1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexameth 2 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Dexamethasone Sodium Phosphate 2 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl Alcohol	20 mg
Sodium Dihydrogen Phosphate	
Sodium Hydrogen Phosphate	
Disodium Edetate	
Water for Injections	

Clear, colourless, sterile solution.

3. CLINICAL INFORMATION

3.1 Target Species

Horses, cattle, dogs and cats.

3.2 Indications for use for each target species

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

The veterinary medicinal product 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. The veterinary medicinal product has a marked glucogenic action.
3) Inflammatory conditions in all species: The veterinary medicinal product will suppress inflammation and is indicated in the treatment of arthritis, dermatitis etc.

3.3 Contraindications

Do not use in patients with renal disease and diabetes mellitus.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species

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

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

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses, cattle, dogs, cats.

Undetermined frequency (cannot be estimated from the available data):	Iatrogenic hyperadrenocorticism (Cushing's disease)[1] Polyuria[2], polydipsia[2], polyphagia[2] Sodium retention[3], water retention[3], hypokalaemia[3] Cutaneous calcinosis Delayed wound healing, weakened resistance to or exacerbation of existing infections Gastro-intestinal ulceration[4], hepatomegaly[5] Changes in blood biochemical and haematological parameters Laminitis[6]

[1]Involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g., redistribution of body fat, muscle weakness and wastage and osteoporosis may result.
[2]After systemic administration and particularly during early stages of therapy.
[3]Upon long-term use.
[4]May be exacerbated in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.
[5]With increased serum hepatic enzymes.
[6]Horses only.

In the presence of viral infections, steroids may worsen or hasten the progress of the disease.

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).

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 upon

long-term use and when esters possessing a long duration of action are administered. During medium to long-term use, the dose should therefore generally be kept to the minimum necessary to control symptoms.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
The use is not recommended during pregnancy. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

By intravenous or intramuscular injection.
Normal aseptic precautions should be observed.
To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle:
Meat and offal: 21 days.
Milk: 72 hours.

Horses:
Meat and offal: 21 days.
Not authorised for use in horses producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QH02AB02

4.2 Pharmacodynamics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

100 ml amber Type II glass vials sealed with bromobutyl rubber bungs.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chem-Pharm Ltd

7. MARKETING AUTHORISATION NUMBERS

VPA10823/013/001

8. DATE OF FIRST AUTHORISATION

01/10/1999

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

28/11/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).