Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Colvasone 2 mg/ml Solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance		
Dexamethasone Sodium Phosphate	2	mg

Excipient		
Benzyl Alcohol	20	mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless, sterile 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 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. Colvasone has a marked glucogenic action.
3)Inflammatory conditions in all species: Colvasone will suppress inflammation and is indicated in the treatment of arthritis, dermatitis etc.

4.3 Contraindications

Do not use 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. In the presence of bacterial infection, antibacterial drug cover is usually required when steroids are used.
Special precautions to be taken by the person administering the veterinary medicinal product to animals
No special precautions.

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-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 minimising problems of adrenal insufficiency following the withdrawal of treatment, e.g. a gradual reduction 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 tract 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 the presence of viral infections, steroids may worsen or hasten the progress of the disease.

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 interactions

Gastrointestinal tract ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs.

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 (0.08 mg dexamethasone per kg bodyweight)
Dogs and cats:	1 ml per 10 kg bodyweight (0.2 mg dexamethasone per 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

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

Not applicable.

4.11 Withdrawal period(s)

Cattle and horses must not be slaughtered for human consumption during treatment. Cattle and horses may be slaughtered for human consumption only after 21 days from the last treatment. Milk must not be taken for human consumption during treatment. Milk for human consumption may be taken from cows only after 72 hours from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroids for systemic use
ATCvet 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 corticosterioids exert their effect at 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

Sodium Dihydrogen Phosphate
Sodium Hydrogen Phosphate
Disodium Edetate
Benzyl Alcohol
Water for Injections

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.

6.5 Nature and composition of immediate packaging

50 ml and 100ml amber Type II glass vials sealed with bromobutyl rubber bungs and aluminium seals.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/028/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1989
Date of last renewal: 30 September 2009

10 DATE OF REVISION OF THE TEXT

January 2019