kortikosteroïede, soos deksametasoon, aanleiding tot 'n wye reeks newe-effekte kan gee. Alhoewel enkele hoë dosisse gewoonlik goed verdra word, kan dit ernstige newe-effekte na lang termyn gebruik veroorsaak, sowel as waneer dit saam met esters met 'n langdurende werkingaksie gebruik word. Die dosis gedurende medium- tot langtermyn behandeling behoort in die algemeen tot die minimum wat nodig is om die simptome te beheer, beperk te word.

Steroïede kan op hulle eie gedurende behandeling, Cushingtipe sindrome veroorsaak met merkbare verandering in vet-, koolhidraat-, proteïen- en mineraalmetabolisme met byvoorbeeld die voorkoms van herdistribusie van liggaamsvet, spierswakheid en weefselkwyning en osteoporose. Gedurende behandeling onderdruk effektiewe dosisse die Hipothalamo -pituitêre-adrenale asse. Na staking van behandeling kan simptome van adrenale ontoereikendheid tot adrenokortikool atropie voorkom en dit kan veroorsaak dat die dier nie spanningvolle situasies behoorlik kan hanteer nie. Aandag behoort dus gegee te word om die probleme van adrenale ontoereikenheid na staking van behandeling te verminder deur byvoorbeeld die dosis gelydelik te verminder.

Sistemieswerkende kortikosteroïede kan aanleiding gee tot poliurie, polydipsie en polyfagie, veral gedurende die vroeë stadiums van behandeling. Sommige kortikosteroïede kan tydens langdurende gebruik aanleiding gee tot natrium- en waterretensie en hipokalemie. Sistemiese kortikosteroïede het neerslag van kalsium in die vel gehad (Calcinosis cutis).

Steroïede kan vergroting van die lewer (hepatomegalie) met 'n toename in serum lewerensieme veroorsaak.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Geen.

IDENTIFIKASIE
Steriele oplossing glasfles.

AANBIEDING
Helder/amberkleurige 50 mℓ glasfles met bromobutielrubberprop en 'n aluminium seël.

BERGINGSAANWYSINGS
HOU BUITE DIE BEREIK VAN KINDERS.
Bewaar teen of benede 25°C.

REGISTRASIENOMMER
83/43 (Wet 101 van 1965).

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
13 November 2003

NS2

Namibië: V10/3.1.1/1176

VETERINARY MEDICINES

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

COLVASONE INJECTION

COMPOSITION
A sterile solution containing Dexamethasone sodium phosphate 2 mg/ml and Benzyl alcohol 20 mg/ml as preservative.

PHARMACOLOGICAL CLASSIFICATION
C 3.1.1 Steroidals

PHARMACOLOGICAL ACTION
Dexamethasone is a corticosteroid with anti-inflammatory and glucogenic properties, and little mineralocorticoid activity. Corticosteroids influence protein, carbohydrate and fat metabolism, electrolyte and water balance and the functional capabilities of the cardiovascular system, the kidneys and skeletal muscles, the nervous system and other organs and tissues.

TARGET SPECIES
Horses, cattle, calves, pigs, sheep and goats, dogs and cats.

INDICATIONS
Dexamethasone is a synthetic corticosteroid with a highly potent anti-inflammatory action.
COLVASONE can be used for:
1) Intravenous therapy in cases where emergency treatment is indicated, particularly shock and circulatory collapse, fog fever (acute bovine pulmonary oedema and emphysema), acute mastitis and burns.
2) Acetonaemia (ketosis) in cattle. COLVASONE has a marked gluconeogenic action.
3) Inflammatory conditions in all species: COLVASONE will suppress inflammation and is indicated in the treatment of arthritis, laminitis, dermatitis, etc.

CONTRAINDICATIONS
Systemic corticosteroid therapy is generally contraindicated in patients with renal disease, diabetes mellitus, and congestive heart failure and generalised bone disease (osteoporosis).
Corticosteroids are not recommended for use in pregnant animals.
Administration in early pregnancy is known to have caused foetal abnormalities in animals. Administration in late pregnancy may cause early parturition or abortion.
Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of bacterial infection, anti-bacterial medicine cover is usually required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of the disease.
Gastrointestinal ulceration has been reported in animals treated with corticosteroids and this may be exacerbated by steroids in patients given nonsteroidal anti-inflammatory medicines and corticosteroid-treated animals with spinal cord trauma.
Use of this product in horses may induce laminitis and therefore careful observations during treatment should be made.
During the course of treatment the situation should be reviewed frequently by close veterinarian supervision.

WARNINGS AND SPECIAL PRECAUTIONS
Wound healing may be delayed.
Gradual withdrawal is advisable following a prolonged course of treatment.
Administration during the latter stages of pregnancy in cattle and sheep may induce early parturition. Foetal abnormalities have been observed in rodents, rabbits and dogs, particularly when the medicine was administered during the first trimester.
Following injection with COLVASONE, corticosteroid activity persists for up to 12 hours.
Withdrawal times:
Cattle, pigs, sheep and goats must not be slaughtered for human consumption during treatment. Cattle, pigs, sheep and goats may be slaughtered for human consumption only after 21 days from the last treatment.
Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from treated cattle, sheep and goats only after 72 hours from the last treatment.
Do not use in horses intended for human consumption.

DOSAGE AND DIRECTIONS FOR USE
By intravenous or intramuscular injection. Normal aseptic precautions should be observed.

Horses and Cattle:	5 to 20 mℓ
Calves, pigs, sheep and goats:	1 to 5 mℓ
Dogs:	0,25 to 2 mℓ
Cats:	0,25 to 0,5 mℓ

e.g

Horse	500 kg	10 to 20 mℓ
Cow	400 kg	10 to16 mℓ
Sheep	50 kg	2 mℓ
Pig	50 kg	2 mℓ
Dog	10 kg	0,5 to 1 mℓ
Cat	5 kg	0,25 to 0,5 mℓ

SIDE EFFECTS
Anti-inflammatory corticosteroids, such as dexamethasone, are known to exert a wide range of side effects. Whilst single high doses are generally well tolerated, they may induce severe side effects in long term use and when esters possessing a long duration of action are administered. Dosage in medium to long term use should therefore generally be kept to a minimum necessary to control symptoms.

Steroids themselves, during treatment, may cause Cushingoid symptoms involving significant alterations of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, muscle weakness and wastage and osteoporosis may result. During therapy effective doses suppress the Hypothalamo-pituitreal-adrenal axis. Following cessation of treatment, symptoms of adrenal insufficiency extending to adrenocorticol atrophy can arise and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means of minimizing problems of adrenal insufficiency following the withdrawal of treatment, e.g. a gradual reduction of dosage.

Systemically acting corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia in long term use. Systemic corticosteroids have caused deposition of calcium in the skin (Calcinosis cutis).

Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
None.

IDENTIFICATION
Sterile solution in glass ampoules.

PRESENTATION
Clear/amber 50 mℓ glass vials with bromobutyl rubber bung with aluminium overseal.

STORAGE INSTRUCTIONS
KEEP OUT OF REACH OF CHILDREN.
Store at or below 25 °C.

REGISTRATION NUMBER
Ref no: 83/43 (Act 101 of 1965)

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

Marketed by:

Biotech Laboratories (Pty) Ltd
Tel: (011) 848 3050
Fax: (011) 848 3065
Email: info@biotechlabs.co.za
www.biotechlabs.co.za

DATE OF PUBLICATION OF THE PACKAGE INSERT
13 November 2003

NS2

Namibia: V10/3.1.1/1176

TRIAL

017457/08