PACKAGE LEAFLET FOR USE

Prednivet 5 mg tablets

Dogs and cats

Prednisolone

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER, IF DIFFERENT

Name and permanent address of the marketing authorisation holder

Antibiotic-Razgrad AD

Office 201, 68 “Aprilsko vastanie” Blvd

Razgrad 7200, Bulgaria

Name and address of the manufacturing authorisation holder responsible for batch release

Balkanpharma-Razgrad AD

68 “Aprilsko vastanie” Blvd

Razgrad 7200, Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prednivet 5 mg tablets

Dogs and cats

Prednisolone

3. CONTENTS OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each tablet contains prednisolone of 5 mg and other ingredients to 100 mg.

4. THERAPEUTIC INDICATIONS

Prednisolone is a glucocorticoid with anti-inflammatory, anti-allergic, immunosuppressive, antitoxic and antishock effects. It inhibits all manifestations

of the inflammatory process by inhibiting the activity of inflammatory mediators and, mostly, of prostaglandins and leukotrienes. It also inhibits the cyclooxigenase activity. It limits capillary permeability and hyaluronidase activity and simultaneously enhances the hyaluronic acid polymerisation. It decreases the histamine synthesis. It inhibits cell-mediated and humoral immunity. It diminishes the reaction to pyrogens and toxins. It damages directly the neoplastic cells.

It absorbs rapidly and almost completely in the gastrointestinal tract. It is transported by a special protein, called transcortin. It is metabolised in the liver to water-soluble metabolites, which are excreted in the urine as sulphates and glucuronides.

The product is used for the treatment of primary and secondary adrenal failure; inflammatory diseases of the locomotory system and ocular tissues; allergic diseases; infections with severe toxicosis (in combination with antibacterial therapies) ; cranial-cerebral trauma and elevated intracranial pressure; interstitial nephritis; thyroiditis; otitis; venomous snake bites or venomous insect stings; hypercalcaemia and intoxication with vitamin D; autoimmune diseases; as an add-on therapy in malignant haematological diseases; scleroderma.

5. CONTRAINDICATIONS

The product should not be used in hypercorticoidism, osteoporosis, diabetes mellitus, pregnancy and lactation, viral and generalised fungal infections, severe renal and heart failure. During the treatment with Prednivet, no vaccinations with viral, bacterial and antimycotic vaccines and toxoids should be performed, as well as allergy diagnostic tests.

6. ADVERSE REACTIONS

During a continuous high-dose administration in dogs, hyperadrenocorticalism with atrophy of the adrenal glands, behavioural changes, difficulty in breathing, polyphagia or anorexia, polydipsia and polyuria, diarrhoea, myopathy,

osteoporosis with bone fracturing, delayed wound and fracture healing, gastric and intestinal ulcers and bleeding, skin atrophy and alopecia, steroidogenic diabetes, anoestrus, decreased libido and transient infertility, increased susceptibility to or exacerbation of existing infections, changes of several haematological and biochemical parameters are likely to occur. In cats, the side effects are rare and presented by polyphagia with weight gain, polydipsia, polyuria, diarrhoea and depression.

If you notice any serious effects or other effects due to the use of this VMP, not mentioned in this leaflet, please inform immediately your veterinary physician.

7. TARGET SPECIES

Dogs and cats.

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

Method of administration:

Enteral

Dosage:

Prednisolone dosage varies widely according to the objective of treatment, dose regimen, duration of administration, age and clinical status of the animal, response to medication and eventual occurrence of side effects. The objective of treatment is to use effective doses as lower as possible, for the shortest period of treatment possible. Usually, the therapy starts at a high dose for several days, to achieving the desired effect; after then, the dose is gradually decreased to the minimal effective dose for maintaining the effect, as the number of administrations is also reduced to once a day or every other day.

In dogs, the following doses are recommended: in adrenocortical failure with the objective of substitution: 0.2 – 0.3 – 0.4 mg/kg m. daily; as an anti-inflammatory and anti-allergic agent: starting doses of 0.2 – 0.6 mg/kg m. once or two times daily for 5 - 7 days, after then, switching to a maintenance dose (the usual dose

for dogs with body mass of 2 to 7 kg is 2.5 mg, 7 to 18 kg – 5 mg and 18 to 36 kg – 10 mg), administered every other day; as an immunosuppressive agent: 2 to 4 mg/kg m. up to three times daily, after then the dose is gradually decreased; in hypercalcaemia and vitamin D intoxication: 1 – 1.5 mg/kg m.
In cats, the substitution doses are 0.3 – 0.4 mg/kg m., the anti-inflammatory and anti-allergic ones 0.5 – 1 – 2 mg/kg m. and the immunosuppressive ones 2 – 4 mg/kg m.

9. ADVICE ON CORRECT ADMINISTRATION

Directly enterally, with a titbit or after grinding and mixing the tablet with a small amount of favourite food.

10. WITHDRAWAL PERIOD

None.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC.
Keep out of the reach and sight of children.
Do not use after the expiry date which is stated on the blister and carton!

Shelf life: 5 (five) years from the date of manufacturing

12. SPECIAL WARNING(S)

None.

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

VMPs should not be disposed of via household waste or wastewater.
Ask your veterinary physician how to dispose of medicines no longer required. These measures should help protect the environment.

14. DATE OF LAST REVISION OF THE TEXT

December 2011.

15. OTHER INFORMATION

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