PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON 15 g and 30 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trigoderm Gel 0.5 % w/w Fusidic acid, 0.1 % w/w Betamethasone

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains: Fusidic acid 0.5 % w/w and Betamethasone 0.1 % w/w (as the valerate ester), methylparahydroxybenzoate 0.27 % w/w and propylparahydroxybenzoate 0.03 % w/w as preservatives.

3. PHARMACEUTICAL FORM

Gel

4. PACKAGE SIZE

15 g and 30 g

5. TARGET SPECIES

For dogs

6. INDICATION(S)

For topical treatment of surface pyoderma

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
For directions for use see package leaflet.

8. WITHDRAWAL PERIOD

[Not applicable.]

9. SPECIAL WARNING(S), IF NECESSARY

Always wear single-use disposable gloves when applying this 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.
Wash hands after applying the product.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.

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

For directions for use see 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight 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 24883/4001	POM-V
IE: VPA 10803/2/1	POM

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

18. OTHER INFORMATION

Veterinary medicinal product authorised for use in UK and IE.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON 5 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trigoderm Gel 0.5 % w/w Fusidic acid, 0.1 % w/w Betamethasone

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains: Fusidic acid 0.5 % w/w and Betamethasone 0.1 % w/w (as the valerate ester), methylparahydroxybenzoate 0.27 % w/w and propylparahydroxybenzoate 0.03 % w/w as preservatives.

3. PHARMACEUTICAL FORM

Gel

4. PACKAGE SIZE

5 g

5. TARGET SPECIES

For dogs

6. INDICATION(S)

For topical treatment of surface pyoderma

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
For directions for use see package leaflet.

8. WITHDRAWAL PERIOD

[Not applicable.]

9. SPECIAL WARNING(S), IF NECESSARY

For directions for use see package leaflet.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.

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

For directions for use see 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight 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 24883/4001	POM-V
IE: VPA 10803/2/1	POM

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

18. OTHER INFORMATION

Veterinary medicinal product authorised for use in UK and IE.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Tube 15 g and 30 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trigoderm Gel 0.5 % w/w Fusidic acid, 0.1 % w/w Betamethasone

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains: Fusidic acid 0.5 % w/w and Betamethasone 0.1 % w/w (as the valerate ester), methylparahydroxybenzoate 0.27 % w/w and propylparahydroxybenzoate 0.03 % w/w as preservatives.

3. PHARMACEUTICAL FORM

Gel

4. PACKAGE SIZE

15 g and 30 g

5. TARGET SPECIES

For dogs

6. INDICATION(S)

For topical treatment of surface pyoderma

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
For directions for use see package leaflet.

8. WITHDRAWAL PERIOD

[Not applicable.]

9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet for full user warnings.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.
Keep the tube in the outer container.

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

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight 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 24883/4001	POM-V
IE: VPA 10803/2/1	POM

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

18. OTHER INFORMATION

Veterinary medicinal product authorised for use in UK and IE.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Tube 5g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trigoderm Gel 0.5 % w/w Fusidic acid, 0.1 % w/w Betamethasone

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

5 g

4. ROUTE(S) OF ADMINISTRATION

For external use only.

5. WITHDRAWAL PERIOD

[Not applicable.]

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

9. SPECIAL STORAGE CONDITIONS

Do no refrigerate or freeze.

Keep the tube in the outer carton.

B. PACKAGE LEAFLET

TRIGODERM GEL

Fusidic acid 0.5 % w/w
Betamethasone 0.1 % w/w (as the valerate ester)

This leaflet gives you some helpful information about Trigoderm gel. If you have any questions or are not sure about anything, ask your veterinary surgeon.

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
7171 Uldum
Denmark

Manufacturer for the batch release:
Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

What is in Trigoderm gel?
Trigoderm gel is a white translucent gel containing fusidic acid 0.5 % w/w and Betamethasone 0.1 % w/w (as the valerate ester) with methylparahydroxybenzoate 0.27 % w/w and propylparahydroxybenzoate 0.03 % w/w as preservatives.

