**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buprenodale multidose
0.3 mg/ml
Solution for injection for dogs, cats and horses
Buprenorphine

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance:
Buprenorphine 0.3 mg
As Buprenorphine hydrochloride 0.324 mg
Excipient:
Chlorocresol 1.35 mg

## 3. PHARMACEUTICAL FORM

Solution for injection.

## 4. PACKAGE SIZE

10 ml

## 5. TARGET SPECIES

Dogs, cats and horses.

## 6. INDICATIONS

## 7. METHOD AND ROUTE OF ADMINISTRATION

Dog and cat: IM/IV
Horse: IV

## 8. WITHDRAWAL PERIOD

The product is not authorised for use in horses intended for human consumption.

## 9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the vial: 28 days.

## 11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
UK: To be supplied only on veterinary prescription.

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 10434/4081

## 17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

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

**LABEL**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buprenodale multidose 0.3 mg/ml
Solution for Injection for dogs, cats and horses

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

0.3 mg buprenorphine/ml

## 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

## 4. ROUTE(S) OF ADMINISTRATION

Dog/cat: IM/IV
Horse: IV

## 5. WITHDRAWAL PERIOD

The product is not authorised for use in horses intended for human consumption.

## 6. BATCH NUMBER

Lot:

## 7. EXPIRY DATE

EXP:
Once broached use by:

## 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Ad us. vet.

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

Buprenodale multidose
0.3 mg/ml
Solution for injection for dogs, cats and horses

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

**Marketing authorisation holder:**
Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

**Manufacturer responsible for the batch release:**
Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Dales Pharmaceuticals Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buprenodale multidose 0.3 mg/ml solution for injection for dogs, cats and horses.
Buprenorphine.

## 3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml contains: Active substance:
Buprenorphine 0.3 mg (As buprenorphine hydrochloride 0.324 mg)
Excipient: Chlorocresol 1.35 mg
A clear, colourless solution for injection.

## 4. INDICATIONS

Post-operative analgesia in the dog and cat. Post-operative analgesia, in combination with sedation, in the horse. Potentiation of the sedative effects of centrally acting agents in the dog and horse.

## 5. CONTRAINDICATIONS

Do not administer by the intrathecal or peridural route.

Do not use pre-operatively for Caesarean section.
Do not use in known cases of hypersensitivity to the active substance or any of the excipients

## 6. ADVERSE REACTIONS

Dog: Salivation, bradycardia, hypothermia, agitation, dehydration and miosis. Rarely hypertension and tachycardia.
Cat: Mydriasis and signs of euphoria will usually resolve within 24 hours. Buprenorphine may occasionally cause respiratory depression.
Horse: When used as directed in conjunction with sedatives or tranquillisers, excitation is minimal but ataxia may occasionally be marked. Rarely colic. 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 inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs, cats and horses.

## 8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

| Species and route | Post-Operative Analgesia | Potentiation of Sedative Effects |
|---|---|---|
| **Dog:** Intramuscular or intravenous injection | 10 - 20 µg/kg (0.3 - 0.6 ml per 10 kg) repeat if necessary after 3 - 4 hours with 10 µg/kg or 5 - 6 hours with 20 µg/kg doses | 10 - 20 µg/kg (0.3 - 0.6 ml per 10 kg) |
| **Cat:** Intramuscular or intravenous injection | 10 - 20 µg/kg (0.3 - 0.6 ml per 10 kg) repeat once if necessary after 1 - 2 hours | -- |
| **Horse:** Intravenous injection | 10 µg/kg (3.3 ml per 100 kg) 5 minutes after administration of an iv sedative. The dose may be repeated once, if necessary, after not less than 1-2 hours, in combination with intravenous sedation. | 5 µg/kg (1.7 ml per 100 kg) 5 minutes after administration of an iv sedative, repeated if necessary after 10 minutes. |

When used in horses, an intravenous sedative must be administered within five minutes prior to injection of buprenorphine.
In dogs, sedative effects are present by 15 minutes after administration.
Analgesic activity may not develop fully until 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. It may also be possible to reduce the amount of inhalational anaesthetic used.
The response of individual animals should be monitored and subsequent doses adjusted accordingly. In some cases, repeat doses may fail to provide additional

analgesia. An appropriately graduated syringe must be used to allow accurate dosing.

## 9. ADVICE ON CORRECT ADMINISTRATION

None.

## 10. WITHDRAWAL PERIOD

The product is not authorised for use in horses intended for human consumption.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the container in the outer carton. Do not use this veterinary product after the expiry date which is stated on the carton and vial. The expiry date refers to the last day of that month.
Shelf life after first broaching the vial: 28 days.

## 12. SPECIAL WARNINGS

Special precautions for use in animals:
A benefit-risk assessment for using the product should be made by the attending veterinarian in the following conditions:
When treating animals with impaired respiratory function or animals receiving drugs that can cause respiratory depression. In cases of renal, cardiac or hepatic dysfunction, or shock. In clinically compromised cats or horses. In kittens or puppies less than 7 weeks of age. In horses younger than 10 months and less than 150 kg.
Long-term safety of buprenorphine has not been investigated beyond 5 consecutive days of administration in cats or 4 separate administrations on 3 consecutive days in horses.
The effect of an opioid on head injury is dependent on the type and severity of the injury and the respiratory support supplied.
Buprenorphine may reduce gastrointestinal motility in horses.

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 and lactation:
Do not use pre-operatively for Caesarean section. Use is not recommended during lactation.

Interaction with other medicinal products and other forms of interaction:
Buprenorphine may cause some drowsiness, which may be potentiated by other centrally-acting agents.
It is recommended that buprenorphine is not used in conjunction with morphine or other opioid-type analgesics.

Buprenorphine has been used with acepromazine, alphaxalone/alphadalone, atropine, detomidine, dexmedetomidine, halothane, isoflurane, ketamine, medetomidine, propofol, romifidine, sevoflurane, thiopentone and xylazine. In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products. When used in combination with sedatives, depressive effects on heart rate and respiration may be augmented.

Overdose (symptoms, emergency procedures, antidotes):
When administered at overdose to dogs, buprenorphine may cause lethargy. At very high doses, bradycardia and miosis may be observed.
Studies in horses where buprenorphine has been administered with sedatives have shown very few effects at up to five times the recommended dosage, but when administered on its own it can cause excitement.
When used to provide analgesia in horses, sedation is rarely seen, but may occur at dose levels higher than those recommended.
Supportive measure should be instituted, and, if appropriate, naloxone or respiratory stimulants such as Doxapram may be used.
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.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, 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.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

03/2019

## 15. OTHER INFORMATION

Vm 10434/4081

One 10 ml vial per carton.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved: 31 May 2019