

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Seleen® shampoo 1% w/v

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	<u>% w/v</u>
<u>Active ingredient:</u> Selenium sulphide	1.000
<u>Other ingredients:</u> Patent blue V (E131) calcium salt	0.003

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Shampoo.
An olive green shampoo.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use

Seborrhoeic dermatitis.

4.3 Contraindications

Not to be used in cases of known hypersensitivity to the active substance.

4.4 Special warnings for each target species

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

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals,

- i. 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.
Do not allow the animal to lick the suspension.

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

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.

4.6 Adverse reactions

Very rarely, it has been reported that white-coated animals turn pink following the use of this product.

We understand that this undesirable effect is also occasionally observed with a similar shampoo, Selsun Blue, when it is used on white haired people. It seems that the pink colouration is due to a reaction with other chemicals in the coat or among the hairs e.g. talcum powder. It can usually be washed out using a conditioning shampoo containing aloe vera.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

The product can adversely affect painted or coated metals.

4.9 Amounts to be administered and administration route

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. Lather well into the coat and skin avoiding the eyes. 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.

4.10 Overdose (Symptoms, emergency procedures, antidotes)

No data available.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QD01AE13

Selenium sulphide appears to have a cytostatic effect on the cells of the epidermis and follicular epithelium, thus reducing corneocyte production. Selenium sulphide acts as an antiseborrhetic agent which effectively controls itching and dandruff.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent Blue V (E131) calcium salt
Bentonite
Citric Acid Anhydrous
Sodium chloride
Sodium sulphonate linear benzene alkyl
Sodium Acid phosphate dehydrate
Glycerol monoricinolate
Perfume Compound
Purified Water

6.2 Major incompatibilities

Avoid prolonged contact with painted or coated metals.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Container: White high density polyethylene bottle.

Closure: White, low density polyethylene screw cap.

Content: 150 ml olive green shampoo

6.6 Special precautions for the disposal of unused medicinal product 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.

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

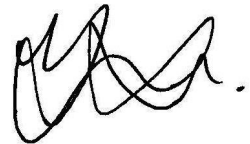
Vm 15052/4010

9. DATE OF THE FIRST AUTHORISATION

28 October 1992

10. DATE OF REVISION OF THE TEXT

September 2022

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 29 September 2022