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BUPREKARE 0.3MG/ML SOLUTION FOR INJECTION FOR DOGS AND CATS

Presentation Each 1 ml ampoule contains:

Buprenorphine 0.3 mg/ml as buprenorphine hydrochloride. A clear, colourless solution.

Uses For post-operative analgesia in cats and dogs, and potentiation of the sedative effects of centrally acting agents in dogs.

Dosage and administration For intramuscular use.

Dogs:

Post-operative analgesia: 10–20 µg buprenorphine per kg (0.3–0.6 ml Buprekare per 10 kg), repeated if necessary after 3–4 hours with 10 µg/kg or 5–6 hours with 20 µg/kg doses.

Sedation: 10–20 µg buprenorphine per kg (0.3–0.6 ml Buprekare per 10 kg).

Cats:

Post-operative analgesia: 10–20 µg buprenorphine per kg (0.3–0.6 ml Buprekare per 10 kg), repeated if necessary, once after 2 hours.

To ensure that analgesia is present immediately on recovery, the product can be administered pre-operatively. Pharmacological effects have an onset within 30 minutes of injection. If additional analgesia is subsequently required, this may be achieved by administration of a further dose of Buprekare or concomitant use of a suitable injectable NSAID. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

When administered pre-operatively in conjunction with other premedicants, it may be possible to reduce the amount of premedicant, such as acepromazine or medetomidine, and also 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 use of an analgesic from an alternative class.

Contra-indications, warnings, etc The product should not be used pre-operatively for caesarean section.

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 may appear as an adverse reaction.

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. As buprenorphine 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 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 section 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.

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: 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 buprenorphine 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, halothane, isoflurane, ketamine, medetomidine, propofol, sevoflurane, thiopentone and xylazine without any observed adverse effects.

Buprenorphine may cause some drowsiness, which may be potentiated by other centrally-acting agents, including tranquillisers, sedatives and hypnotics. The product should not be used in conjunction with morphine or other opioid-type analgesics (e.g. etorphine, fentanyl, pethidine, methadone, papaveretum and butorphanol).

Overdose: Adverse reactions such as bradycardia and respiratory depression may indicate overdosage (see Adverse reactions section).

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 section 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.

Pharmaceutical 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.

Disposal: Any unused product or waste materials should be disposed of in accordance with national requirements.



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

Further information 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 23 ml/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.

<p>UK Vm 10347/4024 POM-V  Sch III</p>	<p>IE VPA 10778/1/1 </p>
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