# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELGIAN 10 mg film-coated tablets

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
**Active substances:**
(-) selegiline hydrochloride 10.00 mg

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Titanium dioxide (E171) | 1.8 mg |
| Povidone K30 | |
| Maize starch | |
| Lactose monohydrate | |
| Microcrystalline cellulose | |
| Magnesium stearate | |
| Hydrochloric acid | |
| Hypromellose | |
| Macrogol stearate 40 | |
| Purified water | |

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

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dogs

### 3.2 Indications for use for each target species

- Treatment of behavioural disorders of purely emotional origin: depression, anxiety.

- In association with behaviour therapy, treatment of signs of emotional origin observed in behavioural conditions such as over activity, separation problems, generalised phobia and unsociable 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).

## 3.3 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.

## 3.4 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.

## 3.5 Special precautions for use

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.

Special precautions for the protection of the environment:

Not applicable.

## 3.6 Adverse events

Dogs:

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

[1] 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

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

### 3.8 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.

### 3.9 Administration routes and dosage

Oral route: 0.5 mg/kg/day of (–) selegiline hydrochloride in a single administration.

| Dog weight in kg | | Number of tablets |
|---|---|---|
| ≥8 | < 12 | ½ |
| ≥12 | < 17 | ¾ |
| ≥17 | < 22 | 1 |
| ≥22 | < 27 | 1 ¼ |
| ≥27 | < 32 | 1 ½ |
| ≥32 | < 37 | 1 ¾ |
| ≥37 | < 42 | 2 |

For dogs weighing more than 8 kg, use Selgian 4 mg.
The treatment should be continued until the clinical condition is stable.

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

The treatment can be stopped suddenly without gradual dose reductions.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Unlikely to occur.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Not applicable

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QN06AX90

### 4.2 Pharmacodynamics

(-) selegiline hydrochloride is an inhibitor of monoamine oxidase (IMAO-B) at the therapeutic dose in the dog; thus it modifies the concentration of monoaminergic neurotransmitters.

### 4.3 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 l-desmethylselegiline, l-amphetamine and l-metamphetamine. At the therapeutic dose recommended in the dog, these derivatives have no pharmacological activity.
Repeated administration of Selgian showed the absence of any cumulative effect after 91 days in the beagle dog.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Do not administer with other alpha-2 agonists.

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale in PVC aluminium blisters: 3 years
Shelf life after first opening the immediate packaging: 4 days

### 5.3 Special precautions for storage

Do not store above 25°C.
The tablets are divisible into quarters. Tablet portions can be kept for 4 days in the blister packs.

### 5.4 Nature and composition of immediate packaging

Nature of primary container
Polyvinylchloride film / Aluminium foil blister pack.

Models intended for sale
Box containing 3 blisters of 10 tablets
Box containing 5 blisters of 10 tablets
Box containing 10 blisters of 10 tablets
Box containing 50 blisters of 10 tablets

Not all pack sizes may be marketed.

### 5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale
10, av. de La Ballastiere
Libourne
33500
France

## 7. MARKETING AUTHORISATION NUMBER

Vm 14966/4001

## 8. DATE OF FIRST AUTHORISATION

22 July 1997

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

September 2025

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

*Gavin Hall*

Approved: 17 December 2025