

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Cardboard box)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

SELGIAN 4 mg Film-Coated Tablets

**2. STATEMENT OF ACTIVE SUBSTANCES**

(-) Selegiline hydrochloride, 4 mg per tablet

**3. PACKAGE SIZE**

3 x 10 tablets (pictogram of a tablet) or 5 x 10 tablets (pictogram of a tablet)  
or 10 x 10 tablets (pictogram of a tablet) or 50 x 10 tablets (pictogram of a  
tablet)

**4. TARGET SPECIES**

Dogs

**5. INDICATIONS**

For the treatment of behavioural disorders of emotional origin including anxiety, depression, unsociable behaviour, hyperactivity and phobias.

**6. ROUTES OF ADMINISTRATION**

One tablet orally per 8 kg bodyweight, once daily (weigh the dog to ensure accuracy of dosing).

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

EXP {mm/yyyy}

**9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C. Keep the blister strips in the outer carton.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Ceva Santé Animale  
10, av. de La Ballastière  
Libourne  
33500  
France

**14. MARKETING AUTHORISATION NUMBERS**

Vm 14966/4000

**15. BATCH NUMBER**

Lot

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS (BLISTERS)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

SELGIAN 4 mg

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Selegiline hydrochloride, 4 mg (Selegiline (as hydrochloride) 3.35 mg)

**3. BATCH NUMBER**

Lot

**4. EXPIRY DATE**

Exp. {mm/yyyy}

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

### **PACKAGE LEAFLET**

#### **1. Name of the veterinary medicinal product**

Selgian 4 mg tablets

#### **2. Composition**

Each tablet contains:

##### **Active substances:**

(-) selegiline hydrochloride 4.00 mg

##### **Excipients:**

Titanium dioxide (E171) 0.7 mg

White, film-coated tablet with two cross-scored line on one side.

#### **3. Target species**

Dogs

#### **4. Indications for use**

- i) Treatment of behavioural disorders of purely emotional origin: depression, anxiety.
- ii) In association with behaviour therapy, treatment of signs of emotional origin observed in behavioural conditions such as overactivity, separation problems, generalised phobia and unsocial behaviour.

Emotional disorders are characterised by a modification of feeding, drinking, auto-stimulatory behaviour, sleep, exploratory behaviour, aggression related to fear and/or irritation, social behaviour and somatic disorders (tachycardia, emotional micturition...).

#### **5. Contraindications**

Owing to its IMAO properties, (-) selegiline hydrochloride may act on prolactin secretion. In the absence of specific studies, it is recommended that the product should not be administered to pregnant and lactating bitches.

Do not administer the product from the day before until the day after anaesthesia or tranquillisation performed with an alpha-2 agonist.

Do not administer the product concomitantly with pethidine, fluoxetine or phenothiazines.

The narcotic action of morphine is potentiated by the product.

#### **6. Special warnings**

If no clinical improvement is observed after 2 months, continuing the treatment is not likely to provide any additional benefit.

It is advisable to weigh animals before dosing to ensure the correct mg/kg dosage is administered.

#### Special precautions for safe use in the target species

Emotional disorders can mask hierarchical conflicts. In dominant dogs suffering from an emotional disorder, the alleviation of the disorder can sometimes reveal a latent aggressiveness. In such cases, behavioural therapy must be instituted.

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

In the event of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

#### Pregnancy and lactation:

It is recommended to stop the treatment during pregnancy and lactation.

#### Interaction with other medicinal products and other forms of interaction:

Do not administer the product from the day before until the day after an anaesthesia or tranquillisation performed with an alpha-2 agonist.

Do not administer the product concomitantly with pethidine, fluoxetine or phenothiazines. The narcotic action of morphine is potentiated by the product.

#### Overdose:

Unlikely to occur.

## **7. Adverse events**

#### Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Behavioural disorders <sup>1</sup>
--	------------------------------------

<sup>1</sup> Trials have shown that some dominant dogs, with behavioural disorders but no signs of aggression, may become aggressive after treatment. Those previously showing aggression may have this enhanced. Appropriate training is essential in such cases.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

## 8. Dosage for each species, routes

For oral administration to dogs. The dose rate is 0.5 mg of (-) selegiline hydrochloride per kg body weight once daily. This is equivalent to:

Dog weight in kg	Number of tablets Selgian 4mg
≥1.5 < 3	1/4
≥3 < 5	1/2
≥5 < 7	3/4
≥7 < 9	1
≥9 < 11	1 1/4
≥11 < 13	1 1/2
≥13 < 15	1 3/4
≥15 < 17	2

For dogs weighing more than 17 kg, the use of Selgian 10 mg is advisable in order to reduce the number of tablets to be administered.

The treatment should be continued until the clinical condition is stable, when treatment must cease.

The minimum treatment period recommended is 2 months, based on the clinical trials results:

- The treatment period was 2 to 3 months for 20 % of the dogs
- The treatment period was 4 to 5 months for 50 % of the dogs
- The treatment period was 6 to 7 months for 20 % of the dogs
- The treatment period was > 7 months for 10 % of the dogs

If no clinical improvement is observed after two months, further dosing is not indicated. The treatment must be stopped suddenly without gradual dose reductions.

## 9. Advice on correct administration

Weight the dog before starting a course of therapy to ensure accuracy of dosing.

## 10. Withdrawal periods

Not applicable

## 11. Special storage precautions

Do not store above 25°C.

The tablets are divisible into quarters. Tablet portions can be kept for 4 days in the

blister packs.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 14966/4000

Selgian 4 mg:

Pack of 3 blisters of 10 tablets or

Pack of 5 blisters of 10 tablets or

Pack of 10 blisters of 10 tablets or

Pack of 50 blisters of 10 tablets

Not all pack sizes may be marketed.

## **15. 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](http://www.gov.uk).

## **16. Contact details**

Marketing Authorisation Holder:

Ceva Santé Animale  
10 av. de La Ballastière  
Libourne  
33500  
France

Local representative and contact details to report suspected adverse reactions:

Ceva Animal Health Ltd  
Explorer House  
Mercury Park  
Wycombe Lane  
Wooburn Green  
High Wycombe  
Buckinghamshire  
HP10 0HH  
United Kingdom  
Tel: 00800 35 22 11 51  
Email for the reporting of adverse events: [pharmacovigilance@ceva.com](mailto:pharmacovigilance@ceva.com)

Manufacturer responsible for batch release:

Ceva Santé Animale, ZI Très le Bois, 22 600 Loudeac, France

**17. Other information**

**Pharmacodynamics:**

(-) Selegiline hydrochloride has the following properties:

\* Inhibitor of monoamine oxidase (MAO-B) at the therapeutic dose in the dog; thus it modifies the concentrations of monoaminergic neurotransmitters.

**Pharmacokinetics:**

(-) Selegiline hydrochloride is quickly absorbed after oral administration. The oral bioavailability ranges from 65 to 95% in the dog. Selegiline binds rapidly and durably onto the specific cerebral receptors. The duration of the pharmacological effect following such binding is independent of the maintenance of blood levels. Selegiline is quickly metabolised into desmethylselegiline, 1-amphetamine and 1-metamphetamine. At the therapeutic dose recommended in the dog, these derivatives have no pharmacological activity.

POM-V
-------

 For animal treatment only

*Gavin Hall*

Approved: 17 December 2025