

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diurizone Injectable

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains: **Active**

substances:

Hydrochlorothiazide 50 mg

Dexamethasone 0.5 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	0.01 ml
Dimethylacetamide	
Propylene glycol	
Macrogol 300	
Water for injections	

A colourless, slightly viscous solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

Horses declared as not being intended for slaughter for human consumption.

3.2 Indications for use for each target species

Cattle:

- Congestion and oedema of the udder,
- Persistent oedema during lactation,
- Pulmonary congestion and oedema,
- Oedema of surgical wounds,
- Oedema of allergic conditions.

Horses:

- Generalised congestion and oedema,
- Oedema of sheath,
- Anasarca,
- Oedema in allergic conditions.

3.3 Contraindications

Do not use in pregnant animals.

Do not use in animals with viral infections, during the viraemic phase.
 Do not use in animals with diabetes mellitus, congestive heart failure, chronic nephritis, osteoporosis or glaucoma.
 Do not use in animals with hepatic encephalopathy.
 Do not use in cases of severe hypokalaemia.
 Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
 Do not use in horses for the treatment of laminitis.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

For intravenous administration, use a tepid solution and inject slowly.

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

Cattle, horse:

<p>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</p>	<p>Cushing disease^{1,5} Hypokalaemia²; Laminitis³; Osteoporosis⁵, Other immune system disorder⁴, Persistent infection⁴ Hepatic encephalopathy; Tissue atrophy⁵, Polydipsia⁶, Delayed wound healing; Muscle atrophy⁵, Ataxia⁶, Disorientation⁶; Skin thinning⁵, Bacterial skin infection⁶; Polyuria⁶, Urinary tract infection⁶; Aggression⁶, Hyperactivity⁶; Respiratory tract infection⁶; Gastro-intestinal ulceration⁶;</p>
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¹ Inhibition of ACTH release by antehypophysis inducing the suppression of corticoid production by the adrenal cortex may be observed. Decrease of the hypophyseal ACTH response.

² For cattle only. Potassium levels should be monitored.

³ For horses only. Horses treated with such preparations should be monitored frequently during the treatment period.

⁴ Immunosuppressant actions which may weaken resistance to or exacerbate existing infections. In the presence of bacterial infection, anti-bacterial therapy is required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of disease. Immuno depression in the case of long-term corticosteroid therapy.

⁵ In the case of long-term therapy.

⁶ In the case of short-term therapy. It is not necessary to use a special protocol such as progressive diminution of doses, if the treatment lasts less than 15 days.

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:

Do not use during the whole or part of the pregnancy.

Lactation:

The use of the product in lactating cows may cause a reduction in milk yield.

3.8 Interaction with other medicinal products and other forms of interaction

The use of attenuated live virus vaccines is not recommended, the immunosuppressive action of corticoids may cause generalised disease.

Lack of or reduction of the hypoglycaemic activity of insulin, metformin or hypoglycaemic sulfonamides if combined with a corticoid and/or hydrochlorothiazide. Hypokalaemia favours the toxic effects of digitalis or cardiac glucosides.

3.9 Administration routes and dosage

This veterinary medicinal product may be administered by intravenous, intramuscular, subcutaneous injection.

Cattle and adult horses:

- Preventative treatment: 10 ml daily for 3 days.
- Curative treatment:
 - Congestion and mild oedema: 10 ml daily for 2 or 3 days.
 - Congestion and severe oedema: 20 ml daily for 2 days and 10 ml the third day.

Foals and calves: 2 ml per 40 - 50 kg bodyweight daily for 3 days.

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

Given at high dose or following prolonged administration, dexamethasone may induce tissue atrophy, skin fragility and immunodepression.

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: 28 days.

Milk: 7 days.

Horses:

Treated horses may never be slaughtered for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QC03AX01.

4.2 Pharmacodynamics

Dexamethasone is a synthetic glucocorticoid the anti-inflammatory activity of which is increased by a C16 methylation and the presence of a C9 fluorine atom. However, the mineralocorticoid activity is reduced.

The anti-inflammatory effect is the primary action which is obtained by stabilisation of cell membranes, maintaining the micro circulation of the inflamed zone and prevention of oedema, while preserving normal cell permeability.

Dexamethasone possesses other physiological and pharmacological functions such as:

- modification of glucose, protein and lipid-metabolisms, with especially induction of the neoglucogenesis inducing an increase in blood glucose levels, the deposit of hepatic glycogen, lipid demobilisation and protein catabolism.
- regulation of circulation by reduction of peripheral resistance, improvement in venous circulation and increase in cardiac output.
- an anti-allergic action obtained by membrane stabilisation, acting on histamine.

Given at high dose or following prolonged administration, Dexamethasone may induce tissue atrophy, skin fragility and immunodepression.

Hydrochlorothiazide is a diuretic acting by inhibition of sodium resorption. An increase in water excretion occurs, facilitating oedema resorption.

Hydrochlorothiazide also eliminates chloride ions.

Potassium and bicarbonate diuresis is not observed in ruminants. Hydrochlorothiazide does not induce hypokalaemia or acidosis or alkalosis.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store below 25 °C.

5.4 Nature and composition of immediate packaging

50 ml amber type II glass vial closed with chlorobutyl stopper and sealed with an aluminium cap.

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

Vetoquinol S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10521/019/001

8. DATE OF FIRST AUTHORISATION

01/10/1989

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

19/06/2026

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).