PACKAGE LEAFLET

For animal treatment only

DEXAMETHASONE/ PROVET

injectable solution of dexamethasone for lambs, young kids, pigs, dog, cat.

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

Marketing Authorisation Holder:
PROVET S.A.
120, Eleftherias Avenue, Eleousa, Zitsa, 45500 Ioannina, Greece
Tel.: +30 2105508500, +30 2105575770-3
E-mail: vet@provet.gr

Manufacturer responsible for batch release:
PROVET S.A. (FACTORY)
Nikiforou Foka & Ag.Anargyron, Thesi Vrago,
193 00 Aspropyrgos, Attiki, Greece

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

DEXAMETHASONE/ PROVET
injectable solution
Dexamethasone 2mg/ml
Lambs, Young kids (goat milk-fed kids), Pigs, Dog, Cat

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml of solution contains:
Active substance:
Dexamethasone sodium phosphate 2.63 mg (Equivalent to 2 mg Dexamethasone)

Excipients:
Methyl parahydroxybenzoate (EP Monograph: 0409), Propyl parahydroxybenzoate (EP Monograph: 0431), Sodium citrate (EP Monograph: 0412), Sodium hydroxide solution 4% ή Citric acid monohydrate
Water for injections

4. INDICATIONS

Dexamethasone can be used for the treatment of inflammatory or allergic conditions.

5. CONTRAINDICATIONS

Do not administer to animals suffering from diabetes mellitus, renal insufficiency, cardiac insufficiency, tuberculosis, acute pancreatitis, or osteoporosis, except in emergency situations.
Do not use in viral infections during the viraemic phase or in cases of systemic mycotic infections.
Do not use in animals suffering from gastrointestinal or corneal ulcers, or demodicosis.
Do not administer intra-articularly where there is evidence of fractures, bacterial infections and aseptic bone necrosis.
Do not use in known cases of hypersensitivity to the active substance, to corticosteroids and to any other ingredients of the product.

6. ADVERSE REACTIONS

Corticosteroids are known to exert a wide range of side-effects. Whilst single high doses are generally well tolerated, they may induce severe adverse reactions with long term use and when esters possessing a long duration of action are administered. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control clinical signs.
Steroids themselves, during treatment, may cause iatrogenic hyperadrenocorticism (Cushing disease) involving significant alteration of weight, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, increase in body weight, muscle weakness and osteoporosis may result.

During therapy effective doses suppress the hypothalamo-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 minimizing problems of adrenal insufficiency following the withdrawal of treatment.
Systemically administered corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium retention and hypoglycaemia in long term use. Systemic use of corticosteroids may cause dystrophic calcinosis cutis.
Corticosteroid use may delay wound healing and the immunosuppressant actions may induce or exacerbate existing infections. In the presence of bacterial infection, concurrent therapy is usually required. In the presence of viral infections, corticosteroids may worsen or hasten the progress of the disease.
Gastrointestinal tract ulceration may be caused in animals treated with corticosteroids resulting in an outbreak in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.
Corticosteroid use may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes and may increase the risk of acute pancreatitis. Other possible adverse reactions associated with corticosteroid use include changes in blood biochemical and haematological parameters. Acute hyperglycaemia can occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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.

7. TARGET SPECIES
Lambs, Young kids (goat milk-fed kids), Pigs, Dog, Cat

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION
Dosage is determined by the kind and severity of the condition. Dosage is the maximum recommended in acute conditions and in the initiation of treatment in the case of chronic diseases and the minimum, when it is recommended for long-term treatment or it follows the initial high dose.
It can be administered intravenously, intramuscularly or subcutaneously.
Lambs-Young kids: 0.14 mg dexamethasone/ kg body weight at a single dose or 0.35 ml of the product per 5 kg body weight intramuscularly.
Pigs: 0.06 mg dexamethasone/ kg body weight or 0.3 ml of the product per 10 kg body weight intramuscularly, twice with an interval of 24 hours.
Dog-Cat: 0.1 - 0.2 mg dexamethasone/ kg body weight or 0.25 - 0.5 ml of the product per 5 kg body weight intravenously, intramuscularly or subcutaneously.
In dog and cat, can also be administered intra or peri-articularly 0.5 - 5 mg dexamethasone or 0.25 - 2.5 ml of the product.
Injections into joints or bursae should be preceded by the removal of an equivalent volume of synovial fluid. Strict asepsis is necessary. According to the severity of the condition, one or more administrations can take place.

The doses may be repeated as a single dose at 24 – 48 hour intervals, if it is considered to be necessary by the veterinarian.

To measure low doses, of less than 1 ml, a suitably graduated syringe should be used to ensure accurate administration of the correct dose.

9. ADVICE ON CORRECT ADMINISTRATION

Special precautions for use in animals

Response to long-term therapy should be monitored at regular intervals by a veterinarian.
Because of the pharmacological properties of the active ingredient, special care should be taken when the product is used in animals with a weakened immune system.
The administration of corticoids induces more the improvement of the clinical signs rather than treatment, except in cases of acetonaemia and induction of the parturition. The underlying disease should be further investigated. Following intra-articular administration, use of the joint should be minimized for one month and surgery on the joint should not be performed within eight weeks following the use of this route of administration.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician.
People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the veterinary medicinal product.
Pregnant women should not handle this veterinary medicinal product.

10. WITHDRAWAL PERIOD

Lambs-Young kids-Pigs: Meat and edible tissues: 3 days
Dog-Cat: Not required.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 25ºC. Do not freeze.
Shelf life after the first opening of the immediate packaging: 28 days
Do not use the product beyond the expiry date indicated on the label. The expiry date refers to the last day of that month.
Avoid pollution of the content during use.
In case of solution discoloration or microorganism growth, medicine should be discarded.

12. SPECIAL WARNINGS

Do not administer in pregnant animals, except where the intention is to induce parturition. Administration in late pregnancy is likely to cause abortion or early parturition. In laboratory, it has been reported that administration in early pregnancy causes foetal abnormalities.
Concurrent use with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration.
Because corticosteroids can reduce the immune response to vaccination, dexamethasone should not be used in combination with vaccines or within two weeks after vaccination.
Administration of dexamethasone may induce hypoglycaemia and hence increase the risk of toxicity from cardiac glycosides. The risk of hypoglycaemia may be increased if dexamethasone is administered together with potassium depleting diuretics.
Concurrent use with anticholinesterase may lead to increased muscle weakness in patients with myasthenia gravis.
Glucocorticoids antagonise the effects of insulin.
Concurrent use with phenobarbital, phenytoin and rifampicin can reduce the effects of dexamethasone.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

JUNE 2014

15. OTHER INFORMATION

PACKAGE
Vials of 20 ml, 30 ml, 50 ml and 100 ml

Not all pack sizes may be marketed.

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

under veterinary medical prescription

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN