# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**OUTER CARTON**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recudon 5.0 mg/ml + 0.25 mg/ml solution for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

| | |
|---|---|
| Levomethadone hydrochloride | 5.0 mg/ml |
| Fenpipramide hydrochloride | 0.25 mg/ml |

## 3. PACKAGE SIZE

5 ml
10 ml
30 ml
50 ml

## 4. TARGET SPECIES

Horses and dogs

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Slow intravenous use

## 7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 3 days
Milk: Not authorised for use in horses producing milk for human consumption.

## 8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

## 9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

## 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 the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

## 14. MARKETING AUTHORISATION NUMBERS

Vm 36408/3018

## 15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Glass vials of 5 mL, 10 mL, 30 mL or 50 mL**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recudon

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

| | |
|---|---|
| Levomethadone hydrochloride | 5.0 mg/ml |
| Fenpipramide hydrochloride | 0.25 mg/ml |

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Recudon 5 mg/ml + 0.25 mg/ml solution for injection for horses and dogs

## 2. Composition

Each ml contains:

**Active substances:**
4.4 mg Levomethadone equivalent to 5 mg levomethadone hydrochloride
0.22 mg Fenpipramide equivalent to 0.25 mg fenpipramide hydrochloride

**Excipients:**
Methyl parahydroxybenzoate (E218) 1.0 mg

Clear colourless solution for injection, practically free from visible particles.

## 3. Target species

Horses and dogs

## 4. Indications for use

Analgesia and premedication before procedures.

## 5. Contraindications

Do not use in animals with advanced respiratory failure.
Do not use in animals with severe liver or renal dysfunction.
Do not use in animals suffering from epileptic or strychnine seizures or tetanus.
Do not use in cases of known hypersensitivity to any of the active substances or excipients.

## 6. Special warnings

Special warnings:
Due to the variable individual response to levomethadone, animals should be monitored regularly to ensure sufficient efficacy for the desired duration of effect.
For methadone it has been described that Greyhounds may require higher doses than other breeds to achieve efficacious plasma levels. No corresponding information is available on the requirement for higher doses of specifically levomethadone in greyhounds, when compared to other breeds.

Special precautions for safe use in the target species:
It is recommended that dogs are fasted for 12 hours prior to administration of the veterinary medicinal product. In dogs, this veterinary medicinal product should be injected very slowly when used intravenously. Restlessness and howling of the

animals during the injection are signs of underdosing, so the injection should be continued.
Because the effects last for several hours, the animal should be protected from acoustic stimuli, and should be kept warm and dry until fully recovered.
Adequate oxygenation should be ensured during treatment, treated animals should be monitored regularly, including examination of heart rate and respiratory rate.
Use cautiously in animals with head injuries, as the effect of an opioid on head injury is dependent on the type and severity of the injury and the respiratory support supplied.
As methadone is metabolised by the liver, its intensity and duration of action may be affected in animals with impaired liver function.
In case of renal, cardiac or hepatic dysfunction, or shock, there may be greater risk associated with the use of the veterinary medicinal product.
It should be noted that antagonising the levomethadone component in the veterinary medicinal product can lead to an overhang by fenpipramide hydrochloride, which can lead to tachycardia, for more information see section on Overdose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Levomethadone is an opioid and can cause respiratory depression following accidental self-injection.
Prolonged dermal exposure may also cause adverse effects.
(Levo)Methadone may harm the unborn child. The veterinary medicinal product should not be administered by pregnant women.
Avoid skin, eye and mouth contact. In cases of spillage onto the skin, or splashing into the eyes, wash immediately with large amounts of water. Remove contaminated clothes.
People with known hypersensitivity to levomethadone and/or parabens should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician but DO NOT DRIVE as sedation may occur.

ADVICE TO DOCTORS: Levomethadone is an opioid whose toxicity may cause clinical effects including respiratory depression or apnoea, sedation, hypotension and coma. When respiratory depression occurs controlled ventilation should be initiated. Administration of the opioid antagonist naloxone to reverse the symptoms is recommended.

Pregnancy:
Levomethadone penetrates the placental barrier and can lead to respiratory depression in new-borns. Studies in laboratory animals have shown adverse effects on reproduction. The safety of the veterinary medicinal product has not been established during pregnancy. Use only according to the benefit/risk assessment by the responsible veterinarian.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
The veterinary medicinal product can potentiate the effects of analgesics, central nervous system inhibitors and substances that cause respiratory depression.
Concomitant or subsequent use of the veterinary medicinal product with buprenorphine may lead to lack of efficacy.
The effect of metoclopramide on accelerating gastric emptying is reduced.

Overdose:
Overdosage may produce profound respiratory and/or CNS depression.
Other side effects can include cardiovascular collapse, hypothermia, convulsions, and skeletal muscle hypotonia. Horses may demonstrate CNS excitability (hyperreflexia, tremors) and seizures at high doses or if given rapidly intravenously.
Mechanical respiratory support should be considered in cases of severe respiratory depression.
Naloxone hydrochloride can be used as an antagonist for levomethadone. It should be noted that antagonising the levomethadone component in the veterinary medicinal product can lead to an overhang by fenpipramide hydrochloride, which can lead to tachycardia. Naloxone is the agent of choice in treating respiratory depression. In massive overdoses, naloxone doses may need to be repeated. Animals should be closely observed since naloxone's effects might diminish before sub-toxic levels of levomethadone are attained.

