

## **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**

#### **i. 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.

#### **ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals**

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 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.

#### **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 period**

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.

**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 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 material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

### **7. MARKETING AUTHORISATION HOLDER**

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

### **8. MARKETING AUTHORISATION NUMBER(S)**

**Vm:** 02000/4009

### **9. DATE OF FIRST AUTHORISATION**

1<sup>st</sup> September 1994

### **10. DATE OF REVISION OF THE TEXT**

November 2009