PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednidale 25 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Prednisolone 25 mg

3. PACKAGE SIZE

100 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Store in tightly closed original container.
Store in a dry place.

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

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 50406/3024

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE -LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednidale 25 mg tablets

100 tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Prednisolone 25 mg

3. TARGET SPECIES

Dogs

4. ROUTES OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Store in tightly closed original container.
Store in a dry place.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Prednidale 25 mg tablets for dogs

2. Composition

Each tablet contains:
Active substance:
Prednisolone 25 mg.

White, 11 mm circular tablets.

3. Target species

Dogs

4. Indications for use

Prednidale 25 mg tablets are indicated in the treatment of inflammatory and allergic diseases, including some autoimmune diseases and some neoplastic conditions, in dogs. Inflammatory, allergic and autoimmune processes may be involved in cutaneous, alimentary, respiratory, musculo-skeletal and haematological manifestation of disease.

5. Contraindications

Do not use in animals with renal insufficiency, diabetes mellitus or corneal ulceration.
Do not use in animals receiving vaccines containing live organisms.
Do not use in pregnant animals.
.

6. Special warnings

Special precautions for safe use in the target species:
Treatment may render concurrent vaccination inoperative.
Appropriate therapy should be instituted in animals with concurrent bacterial infections.
Use of corticosteroids may exacerbate viral infections.
Prolonged use at high dose levels may result in undesirable effects.
Do not withdraw corticosteroid therapy suddenly.
Serum electrolytes should be monitored.
Consideration should be given to the use of antimicrobials due to the potential suppression of the immune system.
Corticosteroids, including prednisolone, have a wide range of effects.

Polydipsia, polyuria and polyphagia may develop, particularly during the early stages of therapy.
In the longer term, iatrogenic Cushing's disease may develop.
Gastrointestinal ulceration has been reported in animals treated with corticosteroids.
Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.
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.
Adrenal insufficiency may be minimised by institution of alternate-day therapy if practical.
The dosage should be reduced and withdrawn gradually to avoid precipitation of adrenal insufficiency.

Gastrointestinal ulceration may be exacerbated by corticosteroids in animals given non-steroidal anti-inflammatory drugs (NSAIDs).
Regular veterinary re-evaluation of animals on prolonged courses of prednisolone is recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of gloves should be worn when handling the product. Wash hands immediately after administration.
In the case of accidental ingestion, particularly by a child, seek medical advice and show the package leaflet or the label to the physician.

Pregnancy and lactation:
Corticosteroids are not recommended for 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.
Insignificant amounts of prednisolone are generally eliminated in the milk of lactating animals, and therefore such use is not contraindicated.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
Signs of overdosage should be treated symptomatically.

Major incompatibilities:
None known

7. Adverse events

Dog:

Rare (1 to 10 animals / 10 000 animals treated):	Polyuria[a] Polydipsia[a] Eosinopenia, neutrophilia, lymphopenia
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Adrenal gland disorder[b] Cortisol suppression[c], hyperalbuminaemia, elevated serum alkaline phosphatase (SAP), elevated liver enzymes, decreased aspartate transaminase, decreased lactate dehydrogenase, hypokalaemia[d], low thyroxine (T4) Weight gain, polyphagia[a], delayed healing (wound), weakend resistance to, or exacerbation of existing infections[e], depression Cutaneous calcinosis, skin thinning Gastrointestinal ulceration[f], pancreatitis Diabetes Mellitus Excitation
Undetermined frequency (cannot be estimated from the available data)	Elevated triglyceride[g], low tri-iodothyronine (T3), elevated parathyroid (PTH) concentration Inhibition of longitudinal growth of bones Sodium and water retention[d]

[a] May be caused by systemically administered corticosteroids, particularly during the early stages of therapy.

[b] Following cessation of treatment, signs of adrenal insufficiency can arise, and this may render the animal unable to deal adequately with stressful situations.

[c] Significant dose related suppression noticed during therapy is a result of effective doses suppressing the hypothalamic-pituitary-adrenal-axis.

[d] After long term use.

[e] The immunosuppressant actions may weaken resistance to, or exacerbate existing infections.

[f] May be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs.

[g] The significant increase 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, wastage and osteoporosis may result.

Anti-inflammatory corticosteroids, such as prednisolone, 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. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control symptoms.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, 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 on this label, or via your national reporting system at: Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

Oral use.

Dose: 0.1 – 2.0 mg prednisolone per kg body weight per day.
The lowest effective dose must be used.

These tablets are not appropriate when dosing small dogs at the lower recommended dosage rates and the 5 mg tablet strength may be required.
Treatment should not be withdrawn suddenly.
A gradual reduction of dosage is recommended.
Dogs should be dosed in the morning to coincide with the endogenous cortisol peak.
A single administration may be sufficient for some conditions such as anaphylaxis.
For more general treatment, administration for between one and three weeks at the above dosage levels may be required.
Dosage levels should be monitored carefully to ensure that the lowest effective dose is used.
Alternate-day therapy should be implemented to control symptoms if possible, to minimise the risk of adrenal insufficiency.
Higher dose levels may be used in animals with tumours responsive to corticosteroid therapy. In these cases, the dosage levels of between 20 mg per m^2 and 60 mg per m^2 have been found to be useful.
The potential risks associated with these high dose levels should be assessed before commencing treatment.

Gloves should be worn to administer the product and you should wash hands immediately after administration of the product.

9. Advice on correct administration

10. Withdrawal periods

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.
Store in tightly closed original container.
Store in a dry place.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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

Vm 50406/3024

Polypropylene containers with low density polyethylene push-fit tamper evident closures containing 100 tablets.

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:

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:

Dales Pharmaceuticals
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

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

Local representatives 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

POM-V

Gavin Hall
Approved: 09 July 2026