Special restrictions for use and special conditions for use:
*[Information from SPC section 3.11 appropriate to the package leaflet.]*

## 7. Adverse events

Dogs:

| Frequency | Adverse event |
|---|---|
| Undetermined frequency (cannot be estimated from the available data) | Respiratory depression, Panting, Irregular breathing, Decreased body temperature, Bradycardia[1], Increased sensitivity to sound, Constipation, Vomiting. |

Horses:

| Frequency | Adverse event |
|---|---|
| Undetermined frequency (cannot be estimated from the available data) | Respiratory depression, Decreased body temperature, Bradycardia, Excitation[2], Constipation. |

[1] Only at high doses
[2] The presence or absence of pain influences the response to opioids. Horses in pain may show no adverse reactions to doses which would cause excitement in normal animals

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

## 8. Dosage for each species, routes and method of administration

The veterinary medicinal product is intended for:
- Horses: slow intravenous use
- Dogs: slow intravenous use

**Horses**
Analgesia
0.1-0.15 mg levomethadone-HCL / 0.005-0.0075 mg fenpipramide-HCL per kg bodyweight intravenously.
Corresponding to: Per 100 kg bodyweight: 2.0-3.0 ml veterinary medicinal product.

Use for premedication in combination with xylazine, romifidine or detomidine
The lower end of this dose-range should be used when the veterinary medicinal product is used in combination with one of these substances. Assessment of the combination to be used should be done by the treating veterinarian based on the purpose of treatment and the physical characteristics of the individual patient. All anaesthetics used for induction or maintenance of anaesthesia should be administered guided by effect.

**Dogs:**
Analgesia
0.2-1.0 mg mg levomethadone-HCL / 0.01-0.05 mg mg fenpipramide-HCL per kg bodyweight intravenously.
Corresponding to: Per 10 kg bodyweight: 0.4- 2.0 ml veterinary medicinal product.
Levomethadone is approximately twice as potent as the methadone racemate. The dosage should generally be half of the dose of methadone.

Doses higher than 0.5 mg levomethadone-HCL per kg should only be administered after thorough assessment of the severity of the pain, individual differences in pain sensitivity and the general condition of the dog.

Use for premedication in combination with xylazine, medetomidine or dexmedetomidine
The lower end of this dose-range should be used when the veterinary medicinal product is used in combination with one of these substances.
Assessment of the combination to be used should be done by the treating veterinarian based on the purpose of treatment and the physical characteristics of the individual patient. All anaesthetics used for induction or maintenance of anaesthesia should be administered guided by effect.

## 9. Advice on correct administration

Before administration the body weight should be accurately determined.
The total dose in dogs should not exceed 12.5 ml.
The vial can be broached up to 10 times. The user should choose the most appropriate vial size according to the target species to be treated.

## 10. Withdrawal periods

Meat and offal: 3 days
Milk: Not authorised for use in horses producing milk for human consumption.

## 11. Special storage precautions

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

## 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

Vm 36408/3018

Cardboard box with 1 vial of 5 ml, 10 ml, 30 ml or 50 ml.

## 15. Date on which the package leaflet was last revised

{DD month 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 manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Alfasan Nederland BV
Kuipersweg 9
3449 JA Woerden
The Netherlands.
Tel: +31 348 416945
e-mail: pharmacovigilance@alfasan.nl

*[For MRP/DCP/SRP and national procedures: To be completed nationally.]*

## 17. Other information

Information for the veterinarian:
Levomethadone is approximately twice as potent as the methadone racemate and they can generally be safely replaced by each other on a 2:1 ratio. Its analgesic action is comparable to that of morphine, accompanied by sedation, euphoria, respiratory depression and miosis. Levomethadone analgesic duration of action (as with morphine) varies from 4 to 6 hours. Other substance specific secondary effects include bradycardia, hypertension, constipation and antidiuresis and some effects (e.g. respiratory depression) may last longer than the analgesic effect. The pharmacological potency of levomethadone varies from species to species.

Fenpipramide is a parasympatholytic. By combining fenpipramide with levomethadone, the vagus effect of levomethadone is counteracted and thus the side effects of levomethadone are reduced: Spontaneous defecation, urination or excessive salivation are eliminated. Heart rate and pulse rates do not change. However, a decrease in temperature occurs, as well as slight respiratory depression.

In horses, the veterinary medicinal product causes pronounced sedation and analgesia, but usually no general anaesthesia. The effect is rapid when injected intravenously and manifests in a sawbuck-like posture and upheld tail. Walking often becomes unsteady. Combination with neuroleptics or tranquillizers intensifies the sedative-analgesic effect, but does not achieve anaesthesia on its own.

Approved 21 July 2023