# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexacortone 2.0 mg chewable tablets for dogs and cats

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

**Active substance:**
Dexamethasone 2.0 mg

**Excipients:**

| Qualitative composition of excipients and other constituents |
|---|
| Lactose monohydrate |
| Potato starch |
| Povidone K30 |
| Magnesium stearate |
| Chicken Flavour |
| Yeast (dried) |

Light brown with brown spots, round and convex flavoured 13 mm tablet with a cross-shaped break line on one side.
Tablets can be divided into 2 or 4 equal parts

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dogs and cats.

### 3.2 Indications for use for each target species

For the symptomatic treatment or as adjunct treatment of inflammatory and allergic conditions in dogs and cats.

### 3.3 Contraindications

Do not use in animals with viral or mycotic infections.
Do not use in animals with diabetes mellitus or hyperadrenocorticism.
Do not use in animals with osteoporosis.
Do not use in animals with cardiac or renal dysfunction.
Do not use in animals with corneal ulcers.
Do not use in animals with gastro-intestinal ulceration.

Do not use in animals with burns.
Do not use concomitantly with attenuated alive vaccine.
Do not use in the case of glaucoma.
Do not use during pregnancy (see section 3.7).
Do not use in cases of hypersensitivity to the active substance, to corticosteroids or to any of the excipients.
See also section 3.8.

## 3.4 Special warnings

Corticoid administration is to induce an improvement in clinical signs rather than a cure. The treatment should be combined with treatment of the underlying disease and/or environmental control.

## 3.5 Special precautions for use

Special precautions for safe use in the target species:
In cases where it has been deemed necessary to administer the veterinary medicinal product in the presence of bacterial, parasitic or fungal infection, the underlying infection should be treated concomitantly with suitable antibacterial, antiparasitic or antifungal therapy.
Because of the pharmacological properties of dexamethasone, special care should be taken when the veterinary medicinal product is used in animals with a weakened immune system.
Corticoids such as dexamethasone, exacerbate proteinaceous catabolism. Consequently, the veterinary medicinal product should be used with caution in old or malnourished animals.
Corticoids such as dexamethasone should be used with caution in patients with hypertension.
Since glucocorticoids are known to slow growth, use in young animals (under 7 months of age) should be based on a benefit/risk assessment by the attending veterinarian.
Pharmacologically-active dose levels may lead to atrophy of the adrenal cortex, resulting in adrenal insufficiency. This may become apparent particularly after withdrawal of corticosteroid treatment. The dosage should be reduced and withdrawn gradually to avoid precipitation of adrenal insufficiency.
Avoid long-term use with oral corticosteroids whenever possible. Should long-term use be indicated, a corticosteroid with a shorter duration of action e.g. prednisolone is more appropriate. With prednisolone, alternate-day therapy can be utilised for longer-term use to minimise adrenal insufficiency. Due to the long duration of effect of dexamethasone alternate day therapy is not an adequate way to allow the hypothalamic-pituitary-adrenal axis to recover (see section 3.9).
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Dexamethasone may cause hypersensitivity (allergic) reactions. Skin contact with the veterinary medicinal product should be avoided, especially in people with known hypersensitivity to dexamethasone or any of the excipients (e.g. povidone or lactose). Wash hands after use. Seek medical advice in case of hypersensitivity reactions.
This veterinary medicinal product may be harmful to children after accidental ingestion. Do not leave the veterinary medicinal product unattended. Return unused

part-tablets to the blister pack and use them on the next administration. Keep the blister in the outer carton to prevent access by children. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Dexamethasone can cause harm to unborn children. Pregnant women should avoid exposure. Absorption through the skin is negligible but it is recommended to immediately wash hands after handling the tablets to avoid hand-to-mouth contact.

Special precautions for the protection of the environment:
Not applicable.

### 3.6 Adverse events

Dogs and cats:

| | |
|---|---|
| Very common<br>(>1 animal / 10 animals treated): | Cortisol suppression[1], elevated triglyceride[2] |
| Rare<br>(1 to 10 animals / 10,000 animals treated): | Elevated liver enzymes |
| Undetermined frequency<br>(cannot be estimated from the available data): | Polyphagia[3], polydipsia[3]<br>Polyuria[3]<br>Hyperadrenocorticism (Cushings disease)[4,5], Diabetes mellitus[3]<br>Excitation<br>Gastrointestinal ulceration[6], pancreatitis<br>Enlarged liver (hepatomegaly)<br>Changes in blood biochemical and haematological parameters (e.g. elevated serum alkaline phosphatase (SAP), decreased lactic acid dehydrogenase (LDH), hyperalbuminaemia, eosinopenia, lymphopenia, neutrophilia[7], decreased aspartate aminotransferase).<br>Hypothyroidism, elevated parathyroid (PTH) concentration<br>Inhibition of longitudinal growth of bones<br>Cutaneous calcinosis, skin thinning<br>Delayed healing, immunosuppression[8], weakened resistance to or exacerbation of existing infections[8]<br>Sodium and water retention[9], hypokalaemia[9] |

[1] as a result of effective doses suppressing the hypothalamic-pituitary-adrenal axis.
[2] as part of possible iatrogenic hyperadrenocorticism (Cushings disease).
[3] after systemic administration and particularly during early stages of therapy.
[4] iatrogenic.

[5] involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, increase in body weight, muscle weakness and wastage and osteoporosis may result.
[6] may be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.
[7] increase of segmented neutrophils.
[8] in the presence of viral infections, corticosteroids may worsen or hasten the progress of the disease.
[9] in long-term use.

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. Long-term use should therefore be avoided. Should long-term use be indicated, a corticosteroid with a shorter duration of action e.g. prednisolone is more appropriate (see section 3.5).

Following cessation of treatment, signs 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.

See also section 3.7.

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 its local representative 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 in pregnant animals. Studies in laboratory animals have shown that administration during early pregnancy may cause foetal abnormalities. Administration during the later stages of pregnancy may cause abortion or early parturition.

Lactation:
Use during lactation only according to the benefit-risk assessment by the responsible veterinarian.

## 3.8 Interaction with other medicinal products and other forms of interaction

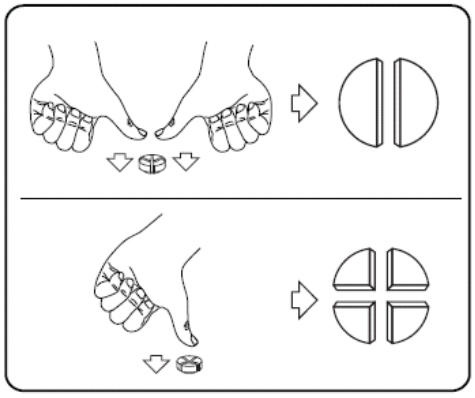
Phenytoin, barbiturates, ephedrine and rifampicin, may accelerate the metabolic clearance of corticosteroids resulting in decreased blood levels and reduced physiological effect.
The concomitant use of this veterinary medicinal product with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration. Because corticosteroids can reduce the immunoresponse to vaccination, dexamethasone should not be used in combination with vaccines or within two weeks after vaccination.

Administration of dexamethasone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides. The risk of hypokalaemia may be increased if dexamethasone is administered together with potassium depleting diuretics.

## 3.9 Administration routes and dosage

Oral use.
Dose: 0.05-0.2 mg/kg/day. The dose and duration of treatment should be determined by the veterinarian based upon the desired effect (anti-inflammatory or anti-allergic) and on the nature and severity of each individual case. The lowest effective dose for the shortest possible period should be used. When the desired effect has been achieved, the dose should gradually be reduced until the lowest effective dose is reached.
Dogs should be treated in the morning and cats in the evening on account of differences in cortisol circadian rhythms.

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



2 equal parts: press down with your thumbs on both sides of the tablet.
4 equal parts: press down with your thumb in the middle of the tablet.

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

An overdose does not cause other adverse effects than those stated in section 3.6.

## 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

Not applicable.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QH02AB02

### 4.2 Pharmacodynamics

Dexamethasone is a long-acting glucocorticosteroid; its potency is about 25 times greater than the short-acting substances, such as hydrocortisone. Glucocorticoids play a role in carbohydrate-, protein- and fat metabolism, and have an antiphlogistic and immunosuppressive effect. The main effect of glucocorticosteroids is the ability of these veterinary medicinal products to suppress inflammatory reactions, independent of the cause of the inflammation (infectious, allergic, chemical, mechanical). Thanks to the ability to inhibit phospholipase enzymes in the cell membranes, the formation of prostaglandins and leukotrienes is prevented.

### 4.3 Pharmacokinetics

Following oral administration dexamethasone is well absorbed in dogs and cats. In plasma, dexamethasone is present in free form and bound to plasma proteins. In the liver, corticosteroids like dexamethasone are metabolised (glucuronidated and sulfated), therefore only a small amount of the active substance can be traced in the urine.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Not applicable.

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life of the divided tablets: 6 days

### 5.3 Special precautions for storage

Return unused part-tablets to the blister pack and use them on the next administration. Do not store above 30 ºC. Keep the blisters in the outer carton in order to protect from light.

### 5.4 Nature and composition of immediate packaging

Aluminium - PVC/PE/PVDC blister. Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9 or 10 blisters of 10 tablets.
Not all pack sizes may be marketed.

### 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

Le Vet Beheer B.V.

## 7. MARKETING AUTHORISATION NUMBER

Vm 41821/3016

## 8. DATE OF FIRST AUTHORISATION

23 January 2018

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

May 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).

*Gavin Hall*
Approved: 08 August 2025