

NOAH Compendium

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Selgian® 4 mg, 10 mg, 20 mg film-coated tablets

Species:Dogs

Therapeutic indication:Pharmaceuticals: Neurological preparations: Others

Active ingredient:Selegiline Hydrochloride

Product:Selgian® 4 mg, 10 mg, 20 mg film-coated tablets

Product index:Selgian

Incorporating:

Qualitative and quantitative composition

Active ingredients:

per tablet

(-) selegiline hydrochloride 4.00 mg / 10.00 mg / 20.00 mg

Excipients:

Titanium dioxide (E171) 0.7 mg / 1.8 mg / 3.6 mg

For a full list of excipients, see Pharmaceutical particulars.

Pharmaceutical form

White, film-coated tablet with two cross-scored line on one side.

Clinical particulars

Target species

Dogs.

Indications for use

1Treatment of behavioural disorders of purely emotional origin: depression, anxiety.

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2In association with behaviour therapy, treatment of signs of emotional origin observed in behavioural conditions such as over activity, separation problems, generalised phobia and unsociable 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)

Contraindications

1Owing 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.

2Do not administer the product from the day before until the day after anaesthesia or tranquillisation performed with an alpha-2 agonist.

3Do not administer the product concomitantly with pethidine, fluoxetine or phenothiazines.

4The narcotic action of morphine is potentiated by the product.

Special warnings for each target species

If no clinical improvement is observed after 2 months, continuing the treatment is not likely to provide any additional benefit.

It is advisable to weigh animals before dosing to ensure the correct mg/kg dosage is administered.

Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

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 medicinal product to animals:

In the event of accidental ingestion, seek medical advice and show the doctor the package leaflet.

Wash hands after use.

Adverse reactions (frequency and seriousness)

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.

Use during pregnancy, lactation or lay

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It is recommend to stop the treatment during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction

1Do not administer the product from the day before until the day after an anaesthesia or tranquillisation performed with an alpha-2 agonist.

2Do not administer the product concomitantly with pethidine, fluoxetine or phenothiazines.

3The narcotic action of morphine is potentiated by the product.

Amounts to be administered and administration route

Selgian 4 mg:

Oral route: 0.5 mg/kg/day of (-) selegiline hydrochloride in a single administration.

Dog weight in kg	Number of tablets
$\geq 1.5 < 3$	$\frac{1}{4}$
$\geq 3 < 5$	$\frac{1}{2}$
$\geq 5 < 7$	$\frac{3}{4}$
$\geq 7 < 9$	1
$\geq 9 < 11$	$1\frac{1}{4}$
$\geq 11 < 13$	$1\frac{1}{2}$
$\geq 13 < 15$	$1\frac{3}{4}$
$\geq 15 < 17$	2

Selgian 10 mg:

Oral route: 0.5 mg/kg/day of (-) selegiline hydrochloride in a single administration.

Dog weight in kg	Number of tablets
$\geq 8 < 12$	$\frac{1}{2}$
$\geq 12 < 17$	$\frac{3}{4}$
$\geq 17 < 22$	1
$\geq 22 < 27$	$1\frac{1}{4}$
$\geq 27 < 32$	$1\frac{1}{2}$
$\geq 32 < 37$	$1\frac{3}{4}$
$\geq 37 < 42$	2

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Selgian 20 mg:

Route of administration: Oral use.

According to the dosage the tablet can be divided into 4.

0.42 mg/kg/day of selegiline, corresponding to 0.5 mg/kg/day selegiline hydrochloride (1 film-coated tablet 20 mg per 40 kg BW) in a single administration in the morning to fasting dogs.

Dog weight in kg	Number of tablets
≥ 26 < 36	$\frac{3}{4}$
≥ 36 < 46	1
≥ 46 < 56	$1\frac{1}{4}$
≥ 56 < 66	$1\frac{1}{2}$
≥ 66 < 76	$1\frac{3}{4}$
≥ 76 < 86	2

The treatment should be continued until the clinical condition is stable.

The minimum treatment period recommended is 2 months, based on the clinical trials results:

- The treatment period was 2 to 3 months for 20% of the dogs
- The treatment period was 4 to 5 months for 50% of the dogs
- The treatment period was 6 to 7 months for 20% of the dogs
- The treatment period was > 7 months for 10% of the dogs

The treatment can be stopped suddenly without gradual dose reductions.

Overdose (Symptoms, emergency procedures, antidotes)

Unlikely to occur.

Withdrawal periods

Not applicable.

Pharmacological particulars

Therapeutic group: Nervous system. ATC Vet Code: QN06AX90

Pharmacodynamic properties

(-) selegiline hydrochloride is an inhibitor of monoamine oxidase (MAO-B) at the therapeutic dose in the dog; thus it modifies the concentration of monoaminergic neurotransmitters.

Pharmacokinetic properties:

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(–) 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 l-desmethylselegiline, l-amphetamine and l-metamphetamine. At the therapeutic dose recommended in the dog, these derivatives have no pharmacological activity.

Repeated administration of Selgian showed the absence of any cumulative effect after 91 days in the beagle dog.

Pharmaceutical particulars

List of excipients

Titanium dioxide, Povidone K30, Maize starch, Lactose monohydrate, Microcrystalline cellulose, Magnesium stearate, Hydrochloric acid, Hypromellose, Cellulose microcrystalline, Macrogol stearate 40, Purified water

Major incompatibilities

Do not administer with other alpha-2 agonists.

Shelf-life

4mg: Shelf life of the veterinary medicinal product as packaged for sale: 5 years. Shelf life after opening the immediate packaging: 4 days

10mg: Shelf life of the veterinary medicinal product as packaged for sale in PVC/aluminium blister: 3 years. Shelf life after opening the immediate packaging: 4 days

20mg: Shelf life of the veterinary medicinal product as packaged for sale: 5 years. Shelf life after opening immediate packaging: 4 days

Special precautions for storage

Do not store above 25°C.

The tablets are divisible into quarters. Tablet portions can be kept for 4 days in the blister packs.

Nature and contents of container

Nature of primary container:

Polyvinylchloride film / Aluminium foil blister pack.

Models intended for sale:

Box containing 3 blisters of 10 tablets; Box containing 5 blisters of 10 tablets; Box containing 10 blisters of 10 tablets; Box containing 50 blisters of 10 tablets.

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Not all pack sizes may be marketed.

Special precautions for the disposal of unused medicinal 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.

Marketing Authorisation Holder (if different from distributor)

CEVA SANTE ANIMALE

Z.I de la Ballastière BP 126

33501 Libourne CEDEX France

Marketing Authorisation Number

UK: Vm 14966/4000, 4001 and 4004

Significant changes

Date of the first authorisation or date of renewal

Selgian 4mg & 20mg: 26 October 2006

Selgian 10mg: 22 July 1997

Date of revision of the text

June 2023

Any other information

Nil

Legal category

Legal category:POM-V

GTIN

GTIN description:Selgian 4 mg 3x10T

GTIN:03411110007815

GTIN description:Selgian 10 mg 3x10T

GTIN:03411110007778

GTIN description:Selgian 20 mg 3x10T

GTIN:03411110045831