LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON 15 g and 30 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isaderm 5 mg/g + 1 mg/g gel for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 g gel contains:
Active substances:

Fusidic acid.	5 mg
Betamethasone (as valerate)	1 mg

3. PHARMACEUTICAL FORM

Gel [already included in the name]

4. PACKAGE SIZE

15 g
30 g

5. TARGET SPECIES

For dogs [already included in the name]

6. INDICATION(S)

[Information to be included for immunologicals only.]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
Cutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

[Not applicable for non-food producing animals.]

9. SPECIAL WARNING(S), IF NECESSARY

[Read the package leaflet before use. Already stated for point 7.]

10. EXPIRY DATE

EXP:
Once broached, use by….
Shelf life after first opening the immediate packaging: 6 weeks.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Do not refrigerate or freeze.
Keep the tube in the outer carton.

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

Disposal: Read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

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

Dechra Veterinary Products A/S
Mekuvej 9
7171 Uldum
Denmark

16. MARKETING AUTHORISATION NUMBER(S)

UK: Vm: 24883/4006

POM-V

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Tube 15 g and 30 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isaderm 5 mg/g + 1 mg/g gel for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 g gel contains:
Active substances:

Fusidic acid	5 mg
Betamethasone (as valerate)	1 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

15 g
30 g

4. ROUTE(S) OF ADMINISTRATION

For external use only.
Cutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD

[Not applicable for non-food producing animals]

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:
Keep the tube in the outer carton.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Keep out of the sight and reach of children
For animal treatment only.

UK: Vm: 24883/4006

POM-V

B. PACKAGE LEAFLET

[PACKAGE LEAFLET]
ISADERM
5 mg/g + 1 mg/g gel for dogs

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

Marketing authorisation holder:
Dechra Veterinary Products A/S
Mekuvej 9
DK-7171 Uldum
Denmark

Manufacturer responsible for batch release[1]:
Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

Dales Pharmaceuticals Limited
Snaygill Industrial Estate
Keighley Road, Skipton
North Yorkshire, BD23 2RW
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isaderm 5 mg/g + 1 mg/g gel for dogs

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

1 g gel contains:
Active substances:

Fusidic acid	5 mg
Betamethasone (as valerate)	1 mg

Excipients:

Methylparahydroxybenzoate (E218)	2.7 mg
Propylparahydroxybenzoate	0.3 mg

White translucent gel.

4. INDICATIONS

For the topical treatment of certain skin diseases in the dog such as acute moist dermatitis (‘hot spots’) and intertrigo (skin fold dermatitis).

[1] Printed leaflet will state only actual batch release site

5. 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 present.
Do not apply to the eye.
Do not use over large surface areas or for prolonged treatment.
Do not use in cases of known hypersensitivity to the active substances or to any of the excipients.
See section 'Special warnings'.

6. ADVERSE REACTIONS

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.
Locally applied steroids may cause depigmentation of the skin.
Discontinue use if hypersensitivity develops to the product.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

Cutaneous use.
First, the hairs covering the lesions should be gently clipped. The affected area should then be thoroughly cleaned with an antiseptic wash before daily application of the gel. The amount applied should cover the affected area in a thin layer. Apply approximately 0.5 cm length of gel per 8 cm^2 of lesion, twice daily, for a minimum period of 5 days. Treatment should continue for 48 hours after the lesion has resolved. The treatment period should not exceed 7 days. If there is no response within three days, or the condition deteriorates, the diagnosis should be re-evaluated.

[9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.]

[10. WITHDRAWAL PERIOD

Not applicable.]

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30°C.

Do not refrigerate or freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and tube label after EXP. The expiry date refers to the last day of that month
Shelf life after first opening the immediate packaging: 6 weeks.
The discard date should be written in the space provided on the carton.
Keep the tube in the outer carton.

12. SPECIAL WARNINGS [(4.4., 4.5., 4.7., 4.8., 4.10., 6.2. from SPC)]

Special precautions for use in animals:
Official, national and regional antimicrobial policies should be taken into account when the product is used.
Betamethasone valerate can be absorbed percutaneously and may cause temporary suppression of adrenal function.
The dog should be prevented from licking treated lesions and so ingesting the product. Where there is a risk of self-trauma, 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 combination has not been assessed in puppies of less than 7 months.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Corticosteroids may produce irreversible effects in the skin; they can be absorbed and may have harmful effects, especially with frequent and extensive contact or in pregnancy. Pregnant women should take special care to avoid accidental exposure.
Always wear single-use disposable gloves when applying this product to animals.
Wash hands after having applied the product.
Care should be taken to avoid accidental ingestion by a child. In the case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.
People with known hypersensitivity to the active ingredients or to any of the excipients should avoid contact with the veterinary medicinal product.

Use during pregnancy and lactation:
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. The use of the product during pregnancy and lactation is not recommended.

Overdose (symptoms, emergency procedures, antidotes):
For possible signs see section ‘Adverse reactions’.

Incompatibilities:
None known.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2023

15. OTHER INFORMATION

POM-V Prescription Only Medicine - Veterinarian

Internally lacquered aluminium tubes of 15 g or 30 g closed with a white HDPE screw cap.
Not all pack sizes may be marketed.

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

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall, Shrewsbury
Shropshire
SY4 4AS
United Kingdom

Approved 29 September 2023