Animalcare Limited

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Clevor 30 mg/ml eye drops, solution in single-dose container for dogs

Species: Dogs

Therapeutic indication:Pharmaceuticals: Miscellaneous, **Pharmaceuticals: Neurological preparations:** Others

Product: Clevor 30 mg/ml eye drops, solution in single-dose container for dogs

Product index: Clevor 30mg/ml eye drops, solution in single-dose container for dogs

Incorporating: Ropinirole (ropinirol) 30 mg (equivalent to 34.2 mg ropinirole hydrochloride)

Qualitative and quantitative composition

Each ml of solution contains:

Active substance:

Ropinirole (ropinirol) 30 mg (equivalent to 34.2 mg ropinirole hydrochloride)

Excipients

Citric acid monohydrate,

Sodium citrate

Sodium chloride

Sodium hydroxide (to adjust pH)

Hydrochloric acid (to adjust pH)

Water for injections

Pharmaceutical form

Eye drops solution in single-dose container.

Very slightly yellow to yellow clear solution. pH 3.8–4.5 and osmolality 300–400 mOsm/kg.

NOAH Compendium

Clinical particulars

Target species

Dogs

Indications for use

Induction of vomiting in dogs.

Contraindications

Do not use in dogs with depression of the central nervous system, seizures or other marked neurologic impairments that could lead to aspiration pneumonia.

Do not use in dogs which are hypoxic, dyspnoeic or lacking pharyngeal reflexes.

Do not use in cases of the ingestion of sharp foreign objects, corrosive agents (acids or alkalis), volatile substances or organic solvents.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Amounts to be administered and administration route

Ocular use.

The veterinary medicinal product should only be administered by a veterinarian or under their close supervision.

The product is to be administered into the eye, at a dose of 1–8 eye drops. The volume of one drop is approximately 27 µl.

Each eye drop contains 810 µg of ropinirole. The dose is equivalent to 2–15 µl/kg bw in dogs. The number of eye drops in each body weight group corresponds to the target dose of 3.75 mg/m2 body surface area (dose range 2.7– 5.4 mg/m2) . These doses have been tested in dogs weighing between 1.8 kg and 100 kg (0.15–2.21 m2 body surface area).

When a quantity of 2 to 4 drops is to be administered, the dose should be divided between both eyes. For example, for the administration of 3 drops: administer 2 drops into the right eye and 1 drop into the left eye. When a quantity of 6 or 8 drops is to be administered, the dose should be divided into 2 alternate administrations given 1–2 minutes apart. For example, for the administration of 6 drops: administer 2 drops into the right eye and 2 drops into the left eye, then after 1–2 minutes pause administer a further 1 drop into each eye.

If the dog does not vomit within 15 minutes after administration of the initial dose a second dose may be given 15 to 20 minutes after administration of the initial dose. The second dose should be the same number of drops as the initial dose.

It is recommended to record the time of first administration.

Be careful not to touch the dropper tip after opening the container in case a second dose is necessary.

Instructions for use

OPENING THE CONTAINER: Open the container by twisting off the tail. Be careful not to touch the dropper tip after opening the container.

ADMINISTRATION: Keep the dog's head steady in a slightly upright position. Hold the container in an upright position without touching the eye. Rest your little finger on the forehead of the dog to maintain the distance between the container and the eye. Squeeze the prescribed number of drops into the eye(s).

STORING THE OPENED CONTAINER: After opening place the container back into the pouch in case a second dose is necessary.

REPEATED DOSE: In case the dog does not vomit within 15 minutes after the initial administration, a second dose can be given 15 to 20 minutes after administration of the initial dose. The additional dose should be the same as the initial dose.

Pharmacological particulars

Pharmacodynamic properties

Ropinirole is a full dopamine agonist with high selectivity for the dopamine D2-like receptor family (D2, D3 and D4 receptors). It induces emesis by activating the D2-like receptors in the chemoreceptor trigger zone, located in the area postrema, which transmits the information to the emesis centre to trigger vomiting.

In a clinical field trial including 100 clinically healthy dogs treated with Clevor, the time from administration to first vomit was 3–37 minutes with a mean time of 12 minutes and median time of 10 minutes. The time between the first to the last vomit was 0–108 minutes (0 if the dog vomited only once) with a mean duration of 23 minutes and a median duration of 16 minutes. Within 30 minutes 95% of the dogs vomited. An additional dose was administered after 20 minutes to 13% of the dogs because of lack of efficacy. Three dogs (3%) did not vomit at all despite an additional dose. 5% of the dogs in the clinical study received anti-emetic treatment (metoclopramide) because their vomiting persisted for more than 60 minutes.

Pharmacokinetic particulars

Absorption

Ropinirole is rapidly absorbed into the systemic circulation of dogs after administration as a solution on their eye surface. At the target dose of 3.75 mg/m^2 (equivalent to 2–15 µl/kg bw), a peak plasma concentration (Cmax) of 26 ng/ml is reached 10 to 20 minutes (tmax) after administration. The systemic bioavailability of the drug by this ocular route of administration is 23%. Vomiting starts before the Cmax in plasma is reached; at 4–6 minutes in a pharmacokinetic study in dogs. No direct correlation between ropinirole concentration in plasma and the duration of vomiting was observed

after ocular administration. The time to last vomit ranged from 30 to 82 minutes following ocular administration in a pharmacokinetic study in dogs.

Distribution

Ropinirole is rapidly distributed and has a relatively high apparent volume of distribution. In dogs, the volume of distribution (Vz) is 5.6 l/kg after intravenous administration. The fraction bound to plasma proteins in dogs is low (37%).

Elimination

Ropinirole is mainly eliminated by hepatic metabolism. The half-life of elimination (t½) is 4 hours after intravenous administration to dogs. Biotransformation occurs by dealkylation, hydroxylation and subsequent conjugation with glucuronic acid or oxidation to carboxylic acid. About 40% of radioactive ropinirole is excreted in the urine within 24 hours after intravenous administration to dogs. Excretion in the urine occurs mainly as metabolites. The portion recovered as unchanged ropinirole in the urine is below 3% within the first 24 hours.

Pharmaceutical particulars

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

Shelf life after first opening the immediate packaging (pouch and container): 30 minutes.

Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions. Store the container in the pouch in order to protect from light. After opening the pouch, the container should be kept in the pouch to protect from light. Discard any opened individual pouch or container with any remaining liquid after 30 minutes.

Nature and composition of immediate packaging

Low density polyethylene plastic single-dose container containing 0.6 ml. Each plastic container is packed in an individual aluminium foil laminate pouch. The pouch/pouches are then packed in a cardboard box together with the same number of package leaflets (intended for the animal owners) as the number of single-dose containers in the outer package.

Special precautions for the disposal of unused veterinary medicinal product

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)

Orion Corporation

Orionintie 1

FI-02200 Espoo

FINLAND

Marketing Authorisation Number

VM 06043/5000 (GB)

EU/2/17/222/001-008 (NI - EPAR)

Significant changes

Date of the first authorisation or date of renewal

13/04/2018

Date of revision of the text

Any other information

Legal category

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