

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selgian 40 KG Film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains :

Active substance:

16.74 mg selegiline equivalent to 20.00 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 1020.00 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 hypersensitivity/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

In case of accidental ingestion, seek medical advice and show the package insert or the label to the physician.

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

Not 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
≥ 26 and < 36	3/4
≥ 36 and < 46	1
≥ 46 and < 56	1 - 1/4
≥ 56 and < 66	1 - 1/2
≥ 66 and < 76	1 - 3/4
≥ 76 and < 86	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 2 times the therapeutic dosage recommended in dogs did not induce any side effect.

The administration of the product at a dose equal to 5 times the therapeutic dosage for three months is well tolerated. The first overdosage symptoms are observed by ptialism and vomiting.

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 concentrations 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: 3 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Nature of primary container

- * thermoformed PVC-Aluminium blister

Model(s) intended for sale

- * Box containing 3 thermoformed blisters of 10 tablets divisible in four.
- * Box containing 5 thermoformed blisters of 10 tablets divisible in four.
- * Box containing 10 thermoformed blisters of 10 tablets divisible in four.
- * Box containing 50 thermoformed blisters of 10 tablets divisible in four.

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

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

VPA10815/062/003

8. DATE OF FIRST AUTHORISATION

22/11/2002

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

20/09/2024

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>).