LABELLING AND PACKAGE LEAFLET

LABELLING

PARTICULARS TO APPEAR ON OUTER CARTON AND THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adaxio Shampoo for Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Shampoo.
A clear light yellow to yellow liquid

4. PACKAGE SIZE

200 ml
500 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 3 months
Once opened, use by

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

16. MARKETING AUTHORISATION NUMBER

Vm 14966/3043

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PACKAGE LEAFLET

Veterinary Medicinal Product

Adaxio Shampoo for Dogs

PART I B

LEAFLET

Pharmaceutical Form

Shampoo

PACKAGE LEAFLET:

Adaxio Shampoo for Dogs

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

Marketing authorisation holder

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Manufacturer responsible for batch release:

Thepenier Pharma & Cosmetics
Route départementale 912
61400 St Langis Les Mortagne
FRANCE

Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 Louverné
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adaxio Shampoo for dogs

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

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

Methylchloroisothiazolinone 0.0075 mg
Methylisothiazolinone 0.0025 mg
Benzoic acid 1.35 mg

Shampoo.
A clear light yellow to yellow liquid.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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)

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf life after first opening the container: 3 months
Do not use this veterinary medicinal product after the expiry date which is stated on the bottle and carton after "EXP". The expiry date refers to the last day of that month.

When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

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.

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.

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. This product can cause 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.

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 "Special precautions for use in animals").
Interaction with other medicinal products and other forms of interaction:
No data are available to evaluate interactions with other topically applied products.

Overdose (symptoms, emergency procedures, antidotes):
No data available.

Incompatibilities:
None known.

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

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

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

For animal treatment only

PACKAGE SIZE

Cardboard box of 1 Bottle of 200 ml
Cardboard box of 1 Bottle of 500 ml
bottle of 200ml
bottle of 500ml

Not all pack size may be marketed

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

MA number
Legal status (national issue)

Veterinary Medicinal Product

Adaxio Shampoo for dogs

PART I B

LABEL (for bottle without outer carton)

Pharmaceutical Form

Shampoo

LABEL/LEAFLET

Adaxio Shampoo for Dogs

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

Marketing authorisation holder:

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Manufacturer responsible for batch release:

Thepenier Pharma & Cosmetics
Route départementale 912
61400 St Langis Les Mortagne
FRANCE

Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 Louverné
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adaxio Shampoo for Dogs
chlorhexidine digluconate / miconazole nitrate

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

Each ml contains:
Active substances:
Chlorhexidine dicgluconate 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 1.35 mg

Shampoo.
A clear light yellow to yellow liquid.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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)

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

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

9. ADVICE ON CORRECT ADMINISTRATION

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	

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf life after first opening the container: 3 months

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

When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

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.

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.

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. This product can cause 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.

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 "Special precautions for use in animals").

Interaction with other medicinal products and other forms of interaction:
No data are available to evaluate interactions with other topically applied products.

Overdose (symptoms, emergency procedures, antidotes):
Not data available.

Incompatibilities:
None known.

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

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

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

For animal treatment only

PACKAGE SIZE

Bottle of 200 ml
Bottle of 500 ml
Cardboard box of bottle of 200ml
Cardboard box of bottle of 500ml

Not all pack size may be marketed

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

BATCH NUMBER:

EXPIRY DATE:

MA n°
Legal status (national issue)

Gavin Hall
Approved: 16 October 2025