Summary of Product Characteristics

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

Excipient

Benzyl Alcohol	0.01	ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
A colourless, slightly viscous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

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

4.2 Indications for use, specifying the 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
AnasarcaOedema in allergic conditions

4.3 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 hypokalemia. Do not use in animals with known hypersensitivity to the active ingredients. Do not use in horses for the treatment of laminitis.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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
None.

4.6 Adverse reactions (frequency and seriousness)

The association of Hydrochlorothiazide and Dexamethasone acetate may induce hepatic encephalopathy.
Corticosteroids may delay wound healing and the immunosuppressant actions 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.

Due to the risk of hypokalaemia in ruminants treated with corticosteroids, potassium levels should be monitored.

Moreover, risks may be associated according to the length of therapy:
In the case of long term corticosteroid therapy, Cushings' syndrome, tissue atrophy, reduction of muscular weight, osteoporosis, diminution of skin thickness, immuno depression, or the inhibition of ACTH release by antehypophysis inducing the suppression of corticoid production by the adrenal cortex may be observed.
In the case of short term therapy: polyuria, polydipsia, euphoria, ataxia, disorientation, aggressiveness, risks of urinary, skin or pulmonary infectious complications, gastro-intestinal ulceration or decrease of the hypophyseal ACTH response may occur.
However, it is not necessary to use a special protocol such as progressive diminution of doses, if the treatment lasts less than 15 days.
Use of corticosteroids in horses has been reported to induce laminitis. Therefore, horses treated with such preparations should be monitored frequently during the treatment period.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use during pregnancy.

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

4.8 Interaction with other medicinal products and other forms of interactions

The use of attenuated live virus vaccines is not to be recommended, the immunosuppressive action of corticoids may cause generalised disease.
Lack of or reduction of the hypoglycemic activity of insulin, metformine or hypoglycemic sulfonamides if combined with a corticoid and/or hydrochlorothiazide.Hypokalemia favours the toxic effects of digitalics or cardiac glucosides.

4.9 Amounts to be administered and administration route

Diurizone injection 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 - Calves:

2 ml per 40 - 50 kg bodyweight daily for 3 days.

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

See section 5.

4.11 Withdrawal period(s)

Cattle:
Meat and offal: 28 days
Milk: 7 days

Treated horses may never be slaughtered for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Cardiovascular system, low-ceiling diuretics, thiazides, hydrochlorothiazide, combinations
ATC vet code: QC03AX01

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 hypokalemia or acidosis or alkalosis.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dimethylacetamide
Propylene glycol
Macrogol 300
Benzyl alcohol Water for injections

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 yearsShelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and composition of immediate packaging

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

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

Vetoquinol Ireland Limited
12 Northbrook Road
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Dublin 6
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989

Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

August 2019