

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selgian 20 KG Film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains :

Active substance:

8.37 mg selegiline equivalent to 10.00 mg selegiline hydrochloride.

Excipients:

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

White film-coated tablet of 510,00 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
8 \leq	< 12	1/2
12 \leq	< 17	3/4
17 \leq	< 22	1
22 \leq	< 27	1 - 1/4
27 \leq	< 32	1 - 1/2
32 \leq	< 37	1 - 3/4
37 \leq	< 42	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, excepted 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 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: 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 authorisation: {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>).