VETERINARY MEDICINES

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

COLVASONE INJECTION

COMPOSITION
Each 1,0 mℓ solution contains:
Dexamethasone sodium phosphate 2 mg
Preservative:
Benzyl alcohol 2 % *m/v*

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, goats, dogs and cats.

INDICATIONS
Dexamethasone is a synthetic corticosteroid with a highly potent anti-inflammatory action.

Colvasone Injection 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 Injection has a marked gluconeogenic action.
3) Inflammatory conditions in all species: Colvasone Injection 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, 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 Injection, corticosteroid activity persists for up to 12 hours.

Withdrawal times:
Meat:
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:
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 to 16 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 Hypothalamic-pituitary-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 AND UNINFORMED PERSONS.
Store at or below 25 °C.

REGISTRATION NUMBER
83/43 (Act 101 of 1965)

Export countries:
Botswana: POM BV2100105
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