# ANNEX III

# LABELLING AND PACKAGE LEAFLET

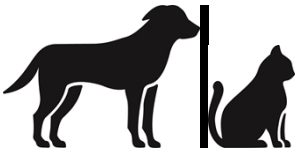
# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARDBOARD BOX**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexacortone 0.5 mg chewable tablets for dogs and cats
Dexamethasone



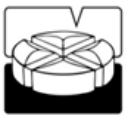
## 2. STATEMENT OF ACTIVE SUBSTANCES

1 tablet contains
**Active substance:**

Dexamethasone 0.5 mg

## 3. PHARMACEUTICAL FORM

Chewable tablet.



Divisible tablet

## 4. PACKAGE SIZE

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

## 5. TARGET SPECIES

Dogs and cats.

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP .....
Shelf life of the divided tablets: 6 days

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 30ºC. Store in the original package in order to protect from light.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

## 14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

## 16. MARKETING AUTHORISATION NUMBER

Vm 41821/3015

## 17. MANUFACTURER'S BATCH NUMBER

Lot

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

**Alu/PVC/PE/PvDC blisters**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexacortone 0.5 mg chewable tablets
Dexamethasone

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet. Beheer B.V.

## 3. EXPIRY DATE

EXP:

## 4. BATCH NUMBER

Lot.

## 5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET:

## Dexacortone 0.5 mg chewable tablets for dogs and cats

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

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

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexacortone 0.5 mg chewable tablets for dogs and cats
dexamethasone

## 3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 tablet contains
**Active substance**:

Dexamethasone 0.5 mg

Light brown with brown spots, round and convex flavoured 8 mm tablet with a cross-shaped break line on one side.
Tablets can be divided into 2 or 4 equal parts.

## 4. INDICATION(S)

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 cardia 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 and lactation).
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. ADVERSE REACTIONS

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).

The significant dose related cortisol suppression noticed during therapy is a result of effective doses suppressing the hypothalamic-pituitary-adrenal axis. 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.
The significant increase in triglycerides noticed can be a part of possible iatrogenic hyperadrenocorticism (Cushing's disease) 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. Cortisol suppression and an increase in plasma triglycerides is a very common side-effect of medication with corticoids (more than 1 in 10 animals treated).
The increase of alkaline phosphatase by glucocorticoids could be related to enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.
Other changes in blood biochemical and haematological parameters probably associated with the use of glucocorticosteroids were significant effects noticed on lactate dehydrogenase (decrease) and albumin (increase) and on eosinophils, lymphocytes (decrease) and segmented neutrophils (increase).
A decrease in aspartate transaminase is also noticed.
Systemically administered corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia in long-term use. Systemic corticosteroids have caused deposition of calcium in the skin (calcinosis cutis).
Corticosteroid use may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of viral infections, corticosteroids may worsen or hasten the progress of the disease.
Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal ulceration may be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.
Other adverse reactions that may occur are: inhibition of longitudinal growth of bones, skin atrophy, diabetes mellitus, euphoria, pancreatitis, decrease in thyroid hormone synthesis, increase in parathyroid hormone synthesis.
See also the section on Special warnings: Pregnancy and lactation. 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 inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

## 7. TARGET SPECIES

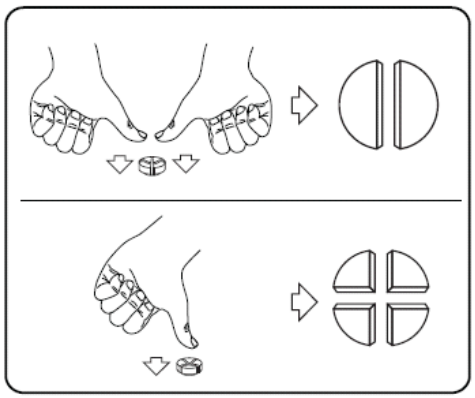
Dogs and cats.

## 8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

For oral administration.
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 PERIOD(S)

Not applicable

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Shelf life of the divided tablets: 6 days.
Return unused part-tablets to the blister pack and use them on the next administration. Do not store above 30ºC. Store in the original package 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.

## 12. SPECIAL WARNING(S)

Special warnings for each target species:
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 use in animals:
In cases where it has been deemed necessary to administer the 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 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: Amounts to be administered and administration route).
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 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 product may be harmful to children after accidental ingestion. Do not leave the 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 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 and lactation:
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.
Use during lactation only according to the benefit /risk assessment by the responsible veterinarian.

Overdose (symptoms, emergency procedures, antidotes):
An overdose does not cause other adverse effects than those stated in the section on adverse reactions.

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.

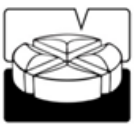
## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

## 15. OTHER INFORMATION

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.



Divisible tablet

Approved 19 July 2022