

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

10995/015/001

Case No: 7002386

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Ceva Animal Health Limited

90 The Broadway, Chesham, Bucks HP15 1EG, United Kingdom

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Seleen

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **15/12/2006** until .

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Seleen

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Shampoo.

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 in dogs.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Detergents may irritate. The eyes of the animals may be protected by liquid paraffin or a mild ophthalmic ointment. Do not allow the animal to lick the suspension.

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

Wash hands thoroughly after use.
Protective waterproof gloves should be worn when using this product, especially by women of childbearing age.

4.6 Adverse reactions (frequency and seriousness)

Very rarely, it has been reported that white-coated animals turn pink following the use of this product. It is thought that the pink colouration may be 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.

The incidence of such cases reported is very infrequent.

4.7 Use during pregnancy, lactation or lay

Seleen shampoo may be used during pregnancy.

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

For external use only.

Wash the coat thoroughly using a mild toilet soap. Then rinse.

Shake the container before use. Mix 25 to 100 ml depending upon the size of the animal with ¼ to 1 cup of warm water. 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.

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

Do not exceed the recommended volume of shampoo.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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. It has activity against certain dermatophytes.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Bentonite
Ultrawet K
(Sodium alkyl benzene sulfanat)
Sodium Acid Phosphate
Glycerol monoricinoleate-S
Perfume compound
Patent blue V (E 131)(calcium salt)
Anhydrous Citric Acid
Sodium Chloride
Purified Water

6.2 Incompatibilities

None

6.3 Shelf-life

3 years.

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and composition of immediate packaging

Container: White high density polyethylene bottle.
Closure: White, low density polyethylene screw cap.
Content: 150 ml.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Ceva Animal Health Limited,
90 The Broadway,
Chesham,
Bucks,
HP5 1EG,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10995/15/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2001