This leaflet has been reviewed and approved 05/2019

SUMMARY OF PRODUCT CHARACTERISTICS
Veterinary use only - Prescription only medicine

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colvasone Veterinary, 2mg/ml, Solution for injection
I.M, I.V injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active Substance:
Dexamethasone Sodium Phosphate 2mg
For a full list of excipients, see section 13 "further information"

3. indications for use

Dexamethasone is a synthetic corticosteroid with a potent anti-inflammatory action.
Colvasone can be used for:

(1) Intravenous therapy in cases where emergency treatment is indicated, particularly shock and circulatory collapse, acute mastitis and burns.
(2) Inflammatory conditions: the product will suppress inflammation and is indicated in the treatment of arthritis, laminitis, dermatitis etc..
(3) Acetonaemia (ketosis) in cattle. Dexamethasone has a marked glucogenic action

Pharmacotherapeutic Group: corticosteroids

4. Contraindications

Systemic corticosteroid therapy is generally contra-indicated in patients with renal disease and diabetes mellitus.

5. Adverse reactions (frequency and seriousness)

Steroids themselves, during treatment, may cause Cushingoid symptoms involving significant alteration 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-Pituitary-Adrenal axis. Following cessation of treatment, symptoms of adrenal insufficiency extending to adrenocortical atrophy can arise and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment, e.g. a gradual reductions of dosage (for further discussion see standard texts).
- 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). Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections.
- Gastrointestinal ulceration has been reported in animals treated with corticosteroids and g.i.t. ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in corticosteroid-treated animals with spinal cord trauma.
- Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting adverse events due to drug treatment" found on the home page of the Ministry of Health website (www.health.gov.il) which refers to the online form for reporting adverse events, or by entering the link:
https://sideeffects.health.gov.il

6. Target Species:

Horse, Cattle, Dogs, Cats

7. Amounts to be administered and administration route

Horses ~~and cattle~~: 1 ml per 25 kg bodyweight
Cattle: 0.33-1 ml per 25 kg bodyweight
Dogs and cats: 1 ml per 10 kg bodyweight
e.g.

Horses	500 kg	-	20 ml
Cattle	400 kg	-	5.28-16 ml
Dogs	10 kg	-	1 ml
Cats	5 kg	-	0.5 ml

8. How to use the preparation:

The product is injected by intramuscular or intravenous routes.
Normal aseptic precautions should be observed.
To ensure accuracy of dosing, a suitably graduated syringe must be used when treating small animals.

9. Withdrawal period

Cattle: Meat: 21 days.
Milk: 84 hours (7 milking).
Do not use in horses intended for human consumption.

10. Special warnings and precautions for use:

Special precautions for use in animals:
In the use of horses - the product can cause inflammation of the hooves (Laminitis) and therefore should be monitored during treatment.
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 the minimum necessary to control symptoms.
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Use caution when using the product. In case of accidental self-injection, seek medical advice immediately and show the carton to the physician.
Pregnant women should not handle this veterinary medicinal product.
Wash hands after use.
Interaction with other medicinal products and other forms of interaction:
In the presence of bacterial infection, antibacterial drug cover is usually required when steroids are used.
In the presence of viral infections, steroids may worsen or hasten the progress of the disease.
Use during pregnancy, lactation or lay
Corticosteroids are not recommended for use in pregnant animals. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals.
Administration in late pregnancy may cause early parturition or abortion.
Overdose:
Exacerbation of effects described in 5 above.

11. Storage instructions

Prevent poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and / or infants and thereby prevent poisoning.
Storage conditions: Do not store above 25°c. keep in outer carton in order to protect from light.
The shelf life of the product as marketed in its original packaging are two years. Do not use this medicine after the exp date on the package. The expiration date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 28 days.
Remedies should be destroyed after 28 days.

12. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products:

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed as toxic waste. Do not dispose of sewage.

13. FURTHER INFORMATION:

In addition to the active ingredient the product also contains:
Benzyl alcohol, Sodium Phosphate Dodecahydrate, Sodiume Phosphate, Disodium edentate dihydrate, Water for injection
Pharmaceutical form: A clear, colourless solution.
Packaging sizes: Glass vials contains 50 ml
Registration holder: Comex Ltd. HABNAYAH ST. 12, INDUSTRIAL AREA HAR TOV "A" , BET SHEMESH
Manufacturer: Norbrook Laboratories Limited , Station Works, Newry, BT35 6JP, Northern Ireland, UK
Product registration number: 153 04 33571 00