IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10861/053/001**
Case No: 7001693

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

Fort Dodge Animal Health

Flanders Road, **Hedge End**, **Southampton SO30 4QH**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Dermobion Green

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Dermobion Green

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tube contains :

Active Substances		
Neomycin Sulphate	0.50 %w/w	(equivalent to 3500iu/g)
Nitrofural	0.09 %w/w	
Prednisolone	0.25 %w/w	
Excipients		
Chlorophyll OC 10	1.99 %w/w	

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Ointment

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats only.

4.2 Indications for use, specifying the target species

For the treatment of superficial bacterial skin infections and associated conditions of allergic or traumatic origin, caused by susceptible organisms. Dermobion Green Ointment also provides relief of associated inflammation and pain, reducing the possibility of complications due to self-trauma

Specific indications include dermatitis, eczema and pyoderma of bacterial, allergic or traumatic origin.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.
Not to be used in any food producing species.

4.4 Special warnings for each target species

Locally applied steroids may cause thinning of the skin.

Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to, or exacerbate existing infections. In the presence of viral infections, steroids may worsen or hasten the progress of the disease.

4.5 Special precautions for use

Special precaution(s) for use in animals

Gastrointestinal ulceration has been reported in animals treated with corticosteroids, so precautions should be taken to prevent the patient from licking the topical treatment.

During a course of treatment, the situation should be reviewed frequently by close veterinary supervision.

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.
Nitrofural is carcinogenic. It has also been observed to cause a severe arthropathy in experimental animals.
Always wear synthetic rubber gloves when administering the product. Wash hands well after use.
People should avoid contact with the area of the animal where the ointment has been applied.

4.6 Adverse reactions (frequency and seriousness)

Anti-inflammatory corticosteroids such as prednisolone are known to exert a wide range of side effects. Long term use may induce severe side effects. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control symptoms. Nitrofural is carcinogenic. It has also been observed to cause a severe arthropathy in experimental animals.

4.7 Use during pregnancy, lactation or lay

Corticosteroids are not recommended for use in pregnant animals. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals.
Administration in late pregnancy may cause early parturition or abortion.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For topical administration only.

Cleanse the area to be treated thoroughly (clipping where necessary). Dermiobion Green Ointment should be applied to the affected area up to 4 times daily. Treatment should be continued for a period of 5-10 days, until at least 48 hours after clinical symptoms have disappeared.

In those cases where Dermobion Green Ointment is applied under a dressing, the dressing should be changed at least once every 48 hours.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No specific recommendations.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The combination of neomycin and nitrofural in Dermobion Green Ointment provides a broad spectrum of antimicrobial action with which to combat superficial skin and wound infections.

Neomycin is a broad-spectrum antimicrobial, which is best used in combination with other antimicrobial agents to avoid the establishment of resistant strains. Nitrofural has the advantage that not only does it have a broad spectrum of antimicrobial activity similar to that of neomycin, but also that bacterial resistance emerges only slowly. No cross-resistance occurs between nitrofural and antimicrobials such as neomycin.

Prednisolone suppresses the connective tissue response to injury whether traumatic, allergic or infective. It also increases capillary tone and selective permeability causing diminution of plasma exudation. Thus, pain and inflammation are reduced.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cod Liver Oil
Chlorophyll OC 10
Neroli Oil
Abiatis Oil
Plastibase 50 w

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

18 months.

6.4 Special precautions for storage

Store below 25^{o}C. Avoid contact between the tube and site to be treated to minimise the risk of contamination of the remaining contents of the tube. Replace the cap securely after use.

6.5 Nature and composition of immediate packaging

Dermobion Green Ointment is packed in 14g and 120g aluminium screw cap tubes, internally lacquered.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Animal owners should return unused ointment to their veterinarian.
Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Fort Dodge Animal Health Limited,
Flanders Road,
Hedge End,
Southampton, SO30 4QH,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10861/53/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2003