What does Trigoderm gel do?
Trigoderm gel is used for the topical treatment of certain skin diseases such as wet eczema (acute moist dermatitis) which can occur in isolated patches on the body or in skin folds.
Wet eczema is often made worse by the dog scratching or licking the affected area because of itching or pain.
The skin problem may be associated with flea allergy and your veterinary surgeon may treat your dog for fleas at the same time.
Trigoderm gel contains a well known antibiotic which helps kill the bacteria and a corticosteroid anti-inflammatory which will help relieve the itching and inflammation.

Contraindications:
As with other topical antibiotic/corticosteroid combinations for treating skin ailments, the gel should not be used if your dog is allergic to the ingredients.
Do not use on skin conditions other than those for which your veterinary surgeon has prescribed Trigoderm gel.
The use of the gel over large surface areas and prolonged treatment should be avoided.
Do not apply to the eye.

Adverse reactions:
Anti-inflammatory corticosteroids, such as betamethasone valerate, are known to exert a wide range of side-effects. Whilst single high doses are generally well tolerated, they may induce severe side-effects in 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 symptoms.

Steroids themselves, during treatment, may cause Cushingoid symptoms involving significant alteration of fat, carbohydrate, protein and mineral metabolism e.g. redistribution of body fat, muscle weakness and wastage and osteoporosis may result. During therapy effective doses suppress the Hypothalamo-pituitreal-adrenal axis.
Following cessation of treatment, symptoms of adrenal insufficiency can arise and this may render the animal unable to deal adequately with stressful situations.
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.
Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.
Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Target species:
Dog.

Dosage for each species, route and method of administration:
If necessary, clean the infected area of any pus or other material before applying the gel. Use cotton wool dampened with water. Dry before applying the gel.
Squeeze a little of the gel onto the affected area of the skin and spread it gently twice daily.
If you forget to use the gel at any time, use it as soon as you remember. Then go on as before.
Complete the normal course as prescribed by your veterinary surgeon which is usually for 5 to a maximum of 7 days.

Advice on correct administration:
Follow your veterinary surgeon’s instructions about when and how to use the gel.
Read the label carefully. Use the gel as your veterinary surgeon has told you.
Avoid getting the gel into your own or your dog’s eyes, since it may cause stinging. If it gets into eyes rinse with water.
Wash your hands well after applying the gel.
After a few days of using the gel, your dog’s skin condition should start to improve. However if the problem gets worse or doesn’t improve, or if there are any other unexpected problems, consult your veterinary surgeon.

Withdrawal period:
Not applicable.

Storage instructions:
Keep all medicines out of the reach and sight of children.
Do not refrigerate or freeze.
Do not use after the expiry date stated on the carton.

Special warnings:
For external use only.

Precautions when used on the dog
The dog should be prevented from licking the affected area. It may be helpful to apply the gel immediately before feeding, or before taking the dog for a walk, in order to distract the dog's attention.
Where there is a risk of the dog scratching or chewing the affected area, preventative measures such as the use of an Elizabethan collar should be considered.
Remember, this treatment is for your dog only. Should the skin condition occur again at a later date, do not use the gel without consulting your veterinary surgeon. Do not use it on other dogs.

Special precautions to be taken by the person administering Trigoderm gel to the dog
When applying the gel, please remember that 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. Always wear single-use disposable gloves when applying this product to animals. Wash hands after use.

Use during pregnancy and lactation
Do not use on pregnant bitches or if you suspect she is pregnant.

Special precautions for the disposal of unused product or waste materials, if any:
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

Date of approval of this leaflet:
IE:
UK: August 2022

Other information:
To be supplied only on veterinary prescription.
For animal treatment only.
Veterinary medicinal product authorised for use in UK and IE.

UK Marketing Authorisation Number:
Vm 24883/4001

Irish Veterinary Product Authorisation Number:
VPA10803/2/1

Legal Category:

UK	POM-V
Ireland	POM

Nature and composition of immediate packaging: Tubes of 5 g, 15 g or 30 g.
Not all pack sizes may be marketed.

Prescribed dose:

Gavin Hall
Approved: 04 December 2024