Methadyne®

Injection

Active Constituents

10 mg/mL Methadone hydrochloride (8.90 mg/mL methadone)

Indications

For analgesia and premedication for general anaesthesia or neuroleptanalgesia in combination with a neuroleptic drug in dogs.

Dosage and Administration

Before administration, the body weight should be accurately determined.

Dogs: 0.55 mg Methadone HCl per kg bodyweight (0.055 mL/kg) by intravenous, intramuscular or subcutaneous injection*.
* Greyhounds may require higher doses than other breeds to achieve efficacious plasma levels.

When using for analgesia: The individual patient's response to methadone varies depending on the dosage, the age of the patient, individual differences in pain sensitivity and general condition. The optimal dosing regimen should be based on the individual patient. In dogs, onset of action is 1 hour following subcutaneous administration, approximately 15 minutes following intramuscular injection and within 10 minutes following intravenous injection. Duration of effect is approximately 4 hours following intramuscular or intravenous administration. The individual patient should be examined thoroughly and regularly to assess if additional analgesia is subsequently required and to ensure sufficient efficacy for the desired duration of effect.

Neuroleptanalgesia and use in combinations: Methadone HCl 0.55 mg/kg body weight, or a lower dose, may be used in combinations such as with:

- **Premedications** - midazolam, diazepam, acepromazine, medetomidine;
- **Non-steroidal anti-inflammatory drugs** such as meloxicam and carprofen;
- and prior to **general anaesthesia** with alfaxalone, propofol, thiopentone and isoflurane.

When using as neuroleptanalgesia and in combinations: Doses are dependent on the desired degree of analgesia and sedation, desired duration of effect and the concurrent use of other analgesics and anaesthetics. When used in combination with other products, a lower dosage of methadone hydrochloride can be used. For safe use with other veterinary medicinal products see dosage recommendations on this leaflet and make reference to the other relevant product literature.

Methadone HCl can be used **prior to total intravenous anaesthesia (TIVA).** TIVA protocol:

- Induction with alfaxalone /propofol
- Maintenance with alfaxalone / propofol

When using in TIVA protocols: Chemical-physical compatibility has only been demonstrated for dilutions 1:5 with the following solutions for infusion: sodium chloride 0.9%, Ringer's solution, and glucose 5%.

Contraindications

Do not use in known cases of hypersensitivity to the active substance.
Do not use in animals with advanced respiratory failure.
Do not use in animals with severe liver and renal dysfunction.

Warnings and Precautions

For veterinary use only

ADVERSE REACTIONS

In very common cases (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment), the following reactions have been observed after administration of the product:

Dogs: Respiratory depression and bradycardia may be seen. Mild reactions have been observed: panting, lip licking, salivation, vocalisation, irregular breathing, hypothermia, fixed stare and body tremors. Occasional urination and defaecation can be seen within the first hour post dose. All reactions were transient.

Special warning:
Methadone may occasionally cause respiratory depression and, as with other opioid drugs, care should be taken when treating animals with impaired respiratory function, or animals that are receiving drugs that can cause respiratory depression. To ensure safe use of the product, treated animals should be monitored regularly, including examination of heart rate and respiratory rate.
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 product.
The safety of methadone has not been demonstrated in dogs less than 8 weeks of age.
The effect of an opioid on head injury is dependent on the type and severity of the injury and the respiratory support supplied.
The benefit/risk ratio for using the product should be made by the attending veterinarian.

Pregnancy and lactation:
Methadone diffuses across the placenta.
Studies in laboratory animals have shown adverse effects on reproduction.
The safety of the product during pregnancy and lactation has not been assessed in the target species. The use of the product is not recommended during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:
For concurrent use with neuroleptics refer to the Directions for Use section.
Methadone 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 a lack of efficacy.

Overdose (symptoms, emergency procedures, antidotes):
Overdose may result in the effects described in the Adverse Reactions section.
Respiratory depression following overdose has been described in dogs.
Methadone can be antagonised by naloxone. Naloxone should be given to effect. A starting dose of 0.1 mg/kg intravenously is recommended.

Major Incompatibilities:

The product is incompatible with injection fluids containing meloxicam, or any other non-aqueous solution.
This product can be mixed in the same syringe with aqueous solutions for injection containing acepromazine as maleate and medetomidine and dexmedetomidine as hydrochlorides. Syringes with these mixtures should be used as soon as practicable. Any unused mixed solution remaining in the syringe should be disposed appropriately. This product may also be mixed with the infusion solutions indicated in the Dosage and Administration section.

In the absence of further compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Methadone can cause respiratory depression following spillage onto the skin or accidental self-injection. Avoid skin, eye and mouth contact, and wear impermeable gloves when handling the product. 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 methadone should avoid contact with the veterinary medicinal product. Methadone has the potential to cause stillbirths. Pregnant women are advised not to handle the product.
In the case of accidental self-injection, seek medical advice immediately and show the leaflet to the physician but DO NOT DRIVE as sedation may occur.
ADVICE TO DOCTORS: Methadone 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 installed. Administration of the opioid antagonist naloxone to reverse the symptoms is recommended.

First Aid

If poisoning occurs, contact a doctor or Poisons Information Centre. In New Zealand, phone 0800 POISON (0800 764 766).

Disposal

Dispose of empty container by wrapping with paper and putting in garbage.

Presentation

A clear, colourless aqueous injection in a 10 mL multi-dose amber vial.

Storage

Store below 30°C (room temperature). Discard unused portion 28 days after first broaching. Chemical and physical stability of the dilutions has been demonstrated for 4 hours at 25°C, protected from light. From a microbiological point of view the dilutions should be used immediately.

Classification

Controlled Drug (B3)

Registration Number

ACVM No. A011854

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