Consumer Leaflet for a Veterinary Product
The medicine is marketed according to a veterinarian's prescription only
For use in animals only

1. Name, form and strength of the veterinary medicine

Isaderm Veterinary, gel for topical skin application in dogs.

Betamethasone (as valerate) 0.1% w/w
Fusidic Acid (as hemihydrate) 0.5% w/w

2. Active ingredients and their quantity per dose unit

Betamethasone (as valerate) 0.1% w/w
Fusidic Acid (as hemihydrate) 0.5% w/w
Each 1 g gel contains:
1 mg Betamethasone (as valerate)
5 mg Fusidic Acid (as hemihydrate)
For the list of inactive ingredients and allergens in the product - see section 13 ("Additional information") in this leaflet.

3. What is the medicine intended for?

Topical treatment of surface pyoderma in dogs such as acute moist dermatitis (hot spots) and skin fold dermatitis (intertrigo).

Therapeutic group: Potent corticosteroid (Betamethasone) in combination with a bacteriostatic antibiotic (Fusidic Acid).

4. Contraindications

Do not use for the treatment of deep pyoderma.
Do not use in pyotraumatic furunculosis and pyotraumatic folliculitis with ”satellite” lesions of papules or pustules.
Do not use where fungal or viral infection is already present.
Do not apply to the eyes.
Do not use over large surface areas, do not use for prolonged treatment.
Do not use in dogs with known hypersensitivity to the active ingredients or to any of the inactive ingredients.
See section 10 ("Warnings").

5. Side effects

Prolonged and intensive use of topical corticosteroid preparations or treatment of a large cutaneous surface (>10%) is known to trigger local or systemic effects including suppression of adrenal function, thinning of the epidermis and delayed healing of lesions.
Locally applied steroids may cause depigmentation of the skin.
Discontinue use if hypersensitivity to the product develops.

Side effects can be reported to the Ministry of Health by clicking the link "Report side effects due to medication" which can be found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the following link: https://sideeffects.health.gov.il

6. Target species: Dogs.

7. Dosage and route of administration

Apply to the affected area twice a day for a minimum of 5 days and not more than 7 days. If there is no response within three days, or the condition deteriorates, consult a veterinarian regarding the diagnosis.

8. How to use the product

See section 7 ("Dosage and route of administration").

9. Withdrawal period

Not applicable.

10. Warnings

- Special warnings for use of the product in the treatment of target animals
  Betamethasone valerate may be absorbed percutaneously and cause temporary suppression of the adrenal function.
  The dog should be prevented from licking treated lesions and so ingesting the product.
  Where there is a risk of self-trauma, or a risk of accidental transmission to the eye, for example, when applied on the front limb, preventative measures such as the use of an Elizabethan collar should be considered.

  Pyoderma is often secondary in nature. The underlying cause should be identified and treated.
  It is recommended that use of the product should be based on bacteriological sampling and susceptibility testing. If this is not possible, therapy should be based on epidemiological information about susceptibility of the target bacteria. Use of the product deviating from the instructions given in the package leaflet text may increase the prevalence of bacteria resistant to fusidic acid.
  The safety of the product has not been assessed in puppies of less than 7 months.

- Special precautions regarding the safety of the person administering the product
  The use of corticosteroids may produce irreversible changes to the skin. Corticosteroids may be absorbed trough it and have harmful effects, especially with frequent and extensive contact or in pregnancy. Pregnant women should take special care to avoid accidental exposure to the product.
  Always wear single-use disposable gloves when applying this product to the treated animal.
  Wash hands after having applied the product.
  Care should be taken to avoid accidental ingestion of the product by a child. In case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.
  People with a known sensitivity to the active ingredient or any of the inactive ingredients should avoid contact with this veterinary medicine.

- Pregnancy and lactation of the treated animal
  Laboratory studies showed that topical application of betamethasone in pregnant females may lead to malformations in neonates. The safety of the product has not been assessed during pregnancy and lactation. Do not use the product during pregnancy and lactation.

- Interactions with other medicines and other forms of interactions
  None known.

- Overdose
  For possible signs see section 5 ("Side effects").

- Incompatibility

None known.

11. Storage instructions

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions: Do not store above 25°C. Do not freeze, do not refrigerate. After the first opening, the product can be used within 6 weeks. Keep the tube in the original carton.

12. Instructions regarding disposal of the product/ waste materials at the end of its use

Any unused veterinary medicinal product or waste materials derived from the use of a veterinary medicinal product, should be disposed of as a toxic waste; do not discard in the wastewater.

13. Additional information

- In addition to the active ingredients, the medicine also contains:
  Dimethicone, Carbomer, Methyl parahydroxybenzoate, Polysorbate 80, Propyl parahydroxybenzoate, Sodium hydroxide, Purified water.

Each 1 g gel contains 2.7 mg of the preservative Methyl parahydroxybenzoate and 0.3 mg of the preservative Propyl parahydroxybenzoate.

- What the medicine looks like and what the package contains: aluminium tube with a screw cap containing a transparent white gel.
- Pack sizes: 15 gram, 30 gram. Not all pack sizes may be marketed.
- Registration holder: Vetmarket Ltd., 23 Derech HaChoresh, Industrial Park, Hevel Modi'in .
- Manufacturer: Dechra Veterinary Products A/S, Mekuvej 9, DK-7171 Uldum, Denmark.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
082-41-92173

Revised in December 2022 according to MOH guidelines.