ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexacortone 2.0 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substance:
Dexamethasone 2.0 mg

3. PACKAGE SIZE

10 tablets
20 tablets
30 tablets
40 tablets
50 tablets
60 tablets
70 tablets
80 tablets
90 tablets
100 tablets

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life of the divided tablets: 6 days

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 ºC. Keep the blisters in the outer carton in order to protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 41821/3016

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Alu/PVC/PE/PvDC blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexacortone

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

2.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life of the divided tablets: 6 days

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Dexacortone 2.0 mg chewable tablets for dogs and cats

2. Composition

Each tablet contains:

Active substance:
Dexamethasone 2.0 mg

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. Target species

Dogs and cats.

4. Indications for use

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

5. 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 gastrointestinal 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 also section: Special warnings; Pregnancy).
Do not use in cases of hypersensitivity to the active substance, to corticosteroids or to any of the excipients.

See also section: Special warnings; Interactions with other medicinal products and other forms of interaction.

6. Special warnings

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.

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 increase protein degradation. 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 high blood pressure.
Since glucocorticosteroids 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 on: Dosage for each species, routes and method of administration).
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.

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.

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.

Overdose:
An overdose does not cause other adverse effects than those stated in the section on adverse events.

7. Adverse events

Dogs and cats:

Very common (>1 animal / 10 animals treated):	Cortisol suppression[1], elevated triglyceride[2]
Rare (1 to 10 animals / 10,000 animals treated):	Elevated liver enzymes
Undetermined frequency (cannot be estimated from the available data):	Polyphagia[3], polydipsia[3] Polyuria[3] Hyperadrenocorticism (Cushings disease)[4,5],

	Diabetes mellitus[3]
	Excitation
	Gastrointestinal ulceration[6], pancreatitis
	Enlarged liver (hepatomegaly)
	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).
	Hypothyroidism, elevated parathyroid (PTH) concentration
	Inhibition of longitudinal growth of bones
	Cutaneous calcinosis, skin thinning
	Delayed healing, immunosuppression[8], weakened resistance to or exacerbation of existing infections[8]
	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 on Special Warnings).

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 the sections on Special warnings: Pregnancy and Lactation.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already

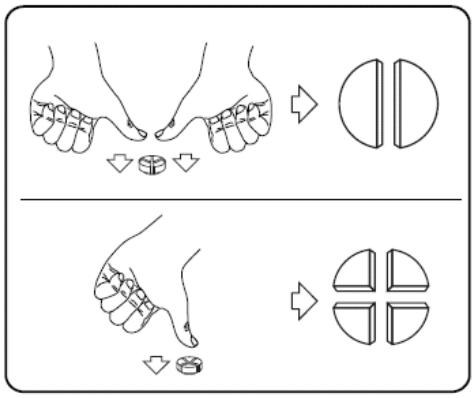
listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

Dogs should be treated in the morning and cats in the evening on account of differences in cortisol day rhythms.
Tablets can be divided into equal 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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and the carton after Exp. The expiry date refers to the last day of that month.
Shelf life of the divided tablets: 6 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation number(s):

Vm 41821/3016

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Le Vet. Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

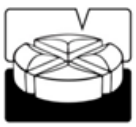
Manufacturer responsible for batch release:
LelyPharma B.V.
Zuiveringweg 42
8243 PZ Lelystad
The Netherlands

Genera d.d.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

Local representative and contact details to report suspected adverse reactions:
Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information



Divisible tablet

Approved 07 January 2026
Gavin Hall