PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednidale 5 mg tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:
Active substance:
Prednisolone 5 mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

1000 tablets

5. TARGET SPECIES

Dogs and Cats

6. INDICATION(S)

For the treatment and control of inflammatory and allergic diseases in cats and dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only.
Treatment should not be withdrawn suddenly. A gradual reduction of dosage is recommended.
Dogs should be dosed in the morning and cats should be dosed at night to coincide with the endogenous cortisol peak.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant animals, those suffering from diabetes mellitus, in animals with renal insufficiency or those with corneal ulceration.
Do not use in animals being vaccinated with products containing live organisms. 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 of high dose levels may result in undesirable effects.
Do not withdraw corticosteroid therapy suddenly.
Acute overdosage should be treated symptomatically.
Serum electrolytes should be monitored.

Consideration should be given to the use an antimicrobials due to the potential suppression of the immune system.
Corticosteroids are not recommended for use in pregnant animals.
Studies in laboratory animals have shown administration during early pregnancy may cause foetal abnormalities.
Administration during the later stages of pregnancy may cause abortion or early parturition.
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.

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

See package leaflet for further details.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF

For animal treatment only.

POM-V Prescription Only Medicine - Veterinarian

To be supplied only on veterinary prescription.

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

Keep out of the reach and site of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10434/4009

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednidale 5 mg tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:
Active substance:
Prednisolone 5 mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

1000 tablets

5. TARGET SPECIES

Dogs and Cats

6. INDICATION(S)

For the treatment and control of inflammatory and allergic diseases in cats and dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only.
Dose: 0.1 – 2.0 mg prednisolone per kg body weight per day.
The tablets are divisible.
The lowest effective dose must be used.
These tablets are not appropriate when dosing cats and small dogs at the lower recommended dosage rate and another tablet size may be required.
Treatment should not be withdrawn suddenly. A gradual reduction of dosage is recommended.
Dogs should be dosed in the morning and cats should be dosed at night to coincide with the endogenous cortisol peak.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant animals, those suffering from diabetes mellitus, in animals with renal insufficiency or those with corneal ulceration.
Do not use in animals being vaccinated with products containing live organisms. 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 of high dose levels may result in undesirable effects.
Do not withdraw corticosteroid therapy suddenly.
Acute overdosage should be treated symptomatically.
Serum electrolytes should be monitored.
Consideration should be given to the use an antimicrobials due to the potential suppression of the immune system.
Corticosteroids are not recommended for use in pregnant animals.
Studies in laboratory animals have shown administration during early pregnancy may cause foetal abnormalities.
Administration during the later stages of pregnancy may cause abortion or early parturition.
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.

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

See package leaflet for further details.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF

For animal treatment only.

POM-V Prescription Only Medicine - Veterinarian

To be supplied only on veterinary prescription.

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

Keep out of the reach and site of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10434/4009

17. MANUFACTURER’S BATCH NUMBER

PACKAGE LEAFLET FOR:

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

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednidale 5 mg
Prednisolone

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each tablet contains: Active substance: Prednisolone 5 mg.

White, circular, flat faced tablets.

4. INDICATION(S)

Prednidale 5mg tablets are indicated in the treatment of inflammatory and allergic diseases, including some autoimmune diseases and some neoplastic conditions in cats and 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 pregnant animals, those suffering from diabetes mellitus, in animals with renal insufficiency or those with corneal ulceration.

Do not use in animals being vaccinated with products containing live organisms.

6. ADVERSE REACTIONS

Administration of single high doses are generally tolerated well, but medium to long term use may provoke reactions.

Corticosteroid therapy may lead to increased time in the healing of wounds and to a reduction in the ability of the body to resist infection. Appropriate anti-infective therapy may be required.

7. TARGET SPECIES

Dogs and Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration only.

Dose: Dogs and cats: 0.1 – 2.0 mg prednisolone per kg body weight per day.
The tablets are divisible.
The lowest effective dose must be used.
These tablets are not appropriate when dosing cats and small dogs at the lower recommended dosage rates and another 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 and cats should be dosed at night 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 PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Store in tightly closed original container.
Store in a dry place.
Keep out of the reach and site of children.

12. SPECIAL WARNING(S)

For Animal Treatment Only
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.
Signs of overdosage should be treated symptomatically.
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.
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.
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.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM-V Prescription Only Medicine – Veterinarian

To be supplied only on veterinary prescription.

Package quantities: Plastic pots containing 1000 tablets.

Vm 10434/4009

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

Approved 17 January 2018