

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clearium 31.2 mg/ml Shampoo for dog

chlorhexidine digluconate

2. STATEMENT OF ACTIVE SUBSTANCES

1ml contains :

Active substance

Chlorhexidine digluconate solution
chlorhexidine)

31.2 mg (corresponding to 17.5 mg

3. PHARMACEUTICAL FORM

Shampoo

4. PACKAGE SIZE

200 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For OTC products:

For the treatment of an overgrowth of the fungal organism *Malassezia pachydermatis* on the skin surface and the control of associated clinical signs in dogs.

7. METHOD AND ROUTE OF ADMINISTRATION

Read package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

This product may cause hypersensitivity following dermal contact and can be irritating to skin.

People with known hypersensitivity to chlorhexidine or any of the excipients should avoid contact with the veterinary medicinal product.

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened use within 2months: by...

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate.

Do not store below 8°C.

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.

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

Virbac
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4216

17. MANUFACTURER’S BATCH NUMBER

<Batch><Lot> {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 200 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clearium 31.2 mg/ml Shampoo for dog

chlorhexidine digluconate

2. STATEMENT OF ACTIVE SUBSTANCES

1ml contains:

Active substance

Chlorhexidine digluconate solution..... 31.2 mg (corresponding to
17.5 mg chlorhexidine)

3. PHARMACEUTICAL FORM

Shampoo

4. PACKAGE SIZE

200ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For OTC products:

For the treatment of an overgrowth of the fungal organism *Malassezia pachydermatis*
on the skin surface and the control of associated clinical signs in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}>

Once opened use within 2 months.

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate.
Do not store below 8°C.

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.

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

Virbac
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4216

17. MANUFACTURER’S BATCH NUMBER

<Batch><Lot> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Clearium 31.2 mg/ml Shampoo for dog

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

Marketing authorisation holder and manufacturer responsible for batch release:

Virbac
1ère avenue 2065m LID
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clearium 31.2 mg/ml Shampoo for dog

chlorhexidine digluconate

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

1 ml contains:

Active substance

Chlorhexidine digluconate solution 31.2 mg (corresponding to 17.5mg chlorhexidine)

Excipients

Ponceau 4R (E124)2.6 micrograms

The shampoo is presented as a pink to orange clear solution.

4. INDICATION(S)

For OTC products:

This product is indicated for the following skin disease in dogs. Please seek advice from your veterinary surgeon before using this product.

For the treatment of an overgrowth of the fungal organism *Malassezia pachydermatis* on the skin surface and the control of associated clinical signs in dogs.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

In a clinical trial, pruritus (itchiness) and erythematous reactions (redness of the skin) were common observations after shampooing with this product. In most cases, these reactions did not necessitate the cessation of treatment and clinical signs resolved completely without any specific therapy. However, if signs persist, please seek advice from your veterinary surgeon.

Conjunctival inflammation (pink eye) may occur and usually resolves without treatment.

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.

Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

Dogs

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

For OTC products;

Please seek advice from your veterinary surgeon before applying this product to your animal.

Cutaneous use

Administer the shampoo topically three times (three treatment sessions) a week for 2 weeks then, if necessary, twice a week for 2 weeks and finally on a weekly basis for 2 weeks. If necessary, further use may be required in accordance with the directions of and a risk/benefit assessment by the prescribing veterinarian.

The table below provides a guide to suitable volumes; however, the amount of the product to be administered has to be adapted to both, the size of the dog and the hair-coat length. The volume of the product applied should be sufficient to develop lather. Follow the procedure below:

Wet the animal thoroughly with clean water and apply the product to the animal at several points. Apply a quantity of product according to the dog's weight and hair-coat length in order to develop lather.

Distribute the product uniformly all over the surface of the hair and ensure that it is applied around the lips, under the tail and between the toes. Massage the animal's body to develop lather and rinse immediately.

Repeat the above procedure using the same volume of product as before, but this time allow a 10-minute contact period before rinsing the hair coat with clean water. Leave the dog to dry naturally in a warm draught-free environment.

