

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selgian 8 KG Film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

3.35 mg selegiline equivalent to 4.00 mg selegiline hydrochloride.

Excipients:

Qualitative composition of excipients and other constituents
Povidone K30
Maize starch
Monohydrate lactose
Microcrystalline cellulose
Magnesium stearate
Hydrochloric acid, concentrated
Sepifilm

White film-coated tablet of 204.00 mg with two cross-scored lines 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, dysthymia, anxiety.
- In combination with behaviour therapy, treatment of disorders of emotional origin found in hypersensibility/hyperactivity, separation anxiety, deprivation syndrome and generalised phobia.

3.3 Contraindications

Owing to its MAOI properties, selegiline may act on prolactin secretion.
See section 3.7 "Use during pregnancy, lactation or lay".

3.4 Special warnings

The use of a dosage less than the recommended dosage may result in exacerbation of the dog's aggressiveness in case of latent hierarchy conflict. If no clinical improvement is observed after 2 months, it is useless to continue the treatment.

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
Not applicable.

Special precautions for the protection of the environment
Not applicable.

3.6 Adverse events

Dogs :

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Trembling Vomiting
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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 its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Do not use during the pregnancy and the lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

0.42 mg/kg/day of selegiline, corresponding to 0.5 mg/kg/day of selegiline hydrochloride in one administration in the morning to fasting dogs in accordance with the following table:

Dog weight in kg		Number of tablets
1.5 \leq	< 3	1/4
3 \leq	< 5	1/2
5 \leq	< 7	3/4
7 \leq	< 9	1
9 \leq	< 11	1 - 1/4
11 \leq	< 13	1 - 1/2
13 \leq	< 15	1 - 3/4
15 \leq	< 17	2

The minimum treatment period is 2 months.

The treatment must be continued until the clinical condition is stable, and it must be stopped suddenly without prior gradual weaning.

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

The administration of selegiline for one year at 2times the therapeutic dosage recommended in dogs did not induce any side effects.

The administration of the product at a dose equal to 5times the therapeutic dosage for three months is well tolerated, except vomiting and ptyalism observed sporadically in a few dogs that can be considered as the first overdosage symptoms.

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 ATC vet code: QN06AX90

4.2 Pharmacodynamics

Selegiline, a structural phenylethylamine analogue, is a monoamine oxidase inhibitor (MAOI). As a MAO-A and MAO-B inhibitor, it modifies the concentration of monoaminergic neurotransmitters (dopamine, serotonin, norepinephrine and epinephrine) and it has a neuroprotective action towards free radicals and neurotoxic substances.

4.3 Pharmacokinetics

Selegiline hydrochloride is quickly absorbed after oral administration. The oral bioavailability ranges from 65 to 95 % in 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, l-amphetamine and l-metamphetamine. At the therapeutic dose recommended in the dog, these derivatives have no pharmacological activity.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Do not store above 25°C.

5.4 Nature and composition of immediate packaging

Nature of primary container

PVC – Aluminium blister

Models intended for sale

Box containing 3 blisters of 10 tablets.

Box containing 10 blisters of 10 tablets.

Box containing 50 blisters of 10 tablets.

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 or household waste.

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 applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorization: {DD/MM/YYYY}

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

{mm/yyyy}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database. (<https://medicines.health.europa.eu/veterinary>).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box containing 30, 100 or 500 tablets.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELGIAN 8 KG Film-Coated Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains : 3.35 mg selegiline equivalent to 4.00 mg selegiline hydrochloride.

3. PACKAGE SIZE

30 tablets

100 tablets

500 tablets

4. TARGET SPECIES

Dogs.

5. INDICATION(S)**6. ROUTES OF ADMINISTRATION**

Oral use.

7. WITHDRAWAL PERIODS**8. EXPIRY DATE**

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

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 sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER



14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELGIAN 8 KG

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

4 mg of selegiline hydrochloride (selegiline (as hydrochloride) 3.35 mg)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Selgian 8 KG Film-Coated Tablets

2. Composition

Each tablet contains:

Active substance:

3.35 mg selegiline equivalent to 4.00 mg selegiline hydrochloride.

White film-coated tablet of 204.00 mg with two cross-scored lines on one side.

3. Target species

Dogs.

4. Indications for use

- Treatment of behavioural disorders of purely emotional origin: depression, dysthymia, anxiety.
- In combination with behaviour therapy, treatment of disorders of emotional origin found in hypersensitivity/hyperactivity, separation anxiety, deprivation syndrome and generalised phobia.

5. Contraindications

Owing to its MAOI properties, selegiline may act on prolactin secretion.
See section 6 "Pregnancy and lactation".

6. Special warnings

Special warnings:

The use of a dosage less than the recommended dosage may result in exacerbation of the dog's aggressiveness in case of latent hierarchy conflict. If no clinical improvement is observed after 2 months, it is useless to continue the treatment.

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:

Not applicable.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.
Do not use during the pregnancy and the lactation.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

The administration of selegiline for one year at 2times the therapeutic dosage recommended in dogs did not induce any side effects.

The administration of the product at a dose equal to 5times the therapeutic dosage for three months is well tolerated, except vomiting and ptyalism observed sporadically in a few dogs that can be considered as the first overdosage symptoms.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Trembling
Vomiting

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.

8. Dosage for each species, routes and method of administration

0.42 mg/kg/day of selegiline, corresponding to 0.5 mg/kg/day of selegiline hydrochloride in one administration in the morning to fasting dogs in accordance with the following table:

Dog weight in kg		Number of tablets Selgian 4mg
≥1.5	< 3	¼
≥3	< 5	½
≥5	< 7	¾
≥7	< 9	1
≥9	< 11	1 ¼
≥11	< 13	1 ½
≥13	< 15	1 ¾
≥15	< 17	2

The minimum treatment period is 2 months.

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.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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 or pharmacist 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

(MA)

Pack sizes:

Box containing 3 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

15. Date on which the package leaflet was last revised

{mm/yyyy}

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

(Name and address to be completed nationally)

Tel: +800 35 22 11 51

Email: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:

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

Ceva Santé Animale, Boulevard de la communication, Zone autoroutière, 53950 Louvern , France