# **TRIAMCOL<sup>®</sup>** Injectable solution

#### ANALGESIC



Triamcol<sup>®</sup>, Tramadol Hydrochloride 5%, Injectable solution, is indicated as an analgesic in the management of acute pain of low to severe intensity that accompanies colic in horses.

# **Technical Specification**

SPECIES

# Horses.

DOSAGE FORM

# Injectable solution.

THERAPEUTIC ACTION

Analgesic

COMPOSITION

Each 1 mL of product contains: Tramadol Hydrochloride ...... 50 mg (Equivalent to 43.9 mg of Tramadol base) Excipients q.s.p ...... 1 mL

# PROPERTIES

Tramadol Hydrochloride is a synthetic opioid agonist that acts primarily through binding to  $\mu$  receptors, in addition to inhibiting the reuptake of the monoamines serotonin and norepinephrine. It is from the two mechanisms mentioned above that the sensation of pain is inhibited at the central level, causing a powerful analgesia (antinociception) and a moderate anxiolytic effect.

# INDICATIONS

Triamcol<sup>®</sup>, Tramadol Hydrochloride 5%, Injectable solution, is indicated as an analgesic in the management of acute pain of low to severe intensity that accompanies colic in horses.

ROUTE OD ADMINISTRATION AND DOSAGE

# Dose of the active principle:

2 mg of Tramadol Hydrochloride / Kg of body weight.

# **Product dosage:**

4 mL / 100 Kg of body weight.

Routes and forms of administration: Intravenous administration.

The administration of the product should be slow (in 5 to 10 minutes) to minimize possible side effects.

# CONTRAINDICATIONS

- Do not administer to horses with known hypersensitivity to Tramadol.
- Do not administer to pregnant or lactating females.
- Do not administer in conjunction with Monoamine Oxidase Inhibitors (MAOIs) such as Selegiline and Isoniazid; Selective Serotonin Reuptake Inhibitors (SSRIs) such as Fluoxetine and Paroxetine; SSRIs and norepinephrine reuptake inhibitors such as Clomipramine; Serotonin antagonists such as Cyproheptadine; Noradrenaline antagonists such as Prazosin; Noradrenaline agonists such as Clonidine.

# PRECAUTIONS

It is recommended not to use in animals with a history of seizures.

# SPECIAL PRECAUTIONS FOR THE OPERATOR

During the handling and application of the product, the use of gloves is recommended. In the case of accidental ingestion, contact or injection it is recommended:

- **First aid:** Persons who develop serious hypersensitivity (anaphylactic) reactions should receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
- **Risk of contact with the skin:** In the event of contact with the skin, it is recommended to wash immediately with plenty of water and soap. In the event of any type of irritation, it is recommended to see a doctor.
- **Risk of contact with the eyes:** In the event of contact with the eyes, it is recommended to wash immediately with plenty of water for approximately 15 minutes. In the event of any type of irritation, it is recommended to see a doctor.
- **Ingestion risk:** In the case of accidental ingestion, it is recommended to rinse the mouth with plenty of water. Do not induce vomiting unless directed by a doctor. It is recommended to go to a healthcare center promptly.

# WARNINGS

Keep out of the reach of children.

# SIDE EFFECTS

In horses, nausea, salivation and tremors may be observed during intravenous administration of Tramadol Hydrochloride. These effects disappear if the administration by this route is done slowly (in 5 to 10 minutes). After intravenous administration, an increase in systolic blood pressure and tachycardia could occur in more sensitive individuals, which should remit within 30 to 60 minutes after administration.

# GUARD PERIOD

Do not administer to horses whose meat is intended for human consumption.

# Special precautions for disposal of unused product or waste material:

Any unused medicine or the waste derived from it must be disposed of in an environmentally safe way and in accordance with local regulations. Empty containers or containers with the product should not be disposed of on the ground or in water courses.

These materials must be disposed of by authorized companies to perform said service safely.

#### CONSERVATION

Keep in a dry place, at a temperature between 2 and 30° C, protected from light.

CONDITION OF SALE

Sale with retained Veterinary Medical prescription.

PRESENTATION

50 mL vial

PREPARED BY

Laboratorio Drag Pharma Chile Invetec S.A.

RECORDS

Chile: Reg. SAG N° 2169

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