SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Microbex 31.2 mg Shampoo

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of shampoo contains:

Active substance
chlorhexidine digluconate ..... 31.2 mg

Excipients
Ponceau 4R (E124) …….0.0026 mg

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.

4.3 Contra-indications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals

For external use only.
In case of accidental contact with eyes, rinse with plenty of water.

This product should not be used in dogs that are known to be hypersensitive to chlorhexidine or any of the other ingredients.
Safety of the product has not been demonstrated in animals of less than five months of age.
Do not allow the animal to lick itself during shampooing and rinsing or before it is dried. Take care to avoid the animal inhaling the product or getting it into the eyes, nose or mouth during shampooing.
Safety of the product has not been demonstrated beyond six weeks of use.

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

People with known hypersensitivity to chlorhexidine or any of the excipients should avoid contact with the veterinary medicinal product.
Avoid contact with eyes. In case of accidental eye contact, rinse with plenty of water. If irritation persists consult your doctor.
Wash hands after use.
Do not eat, drink or smoke while handling this product.
In the event of accidental ingestion, seek medical advice and show the package leaflet or the label to the doctor.

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.

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

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

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 operation a second time but 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.

The following table 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.

Bodyweight	**Volume of product**
≤ 4.9 kg	10 ml x 2 baths
5.0 to 10.9 kg	15 ml x 2 baths
11.0 to 15.9 kg	20 ml x 2 baths
16.0 to 20.9 kg	25 ml x 2 baths
21.0 to 30.9 kg	30 ml x 2 baths
31.0 to 45.9 kg	40 ml x 2 baths
≥ 46.0 kg	50 ml x 2 baths

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: antiseptic agent.

ATCvet code: QD08AC02.

5.1 Pharmacodynamic properties

Chlorhexidine digluconate is an antiseptic agent of the biguanine group with a broad-spectrum bactericidal activity against gram-positive and gram-negative bacteria as well as a fungicidal activity against yeasts.
The mode of action of chlorhexidine (i.e. whether it is bactericidal or bacteriostatic) depends on the concentration used. Chlorhexidine alters the permeability of the bacterial-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 bacterial-cell membrane and causes the destruction of the bacterial cell.
Typical MIC values found in clinical Malassezia pachydermatis isolates are 2-4 µg/ml (2014)
To date (2014) no resistance to chlorhexidine has been shown for *Malassezia pachydermatis*.
Resistance to chlorhexidine is uncommon in Gram (+) bacteria but some resistant Gram (-) isolates have been described in human hospital environments (*Proteus* spp., *Pseudomonas* spp.).
When used in accordance with the recommended dose regimen the development of resistance to chlorhexidine is not expected.

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
- Purified water

6.2 Incompatibilities

None known.

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 at +8°C or below)

6.5 Nature and composition of immediate packaging

Carton box containing one 200-ml white high-density polyethylene bottle closed by a white polypropylene disc top (screw-fit) and an overcap.

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 S.A.
1ère avenue - 2065m – L.I.D.
06516 Carros Cedex
France

8. MARKETING-AUTHORISATION NUMBER

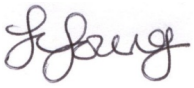
Vm 05653/4143

9. DATE OF FIRST AUTHORISATION

Date: 9 June 2009

10. DATE OF REVISION OF THE TEXT

Date: June 2014

Approved:  **17/06/2014**