PARTICULARS TO APPEAR ON THE OUTER BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELGIAN 10 mg Film-Coated tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

(-) Selegiline hydrochloride, 10 mg per tablet

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

3 x 10 tablets (pictogram of a tablet)
or 5 x 10 tablets (pictogram of a tablet) or 10 x 10 tablets (pictogram of a tablet) or 50 x 10 tablets (pictogram of a tablet)

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For the treatment of behavioural disorders of emotional origin including anxiety, depression, unsociable behaviour, hyperactivity and phobias.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

One tablet orally per 20 kg bodyweight, once daily (weigh the dog to ensure accuracy of dosing).

8. SPECIAL WARNING(S), IF NECESSARY

Do not administer to pregnant or suckling bitches. For full details of dosage administrations, precautions and disposal advice see package leaflet.

9. EXPIRY DATE

Exp:

10. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep the blister strips in the outer carton.

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR MATERIALS, IF ANY

See package leaflet.

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription. For animal treatment only.

13. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale, 10, av. de La Ballastière, Libourne, 33500, France

15. MARKETING AUTHORISATION NUMBERS

Vm 14966/4001
Vm 14966/4000
Vm 14966/4004

16. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SELGIAN 10 mg

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Selegiline hydrochloride, 10 mg

(Selegiline (as hydrochloride) 8.37

mg)

3. PHARMACEUTICAL FORM

Tablets for dogs

4. BATCH NUMBER

5. EXPIRY DATE

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PACKAGE LEAFLET

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:

Ceva Santé Animale, 10, av. de La Ballastière, Libourne, 33500, France

Marketed by:

Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom

Manufacturer responsible for batch release:

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

Ceva Sante Animale, Boulevard de la communication, Zone autoroutière, 53950 Louverné, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Selgian 10 mg tablets for veterinary use

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

(-) Selegiline hydrochloride: 10mg per tablet.

4. INDICATION(S)

i) Treatment of behavioural disorders of purely emotional origin: depression, anxiety.
ii) In association with behaviour therapy, treatment of signs of emotional origin observed in behavioural conditions such as overactivity, separation problems, generalised phobia and unsocial behaviour.
Emotional disorders are characterised by a modification of feeding, drinking, auto-stimulatory behaviour, sleep, exploratory behaviour, aggression related to fear and/or irritation, social behaviour and somatic disorders (tachycardia, emotional micturition...).

5. CONTRAINDICATIONS

1. Owing to its IMAO properties, (–) selegiline hydrochloride may act on prolactin secretion. In the absence of specific studies, it is recommended that the product should not be administered to pregnant and lactating bitches.
2. Do not administer Selgian from the day before until the day after anaesthesia

or tranquillisation performed with an alpha-2 agonist.
3. Do not administer Selgian concomitantly with pethidine, fluoxetine or phenothiazines.
The narcotic action of morphine is potentiated by the product.

6. ADVERSE REACTIONS

Trials have shown that some dominant dogs, with behavioural disorders but no signs of aggression, may become aggressive after treatment. Those previously showing aggression may have this enhanced. Appropriate training is essential in such cases. At the dosage recommended, secondary effects have not been observed in the majority of animals.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration to dogs. The dose rate is 0.5 mg of (-) selegiline hydrochloride per kg body weight once daily. This is equivalent to:

Dog weight in kg		Number of tablets Selgian 10mg
≥8	< 12	½
≥12	< 17	¾
≥17	< 22	1
≥22	< 27	1 ¼
≥27	< 32	1 ½
≥32	< 37	1 ¾
≥37	< 42	2

For dogs weighing more than 17 kg the use of Selgian 10 mg, or Selgian 20 mg is advisable in order to reduce the number of tablets to be administered.
For dogs weighing less than 8 kg, use Selgian 4 mg.
The treatment should be continued until the clinical condition is stable, when treatment must cease.
The minimum treatment period recommended is 2 months, based on the clinical trials results:

4 The treatment period was 2 to 3 months for 20 % of the dogs
5 The treatment period was 4 to 5 months for 50 % of the dogs
6 The treatment period was 6 to 7 months for 20 % of the dogs

7 The treatment period was > 7 months for 10 % of the dogs

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. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

11. SPECIAL WARNING(S)

Keep out of reach of children.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

14. OTHER INFORMATION

a. Pharmacodynamics:

(-) Selegiline hydrochloride has the following properties:
* Inhibitor of monoamine oxidase (IMAO-B) at the therapeutic dose in the dog; thus it modifies the concentrations of monoaminergic neurotransmitters.

b. Pharmacokinetics:

(-) Selegiline hydrochloride is quickly absorbed after oral administration. The oral bioavailability ranges from 65 to 95% in the 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, 1-amphetamine and 1-metamphetamine. At the therapeutic dose recommended in the dog, these derivatives have no pharmacological activity.

Presentations: Selgian 10 mg: Pack of 3 blisters of 10 tablets or Pack of 10 blisters of 10 tablets

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Vm 14966/4004

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Approved 30 July 2025
Gavin Hall