# buprecare®

## 0.3mg/ml Solution for Injection for Dogs and Cats

Buprenorphine (as buprenorphine hydrochloride)

## Statement of the active substances and other ingredients

Each ampoule contains:
**Active substance:** Buprenorphine 0.3mg/ml as buprenorphine hydrochloride.
Clear, colourless solution.

## Indications

**Dog:** Post-operative analgesia.
Potentiation of the sedative effects of centrally-acting agents.
**Cat:** Post-operative analgesia.

## Contraindications

The product should not be used pre-operatively for caesarean section.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

## Adverse reactions

Salivation, bradycardia, hypothermia, agitation, dehydration and miosis can occur in the dog, and rarely hypertension and tachycardia.
Mydriasis and signs of euphoria (excessive purring, pacing, rubbing) commonly occur in cats, and will usually resolve within 24 hours.
Buprenorphine may occasionally cause significant respiratory depression; care should be taken in animals with impaired respiratory function or those being treated with drugs that can cause the condition.
When used to provide analgesia, sedation is rarely seen, but may occur at dose levels higher than those recommended.

## Target species

Dogs and cats.

## Dosage and Administration

For intramuscular use.

| Species | Post-Operative Analgesia | Sedation |
|---|---|---|
| Dog | 10 - 20µg buprenorphine per kg (0.3 - 0.6ml **buprecare**® per 10kg), repeated, if necessary, after 3 - 4 hours with 10µg and 5 - 6 hours with 20 µg doses. | 10 - 20µg buprenorphine per kg (0.3 - 0.6ml **buprecare**® per 10kg). |
| Cat | 10 - 20µg buprenorphine per kg (0.3 - 0.6ml **buprecare**® per 10kg), repeated if necessary, once after 2 hours. | Not applicable. |

While sedative effects are present by 15 minutes after administration, analgesic activity becomes apparent after approximately 30 minutes. To ensure that analgesia is present during surgery and immediately on recovery, the product should be administered preoperatively as part of premedication.
When administered for potentiation of sedation or as part of premedication, the dose of other centrally-acting agents, such as acepromazine or medetomidine, should be reduced. The reduction will depend on the

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degree of sedation required, the individual animal, the type of other agents included in premedication and how anaesthesia is to be induced and maintained. It may also be possible to reduce the amount of inhalational anaesthetic used.
Animals administered opioids possessing sedative and analgesic properties may show variable responses. Therefore, the responses of individual animals should be monitored and subsequent doses should be adjusted accordingly. In some cases, repeat doses may fail to provide additional analgesia. In these cases, consideration should be given to using a suitable injectable NSAID.
An appropriately graduated syringe must be used to allow accurate dosing.

## Special storage precautions

Keep out of the reach and sight of children.
Do not store above 25°C
Protect from light.
Do not refrigerate or freeze.
For single use only.
Do not use after the expiry date stated on the carton.
Keep the container in the outer carton.
The product does not contain an antimicrobial preservative. Use immediately after opening the ampoule. Any solution remaining in the ampoule following withdrawal of the required dose should be discarded.

## Special warnings

**Special precautions for use in animals**
Buprenorphine may occasionally cause significant 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.
Buprenorphine should be used with caution in animals with impaired liver function, especially biliary tract disease, as the substance is metabolised by the liver and its intensity and duration of action may be affected in some animals.
In case of renal, cardiac or hepatic dysfunction, or shock, there may be greater risk associated with the use of the product. The benefit:risk ratio for using the product should be made by the attending vet. Safety has not been fully evaluated in clinically compromised cats.
The safety of buprenorphine has not been demonstrated in animals less than 7 weeks of age, therefore use in such animals should be based on the benefit:risk assessment by the veterinarian.
Repeated administration earlier than the recommended repeat interval suggested in the Dosage and Administration table above is not recommended.
The effect of an opioid on head injury is dependent on the type and severity of the injury and the respiratory support supplied. The product should be used in accordance with the benefit:risk assessment of the attending veterinarian.
**Special precautions to be taken by the person administering the veterinary medicinal product to animals**
As buprenorphine has opioid-like activity care should be taken to avoid accidental self-injection.
In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Naloxone should be available in case of accidental parenteral exposure.
Following eye contamination or skin contact, wash thoroughly with cold running water, seek medical advice if irritation persists.
**Use during pregnancy or lactation**
Laboratory studies in rats have not produced any evidence of a teratogenic effect. However, these studies have shown post-implantation losses and early foetal

deaths. As reproductive toxicity studies have not been conducted in the target species, use only according to the benefit:risk assessment by the responsible veterinarian.
The product should not be used pre-operatively in cases of caesarean section, due to the risk of respiratory depression in the offspring periparturiently, and should only be used post-operatively with special care (see section on lactation below).
Studies in lactating rats have shown that, after intra-muscular administration of buprenorphine, concentrations of unchanged buprenorphine in milk equalled or exceeded that in the plasma. As it is likely that buprenorphine will be excreted in the milk of other species, use is not recommended during lactation. Use only accordingly to benefit:risk assessment by the responsible veterinarian.

