Revised: September 2022 AN: 01599/2022

### MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET

150 ml bottle.

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

<u>Manufacturer responsible for batch release</u>: Ceva Sante Animale,Zone Industrielle de Tres-le-Bois, 22600 Loudeac, France

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Seleen® shampoo 1% w/v

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

#### 4. PHARMACEUTICAL FORM

Shampoo

#### 5. PACKAGE SIZE

150 ml

#### 6. INDICATION(S)

For the treatment of seborrhoeic dermatitis in dogs.

#### 7. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to the active ingredient.

#### 8. ADVERSE REACTIONS

If signs of disease persist or appear, consult your veterinary surgeon.

#### 9. TARGET SPECIES

Dogs

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### 10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Wash the coat thoroughly using a mild shampoo. Then rinse.

Shake the container before use. Mix 25 to 100 ml depending upon the size of the animal with  $\frac{1}{4}$  to 1 cup of warm water (50 – 200 ml). Avoid the eyes and lather well into the coat and skin. Do not allow the animal to lick the suspension.

Leave the suspension in contact for 5-10 minutes. Then rinse thoroughly and dry.

Treatment should be repeated at intervals of one week, if necessary.

#### 11. ADVICE ON CORRECT ADMINISTRATION

#### 12. WITHDRAWAL PERIOD

Not applicable.

#### 13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

#### 14. SPECIAL WARNING(S)

#### SPECIAL PRECAUTIONS FOR USE IN ANIMALS:

For external use only. Detergents may irritate. The eyes of the animals may be protected by liquid paraffin or a mild ophthalmic ointment. Do not exceed the recommended volume of shampoo.

In the absence of specific studies conducted during pregnancy and lactation, use during these times is not recommended.

#### **USER WARNINGS:**

Protective waterproof gloves should be worn when using this product.

Wash hands and exposed skin thoroughly after use.

Poisonous if taken internally.

Avoid contact with eyes. If eye contact occurs, rinse with clean, running water and seek medical advice if irritation persists.

Do not use in cases of known hypersensitivity to the active ingredient.

#### INTERACTIONS:

Avoid prolonged contact with painted or coated metals.

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#### 15. EXPIRY DATE

Exp

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

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

#### 17. DATE ON WHICH THE LABEL WAS LAST APPROVED

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

For animal treatment only

AVM-GSL

#### 19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children

#### 20. MARKETING AUTHORISATION NUMBER

Vm 15052/4010

#### 21. MANUFACTURER'S BATCH NUMBER

Lot:

Approved: 29 September 2022