SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colvasone 0.2% w/v Solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Dexamethasone Sodium Phosphate 2 mg/ml

Excipients:
Benzyl alcohol 20mg/ml.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Horses
Cattle
Dogs
Cats

4.2 Indications for use, specifying the target species

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, fog fever, acute mastitis and burns.
(2) Acetonaemia (ketosis) in cattle. Dexamethasone has a marked glucogenic action.
(3) Inflammatory conditions in all species: the product will suppress inflammation and is indicated in the treatment of arthritis, laminitis, dermatitis etc.

4.3 Contraindications

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

4.4 Special warnings for each target species

Use of the product in horses could induce laminitis and therefore careful observations should be made during treatment.

4.5 Special precautions for use

Special precautions for use in animals

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 the minimum necessary to control symptoms.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This product contains dexamethasone which can cause allergic reactions in some people. People with known hypersensitivity to dexamethasone should avoid contact with the veterinary medicinal 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.

4.6 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 gastrointestinal 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.

In very rare cases, hypersensitivity reactions might occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 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.

4.8 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.

4.9 Amounts to be administered and administration route

By intravenous or intramuscular injection.
Normal aseptic precautions should be observed.

Recommended Dosage Schedule:

Horses and cattle:	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	-	16 ml
Dogs	10 kg	-	1 ml
Cats	5 kg	-	0.5 ml

To ensure accuracy of dosing, a suitably graduated syringe must be used when treating small animals.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Exacerbation of effects described in 4.6 above. No treatment specified.

4.11 Withdrawal periods

Cattle (meat): 21 days.
Cattle (milk): 84 hours.

Do not use in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroids for systemic use, plain; Glucocorticoids
ATC Vet Code: QH02AB02

5.1 Pharmacodynamic properties

Dexamethasone is a potent synthetic glucocorticoid which is 30-35 times as potent as cortisol as an anti-inflammatory agent. The mechanism by which corticosteroids exert their effect at the cellular level remains unclear however several mechanisms have been proposed. There is evidence that corticosteroids are able to de-repress transcription of DNA to mRNA in the target cell nucleus. Other mechanisms proposed for the action of corticosteroids include boosting of cellular levels of cyclic AMP made possible by steroid inhibition of phosphodiesterases which would otherwise metabolise cyclic AMP. Some of the anti-inflammatory activity of corticosteroids could be due to inhibition of prostaglandin synthesis by suppression of the release of arachidonate, the prostaglandin precursor, from cell membranes.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Sodium Phosphate Dodecahydrate
Sodium Phosphate
Disodium Edetate Dihydrate
Water for injection

6.2 Major Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25°C.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.

6.5 Nature and composition of immediate packaging

50 ml Amber Type II glass vials sealed with bromobutyl rubber bungs with aluminium overseals.

6.6 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 of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4009

9. DATE OF FIRST AUTHORISATION

30 June 1994

10. DATE OF REVISION OF THE TEXT

March 2022

Approved 25 March 2022