PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Container pull-out label front face which is also duplicated as the base label attached to the container}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednisolone Tablets B.P. (Vet) 1mg

Prednisolone

2. STATEMENT OF ACTIVE SUBSTANCE

Prednisolone 1 mg

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

500 Tablets

5. TARGET SPECIES

Cats and dogs

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use. Dosage cats and dogs 0.1 – 2.0 mg per kg bodyweight daily.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Take care to avoid accidental eye contact. If eye contact occurs, wash thoroughly with clean running water. Wash hands after use.

10. EXPIRY DATE

EXP {MM/YYYY}

11. SPECIAL STORAGE CONDITIONS

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 APPLICABLE

[Distribution category]

POM-V

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

Millpledge Europe BV
38 Verrekijker
8750 Wingene
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 61300/3003

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:
Prednisolone Tablets B.P. (Vet) 1 mg

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

Marketing Authorisation holder:

Millpledge Europe BV
38 Verrekijker
8750 Wingene
Belgium

Manufacturer responsible for batch release:

Millpledge Ltd
Unit 6/8 Heapham Road Industrial Estate
Gainsborough
Lincolnshire
DN21 1RZ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednisolone Tablets B.P. (Vet) 1mg

Prednisolone

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

Composition active: Prednisolone 1mg

Oral tablets containing stated amount of prednisolone. Flat faced, white circular with bevelled edges One face embossed with letter P and reverse face with a scored half break line, embossed with letters PL above line and with figure 1 below

4. INDICATION(S)

Prednisolone is a glucocorticoid given in the treatment of various disorders in which corticosteroids are indicated, except adrenal deficiency states. It has relatively slight mineralocorticoid effects.

As an anti-inflammatory and anti-allergenic agent in either species. Prednisolone has found to be useful, often as an adjunct to other agents, in the treatment of tumours.

5. CONTRAINDICATIONS

Administration is contra-indicated where corneal ulceration is present. Administration is generally contra-indicated if renal disease or diabetes mellitus is present. Administration may render concurrent vaccination inoperative.

6. ADVERSE REACTIONS

Prednisolone, as with other corticosteroids, has a wide range of effects. Polydipsia, polyurea and polyphagia are common observations. These side effects often diminish as therapy proceeds. Cushingoid symptoms may be provoked and should be monitored for. Consideration should be given to the potential effects of corticosteroids on wound healing and/or the body's ability to deal with infection. Symptoms of infection may be masked or atypical. Careful consideration should be given as to the desirability of administration to patients with systemic infections, if specific anti-infective is neither possible nor instigated. In the presence of viral infection, corticosteroids may worsen or hasten the progress of the disease. Gastrointestinal ulceration has been reported in animals treated with corticosteroids.

7. TARGET SPECIES

Cats and dogs

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

Posology:

Generally 0.1-2.0mg/Kg/day. For treatment of tumours 20mg/ m2 of body surface each other day to 60mg/ m2 of body surface/day. By oral administration only.

9. ADVICE ON CORRECT ADMINISTRATION

The lowest effective dose should be used. Treatment should not be withdrawn suddenly and in many situations a dosage schedule with falling dose will be found of use. Some cases may require continuing therapy; the minimum effective maintenance dose should be established.

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

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

12. SPECIAL WARNING(S)

Special precautions to be taken by the person administering the medicinal product to animals:

Impermeable gloves should be worn whilst administering the product. Take care to avoid accidental eye contact. If eye contact occurs, wash thoroughly with clean running water. Wash hands after use.

Special precautions for use in animals:

It is generally considered that problems associated with the induction of adrenal insufficiency are minimised by dosing once every alternate morning for dogs and every alternate evening for cats. Following long or medium term treatment the dosage should be reduced gradually.

Pregnancy and lactation

Prednisolone is not recommended for use in pregnant animals. Administration of corticosteroids in early pregnancy is known to cause foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition.

Interactions:

Gastrointestinal ulceration may be exacerbated by corticosteroids in patients given non-steroidal anti-inflammatory drugs.

Overdose:

There is no specific treatment for overdose. Treatment will be largely symptomatic. Gross over dosage might result in immunosuppression. Accompanying cover of antibiotics treatment should be restricted to responses to specific signs and symptoms. Serum electrolytes should be monitored.

For Animal Treatment Only

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. 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.

15. OTHER INFORMATION

POM – V To be supplied only on veterinary prescription

Vm 61300/3003

Gavin Hall
Approved: 23 April 2026