Two applications of shampoo are to be applied per treatment session, as shown in the table below:

Bodyweight	1st shampooing		2nd Shampooing	Total volume of product to be used per treatment session
≤ 4.9 kg	10 ml	wash	10 ml	20 ml
5.0 to 10.9 kg	15 ml	wash	15 ml	30 ml
11.0 to 15.9 kg	20 ml	wash	20 ml	40 ml
16.0 to 20.9 kg	25 ml	wash	25 ml	50 ml
21.0 to 30.9 kg	30 ml	wash	30 ml	60 ml
31.0 to 45.9 kg	40 ml	wash	40 ml	80 ml
≥ 46.0 kg	50 ml	wash	50 ml	100 ml

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not refrigerate.

Do not store below 8°C.

Shelf life after first opening the container: 2 months.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:

For OTC products:

Diagnosis of *Malassezia pachydermatis* should be based on clinical examination, exclusion of other dermatoses and presence of *Malassezia pachydermatis* on the skin.

Special precautions for use in animals:

For external use only.

Take care to avoid the animal inhaling the product or the product getting it into the eyes, auditory canal, nose or mouth of the animal during shampooing. In case of accidental contact with eyes, rinse with plenty of water. If eye irritation occurs and persists, consult a veterinarian.

Do not allow the animal to lick itself during shampooing and rinsing or before it is dried.

Safety of the product has not been demonstrated in animals of less than five months of age.

Safety of the product has not been demonstrated beyond six weeks of use.

Resistance to any particular class of antimicrobial may develop following frequent, repeated use of an antimicrobial of that class.

Use of the product deviating from the instructions given in the leaflet may induce a resistance in the population of skin yeasts.

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

This product may cause hypersensitivity following dermal contact and can be irritating to skin.

Avoid prolonged contact with the shampoo by gently washing and drying hands immediately after use of the product.

If you develop symptoms following exposure such a skin rash or skin irritation, you should seek medical advice and show the physician the label or package leaflet.

People with known hypersensitivity to chlorhexidine or any of the excipients should avoid contact with the veterinary medicinal product.

Accidental eye contact with undiluted product may cause serious eye irritation.

Avoid contact with eyes.

In case of accidental eye contact, rinse with plenty of water, seek medical advice and show the physician the label or package leaflet.

Accidental ingestion may cause adverse reactions, such as stomach irritation and nausea.

Avoid contact with mouth and hand-to-mouth transfer.

In the event of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician

Keep the product in the original packaging until use and immediately after use, in order to prevent children from getting direct access to the product.

Avoid handling and stroking of treated animals immediately following treatment.

Do not eat, drink or smoke while handling this product.

Pregnancy and lactation:

For OTC products:

Consult your veterinary surgeon before using the product in pregnant or lactating bitches.

Laboratory studies in rats and dogs have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects due to chlorhexidine. However, the safety of the product in dogs has not been investigated during pregnancy and lactation. Therefore, use in accordance with a benefit/risk assessment by the responsible veterinarian.

Puppies should not come into contact with nursing females after treatment until the coat has dried.

Interaction with other medicinal products and other forms of interaction:

Frequent shampooing may reduce the efficacy of other topically-applied products, e.g. ectoparasiticides.

No data are available to evaluate interactions with other topically-applied products.

For OTC products:

Please consult your veterinary surgeon for advice on simultaneous use of other veterinary medicinal products that are applied to the skin of your animal.

Overdose (symptoms, emergency procedures, antidotes):

A study performed in dogs receiving up to five times the recommended therapeutic dose, three days a week for four consecutive weeks, shows on occasions slight cutaneous reactions only. These reactions were transient, although they could last for several days when shampooing was ongoing. They did not require any particular treatment.

Incompatibilities:

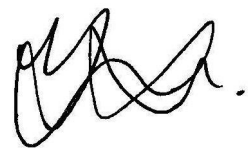
Not applicable.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION



Approved: 16 June 2023