SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adaxio Shampoo for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substances:
Chlorhexidine digluconate 20 mg (equivalent to chlorhexidine 11.26 mg)
Miconazole nitrate 20 mg (equivalent to miconazole 17.37 mg)

Excipients:
Methylchloroisothiazolinone 0.0075 mg
Methylisothiazolinone 0.0025 mg
Benzoic acid (E210) 1,35 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Shampoo.
A clear light yellow to yellow liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

For the treatment and control of seborrhoeic dermatitis associated with *Malassezia pachydermatis* and/or *Staphylococcus pseudintermedius*.

4.3 Contraindications

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

4.4 Special warnings for each target species

In order to prevent recurrence of the infection, appropriate control methods should be employed in the animal's environment (e.g. cleaning and disinfection of kennel, beds.

4.5 Special precautions for use

i. Special precautions for use in animals

Official, national and regional antimicrobial policies should be taken into account when the product is used.
Take care to avoid the animal inhaling the product or getting it into eyes, auditory canal, nose or mouth during shampooing.
In case of accidental contact with eyes, rinse with plenty of water.
If eye irritation persists, consult a veterinarian.

Do not allow the animal to lick itself during shampooing and rinsing, or before it is dried. Puppies should not come into contact with nursing females after treatment until the coat has dried.
Use of the product deviating from the SPC's recommendations may induce a resistance in the population of skin bacteria.

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

- People with known hypersensitivity to chlorhexidine, miconazole or any of the excipients should avoid contact with the product.
- This product may cause hypersensitivity following dermal contact. If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the physician the label or package leaflet.

- Accidental eye contact with undiluted product may cause serious eye irritation. Avoid contact with the eyes. In case of accidental contact with eyes, rinse with plenty of water. If irritation persists consult your physician.

- The product can be irritating to skin. Avoid prolonged contact with the shampoo by gently washing and drying hands.

- Avoid excessive handling and stroking of treated animals immediately following treatment.

4.6 Adverse reactions (frequency and seriousness)

Skin reactions such as itching and redness may occur very rarely.
Pruritic and/or erythematous reaction may appear very rarely in an atopic dog.

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 or lactation

Studies in animals have not produced any teratogenic, foetotoxic or maternotoxic effects due to chlorhexidine or miconazole at the recommended

doses. The safety of the product has not been established during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian. And see section 4.5i)

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

Cutaneous use.

As a general rule, shampoo twice weekly until the symptoms subside and weekly thereafter or as necessary to keep the condition under control.
Wet the animal thoroughly with clean water and apply the product to the animal at several points and massage into the coat. Use sufficient to raise a lather on the coat and skin. Ensure that the shampoo is applied around the lips, under the tail and between the toes. Allow the animal to stand for 10 minutes, then rinse off with clean water and leave to dry naturally in a warm, draught-free environment.

	Number of treatments per 200 mL bottle	
	short hair	long hair
Up to 15kg	13	6
16-24kg	10	5
25kg or more	8	4

	Number of treatments per 500 mL bottle	
	short hair	long hair
Up to 15kg	33	15
16-24kg	25	13
25kg or more	20	10

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

No data available.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: dermatological, ATCvet code: QD08AC52.

5.1 Pharmacodynamic properties

Chlorhexidine digluconate
Chlorhexidine digluconate (ATCvet classification QD08AC02) is a Bisbiguanide antimicrobial agent against Gram-positive and Gram-negative bacteria. It is both bactericidal and bacteriostatic depending on the concentration used. Growth inhibition is achieved by a direct effect on ATP-ase so interfering with the energy transport mechanisms. The bactericidal effect of chlorhexidine results from coagulation of the bacterial cell contents.

Chlorhexidine digluconate is incorporated in the product for its activity against *Staphylococcus pseudintermedius.* Typical MIC values found in clinical *Staphylococcus pseudintermedius* isolates are 2.0 mg/L (2015). *Staphylococcus pseudintermedius* resistance to chlorhexidine has not been reported.

Miconazole nitrate
Miconazole nitrate (ATCvet classification QD01AC02) is an imidazole antifungal agent with activity against yeasts such as *Malassezia pachydermatis.*
It is both fungicidal and fungistatic depending on the concentration used. Miconazole inhibits ergosterol incorporation into cell membranes so increasing concentrations of cytotoxic hydrogen peroxide within the fungal cell wall.

Miconazole nitrate has been incorporated in the product for its activity against *Malassezia pachydermatis.* Typical MIC values found in clinical *Malassezia pachydermatis* isolates are 1 – 4.0 µg/mL (2012). *Malassezia pachydermatis* resistance to miconazole has not been reported.

5.2 Pharmacokinetic particulars

Chlorhexidine digluconate
High concentrations of chlorhexidine digluconate are achieved in the hair coat and on the skin for the 10 minute period following shampooing. These concentrations are well in excess of the MICs for *Staphylococcus pseudintermedius.* Chlorhexidine digluconate is poorly absorbed from the gastrointestinal tract on ingestion. There is little or no percutaneous absorption. In humans it has been shown that 26% remains on the skin at 29 hours after application.

Miconazole nitrate
High concentrations of miconazole nitrate are achieved in the hair coat and on the skin for the 10 minute period following shampooing. These concentrations are well in excess of the MICs for *Malassezia pachydermatis.*
There is little absorption through skin or mucous membranes when applied topically.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methylchloroisothiazolinone
Methylisothiazolinone
Benzoic acid (E210)
Macrogol lauryl ether
Cocamidopropyl betaine
Disodium cocoamphodiacetate
Cetrimonium chloride,
Macrogol 120 methyl glucose dioleate
Magnesium chloride
Sodium chloride
Magnesium nitrate
Citric acid monohydrate (for pH adjustement)
Water, purified

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

Shelf-life after first opening the immediate packaging: 3 months.

6.4 Special precautions for storage

Do not store above 25°C.
Do not refrigerate or freeze.

6.5 Nature and composition of immediate packaging

The container is a white opaque polypropylene bottle with a polypropylene flip top cap.
Bottle of 200 ml
Bottle of 500ml
Cardboard box of 1 bottle of 200 ml
Cardboard box of 1 bottle of 500 ml

Not all pack sizes may be 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 veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

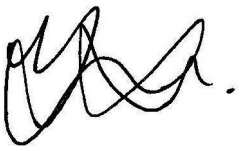
Vm 15052/4090

9. DATE OF FIRST AUTHORISATION

20 November 2014

10. DATE OF REVISION OF THE TEXT

September 2022



Approved: 13 September 2022