

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clearium 31.2 mg/ml Shampoo for dog

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance

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

Excipients

Ponceau 4R (E124) 2.6 micrograms

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Shampoo.

Pink to orange clear solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

For the treatment of *Malassezia pachydermatis* surface proliferation and the control of associated clinical signs in dogs.

4.3 Contraindications

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

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

For external use only.

Take care to avoid the animal inhaling the product or the product getting 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 SPC 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 as 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.

4.6 Adverse reactions (frequency and seriousness)

In a clinical trial, pruritus and erythematous reactions 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, the veterinary surgeon should re-evaluate the treatment.

Conjunctival inflammation 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)

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amounts to be administered and administration route

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	1 st shampooing		2 nd 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

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

A tolerance 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.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiseptics and disinfectants, biguanides and amidines, chlorhexidine.

ATC vet code: QD08AC02

5.1 Pharmacodynamic properties

Chlorhexidine digluconate is an antiseptic agent of the biguanide group with fungicidal activity against yeasts including *Malassezia pachydermatis*.

The mode of action of chlorhexidine is concentration-dependent. Chlorhexidine alters the permeability of the cell wall. At low concentrations, low molecular-weight substances leak out without the cell being irreversibly damaged. At higher concentrations, chlorhexidine enters the cell, causes precipitation of the cytoplasm, prevents repair to the membrane and causes the destruction of the cell.

Typical MIC values found in clinical *Malassezia pachydermatis* isolates are 2-4 µg/ml (2014)

To date (2018) no resistance to chlorhexidine has been shown for *Malassezia pachydermatis*.

5.2 Pharmacokinetic particulars

After topical administration of the product to dogs, there was little or no systemic absorption of chlorhexidine digluconate. Absorption of chlorhexidine after oral administration is also very low. The efficacy of the product is due to the high concentrations of chlorhexidine digluconate achieved on the body surface for the 10-minute period of shampooing.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Ponceau 4R (E124)
- Lauryl glucoside
- Cocamidopropyl betaine
- Glucono δ -lactone (for pH adjustment)
- Water, purified

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 2 months.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Carton box containing one 200-ml white high-density polyethylene bottle closed by a white polypropylene screw cap. A translucent polypropylene cup is placed on top as an administration device.

Pack size : Carton box with 1 bottle of 200 ml

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Virbac
1ère avenue 2065m LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER

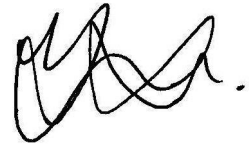
Vm 05653/4216

9. DATE OF FIRST AUTHORISATION

04 December 2018

10. DATE OF REVISION OF THE TEXT

June 2023

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 16 June 2023