PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bupaq 0.3 mg/ml solution for injection

Buprenorphine

2. STATEMENT OF ACTIVE SUBSTANCES

Buprenorphine (as hydrochloride) 0.3 mg/ml

3. PACKAGE SIZE

3 x 2 ml
4 x 2 ml
5 x 2 ml
6 x 2 ml
10 x 2 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

i.m. or i.v. use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 24 hours and store at 2 – 8 °C.

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

VetViva Richter (logo)

14. MARKETING AUTHORISATION NUMBERS

Vm 57446/4008

15. BATCH NUMBER

Lot {number}

(Sch 3)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Clear glass vial type II with bromobutyl rubber stopper and alu-caps}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bupaq

Dogs, cats

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Buprenorphine 0.3 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

2 ml

VetViva Richter (logo)

Commented [MW1]: The applicant kindly asks to include the pack size and VetViva Logo for additional information as per Article 13 of Regulation 2019/6, requested for all concerned member states.

(Sch 3)

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Bupaq 0.3 mg/ml solution for injection for dogs and cats

2. Composition

Each ml contains:

Active substance:
Buprenorphine (as hydrochloride) 0.3 mg

Clear, colourless to almost colourless solution.

3. Target species

Dogs and cats

4. Indications for use

Dogs:
Post-operative analgesia.
Potentiation of the sedative effects of centrally-acting agents.

Cats:
Post-operative analgesia.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not administer by the intrathecal or peridural route. Do not use pre-operatively for Caesarian section (see section “Special warnings - Pregnancy”).

6. Special warnings

Special precautions for safe use in the target species:
Use of the veterinary medicinal product in the below circumstances should only be in accordance with the benefit-risk assessment by the responsible veterinarian.
Buprenorphine may 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.
In case of renal, cardiac or hepatic dysfunction or shock, there may be greater risk associated with the use of the veterinary medicinal product.
Safety has not been fully evaluated in clinically compromised cats.

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 such animals.
The safety of buprenorphine has not been demonstrated in animals less than 7 weeks of age.
Repeat administration earlier than the recommended repeat interval suggested in section “Dosage for each species” is not recommended.
Long-term safety of buprenorphine in cats has not been investigated beyond 5 consecutive days of administration.
The effect of an opioid on head injury is dependent on the type and severity of the injury and the respiratory support supplied.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
As buprenorphine has opioid activity, care should be taken to avoid self-injection or ingestion. Buprenorphine may be absorbed systemically on exposure to mucous membranes. The veterinary medicinal product, which is slightly acidic, may cause skin or eye irritation if contact occurs. Following eye, skin or mouth contact, wash the affected area thoroughly with water. Seek medical advice if irritation persists.
In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after use.
To the physician: In case of accidental self-injection the opioid antagonist naloxone may be used as antidote.

Pregnancy:
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. These may have resulted from a reduction in parental body condition during gestation and in post-natal care owing to sedation of the mothers.
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 veterinary medicinal 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 below section “Lactation”).

Lactation:
Studies in lactating rats have shown that, after intramuscular administration of buprenorphine, concentrations of unchanged buprenorphine in the 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 in accordance with the 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

buprenorphine is not used in conjunction with morphine or other opioid-type analgesics, e.g. etorphine, fentanyl, pethidine, methadone, papaveretum or butorphanol.
Buprenorphine has been used with acepromazine, alphaxalone/alphadalone, atropine, dexmedetomidine, halothane, isoflurane, ketamine, medetomidine, propofol, sevoflurane, thiopental and xylazine. When used in combination with sedatives, depressive effects on heart rate and respiration may be augmented.

Overdose:
In cases of overdosage, supportive measures should be instituted, and, if appropriate, naloxone or respiratory stimulants may be used.
When administered at overdose to dogs, buprenorphine may cause lethargy. At very high doses, bradycardia and miosis may be observed.

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.
In toxicological studies of buprenorphine hydrochloride in dogs, biliary hyperplasia was observed after oral administration for one year at dose levels of 3.5 mg/kg/day and above. Biliary hyperplasia was not observed following daily intramuscular injection of dose levels up to 2.5 mg/kg/day for 3 months. This is well in excess of any clinical dose regimen in the dog.

<Special restrictions for use and special conditions for use:>

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

7. Adverse events

Dogs:
Rare (1 to 10 animals / 10 000 animals treated):
Hypertension (high blood pressure), Tachycardia (rapid heart rate); Sedation[1].

[1] When used to provide analgesia. May occur at dose levels higher than those recommended.

Undetermined frequency (cannot be estimated from the available data):
Hypersalivation (increased salivation); Bradycardia (slow heart rate); Hypothermia (low body temperature), Dehydration; Agitation; Miosis (constricted pupils); Respiratory depression.

Commented [MW2]: Correction according to EU procedure

Cats:
Common (1 to 10 animals / 100 animals treated):
Mydriasis1 (dilated pupils); Behavioural disorder[1,2].

[1] Will usually resolve within 24 hours.
[2] Signs of euphoria (excessive purring, pacing, rubbing).

Rare (1 to 10 animals / 10 000 animals treated):
Sedation[3].

[3] When used to provide analgesia. May occur at dose levels higher than those recommended.

Undetermined frequency (cannot be estimated from the available data):
Respiratory depression.

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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

Intramuscular (i.m.) or intravenous (i.v.) use.

To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

Dogs: **Post-operative analgesia, potentiation of sedation**
Cats: **Post-operative analgesia**

10 - 20 micrograms of buprenorphine per kg bodyweight (i.e. 0.3 - 0.6 ml of the veterinary medicinal product per 10 kg bodyweight).

For further pain relief the dose may be repeated if necessary:

Dogs: Either after 3 - 4 hours with 10 micrograms of buprenorphine per kg bodyweight
or after 5 - 6 hours with 20 micrograms of buprenorphine per kg bodyweight.

Cats: Once, after 1 - 2 hours with 10 - 20 micrograms of buprenorphine per kg bodyweight.

9. Advice on correct administration

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 veterinary medicinal 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 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 response 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.

10. Withdrawal periods

Not applicable.

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.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after “Exp.”. The expiry date refers to the last day of that month.
This veterinary medicinal product does not contain an antimicrobial preservative.
Shelf life after first opening the immediate packaging: 24 hours when stored at 2 - 8°C.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 57446/4008

Pack sizes:
3 x 2 ml, 4 x 2 ml, 5 x 2 ml, 6 x 2 ml, 10 x 2 ml

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

VetViva Richter GmbH,
Durisolstrasse 14, 4600 Wels, Austria
E-Mail: adverse.events@vetviva.com
Tel: +43 664 8455326

17. Other information

POM-V

(Sch 3)

Gavin Hall

Approved: 17 March 2026