**Interaction with other medicinal products and other forms of interaction**

Buprenorphine may cause some drowsiness, which may be potentiated by other centrally-acting agents, including tranquillisers, sedatives and hypnotics.
There is evidence in humans to indicate that therapeutic doses of buprenorphine do not reduce the analgesic efficacy of standard doses of an opioid agonist, and that when buprenorphine is employed within the normal therapeutic range, standard doses of opioid agonist may be administered before the effects of the former have ended without compromising analgesia. However, it is recommended that buprenorpine should not be used in conjunction with morphine or other opioid-type analgesics e.g. etorphine, fentanyl, pethidine, methadone, papaveretum and butorphanol.
Buprenorphine has been used with acepromazine, alphaxalone/alphadalone, atropine, dexmedetomidine, halothane, isoflurane, ketamine, medetomidine, propofol, sevoflurane, thiopentone and xylazine. When used in combination with sedatives, depressive effects on heart rate and respiration may be augmented.

**Overdose**

When administered at overdose to dogs, buprenorphine may cause lethargy. At very high doses, bradycardia and miosis may be observed.
In toxicological studies of buprenorphine hydrochloride in dogs, biliary hyperplasia was observed after oral administration for one year at dose levels of 3.5mg/kg/day and above. Biliary hyperplasia was not observed following daily intramuscular injection of dose levels up to 2.5mg/kg/day for 3 months. This is well in excess of any clinical dose regimen in the dog.
In cases of overdosage, supportive measures should be instituted, and, if appropriate, naloxone or respiratory stimulants may be used. However, dose levels many times higher than those indicated in the Dosage and Administration table have been used without serious side effects.
Naloxone may be of benefit in reversing reduced respiratory rate and respiratory stimulants such as Doxapram are also effective in man. Because of the prolonged duration of effect of buprenorphine in comparison to such drugs, they may need to be administered repeatedly or by continuous infusion.
Volunteer studies in man have indicated that opiate antagonists may not fully reverse the effects of buprenorphine.

## Special precautions for the disposal of unused product or waste material, 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.

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## Date on which the package leaflet was last approved

February 2013

## Other information

For animal treatment only.

Buprenorphine is a potent long-acting analgesic acting at opioid receptor sites in the central nervous system (CNS). Buprenorphine exerts its analgesic effect via high-affinity binding to various subclasses of opiate receptors, particularly μ, in the CNS. At clinical dose levels for analgesia, buprenorphine demonstrates high efficacy and binds to opiate receptors with high affinity, such that its dissociation from the receptor is slow, as demonstrated in *in vitro* studies. This property of buprenorphine could account for its longer duration of activity when compared to morphine. In circumstances where excessive opiate agonist is already bound to opiate receptors, buprenorphine can exert a narcotic antagonistic activity as a consequence of its high-affinity opiate receptor binding, such that an antagonistic effect on morphine equivalent to naloxone has been demonstrated.

Buprenorphine is rapidly absorbed after intra-muscular injection in various animal species and in man. In the cat, pharmacological effects occur within 30 minutes after injection and peak effects are usually observed at about 1–1.5 hours. Following intramuscular injection to cats, the mean terminal half-life was 6.3 hours and the clearance was 23ml/kg/min, however there was considerable inter-cat variability in pharmacokinetic parameters. Combined pharmacokinetic and pharmacodynamic studies in cats have demonstrated a marked delay between plasma concentrations and analgesic effect. Plasma concentrations of buprenorphine should not be used to formulate individual animal dosage regimes, which should be determined by monitoring of the patient's response.

## Pack sizes

Presented in 1ml clear glass, snap ampoules, in boxes of five.

**Marketing Authorisation Holder:**
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**Manufacturer responsible for batch release:**
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**UK only**

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CD Sch III

To be supplied only as veterinary prescription

Vm 10347/4024

**IE only**

VPO

Veterinary Practitioner Only

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