Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Selgian 20 kg, Film coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

For a 510 mg tablet
Active substance:
Selegiline (as hydrochloride) 8.37 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs (from 8 kg to 42 kg)

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Owing to its MAOI properties, selegiline may act on prolactin secretion. For want of specific studies, the product should not be administered to pregnant and lactating bitches.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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

None.

4.6 Adverse reactions (frequency and seriousness)

In very rare occasions (less than 1 animal out of 100,000), undesirable effects as trembling or vomiting may occur in treated animals

4.7 Use during pregnancy, lactation or lay

See contra-indications.

4.8 Interaction with other medicinal products and other forms of interactions

None reported to date.

4.9 Amounts to be administered and administration route

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 ≤ < 12	1/2
12 ≤ < 17	3/4
17 ≤ < 22	1
22 ≤ < 27	1 - 1/4
27 ≤ < 32	1 - 1/2
32 ≤ < 37	1 - 3/4
37 ≤ < 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 with prior gradual weaning.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: antidepressant
ATC vet classification: QN06AX90

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone
Maize starch
Lactose
Cellulose
Magnesium stearate
Hydrochloric acidSepifilm

6.2 Major incompatibilities

None reported to date.

6.3 Shelf-life

2 years.

6.4 Special precautions for storage

None.

6.5 Nature and composition of immediate packaging

Nature of primary container

PVC – Aluminium blister
Glass vial

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
Box containing 1 vial of 30 tablets
Box containing 1 vial of 100 tablets

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

None.

7 MARKETING AUTHORISATION HOLDER

Ceva Santé Animale
10, avenue de La Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10815/062/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 September 1997
Date of last renewal: 05 July 2006

10 DATE OF REVISION OF THE TEXT

April 2019