

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paxcutol 2.5875 % w/v Shampoo

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s)	% w/v
Benzoyl peroxide.....	2.5875 % w/v

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Shampoo.
Whitish, viscous, homogeneous shampoo

4. CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

For the treatment of canine skin disease where bacterial infection and/or seborrhoea are involved.

4.3 Contra-indications

None

4.4 Special warnings for each target species

Avoid contact with the eyes and mucous membranes.

4.5 Special precautions for use

i. Special precautions for use in animals

For external use only.
Avoid contact with dog's eyes and mucous membranes during treatment.

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

Impervious gloves should be worn at all times when applying the product.
Irritant: irritation to skin and eyes.
Avoid contact with the eyes and mucous membranes.

Remove any splashes with plenty of water and in case of contact with eyes, seek medical advice.

When using the product, do not eat, drink or smoke.

Wash hands after use.

iii. Other precautions

Old clothes should be worn when applying the shampoo as contact may damage some fabrics.

4.6 Adverse reactions (frequency and seriousness)

Dogs may show signs of sensitivity to the shampoo.

Should irritation or skin inflammation occur, treatment should be discontinued.

4.7 Use during pregnancy, lactation or lay

The product can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None Known

4.9 Amounts to be administrated and administration route

Shake container before use. Before applying the shampoo, thoroughly wet the coat. The shampoo is to be massaged into the coat in sufficient quantity until a good lather is achieved and then rinsed. The shampoo is applied a second time and left for 10 minutes, followed by rinsing with warm water. In cases where lesions are not widespread, the product may be applied locally. Initially, a once-daily treatment is recommended with use on its own or concurrently with specific therapy. As the skin condition responds to therapy, the interval may be extended to a frequency of once monthly. The suggested volume of shampoo is:

- 10-20 ml shampoo for a small dog,
- 30 ml shampoo for a medium-sized dog,
- 40-100 ml shampoo for a large dog.

Avoid contact with the eyes and mucous membranes.

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

Not applicable

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

ATC vet: QD11AX10

Paxcutol Shampoo is an antibacterial and keratolytic preparation for use on dogs. It contains as active ingredient 2.5875 % w/v benzoyl peroxide, and oxidating substance.

5.1 Pharmacodynamic properties

Benzoyl peroxide, when applied on the skin, decomposes releasing benzoyl peroxy radicals and nascent oxygen, after interacting with biological substances, thermal variation and ultra-violet exposure. When the free radicals are formed, reactions such as interactions with (-OH) hydroxyl and (-SH) sulfhydryl groups, double bonds and aromatic compounds occur. The results of these interactions disrupt the membranes of bacterial cells, altering permeability of the membrane and, subsequently, the function of the cell. It is therefore indicated for the treatment of topical ailments involving bacterial infections. Additionally, benzoyl peroxide reduces the activity of seborrhoeic glands, contributing to resolving seborrhoeic conditions.

5.2 Pharmacokinetic properties

Benzoyl peroxide reacts rapidly with cysteine, an integral amino acid contained in keratin. In reacting with cysteine, benzoyl peroxide is rapidly reduced to benzoic acid and various benzoate salts which do not penetrate the skin and are biologically harmless. The interaction of benzoyl peroxide with skin is usually of no untoward consequence.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Coconut Diethanolamide
Sodium Lauryl Ether Sulphate (28% solution)
Magnesium-Aluminium Silicate
Citric Acid Monohydrate
Water Purified

6.2 Incompatibilities

None Known

6.3 Shelf Life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition if immediate packaging

125 ml, 150 ml, 200 ml, 1 L white opaque high-density polyethylene bottle with white high density polyethylene and polypropylene cap (screw – fit).
Not all pack sizes maybe marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4018

9. DATE OF FIRST AUTHORISATION

20/05/1988

10. DATE OF REVISION OF THE TEXT

September 2009