SUMMARY OF PRODUCT CHARACTERISTICS

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
Microcystalline cellulose
Magnesium stearate
Hydrocloric 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 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
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

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 apllicable, 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 ptyalism 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

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 BOX

Cardboard box containing 30, 50, 100 or 500 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELGIAN 40 KG Film-Coated Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablets contains : 16.74 mg selegiline equivalent to 20.00 mg selegiline hydrochloride.

3. PACKAGE SIZE

30 tablets
50 tablets
100 tablets
500 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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 40 KG

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

20 mg of selegiline hydrochloride (selegiline (as hydrochloride) 16.74 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 40 KG Film-Coated Tablets

2. Composition

Each tablet contains :
Active substance : 16.74 mg selegiline equivalent to 20.00 mg selegiline hydrochloride.

White film-coated tablet of 1020.00 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 hypersensibility/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 lacatation”.

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

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

Interaction with other medicinal products and other forms of interaction:
Not known.

Overdose:
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 ptyalism and vomiting.

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 20 mg
≥ 26 < 36	¾
≥ 36 < 46	1
≥ 46 < 56	1¼
≥ 56 < 66	1½
≥ 66 < 76	1¾
≥ 76 < 86	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

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

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 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.

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).

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