

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dolorex 10mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Butorphanol 10 mg equivalent to butorphanol tartrate 14.6 mg

3. PACKAGE SIZE

10 ml

50 ml

4. TARGET SPECIES

Horses, dogs, cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Horses: Intravenous use.

Dogs: Intravenous use.

Cats: Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Horses:

Meat and offal zero days

Milk zero hours

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within: 28 days.

Once opened, use by:

9. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.
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

MSD Animal Health UK Ltd.

14. MARKETING AUTHORISATION NUMBER

Vm 01708/3041

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL 10 and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dolorex

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:

Butorphanol 10 mg equivalent to butorphanol tartrate 14.6 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

Once opened use by....

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Dolorex 10mg/ml Solution for Injection for Horse, Dog, and Cat

2. Composition

Each ml contains:

Active substance:

Butorphanol 10 mg (equivalent to butorphanol tartrate 14.6 mg).

Excipients:

Benzethonium chloride 0.1 mg.

Aqueous colourless solution

3. Target species

Horses, dogs and cats.

4. Indications for use

Butorphanol is intended for use where short (horses and dogs) or short to medium (cats) duration analgesia is required. For information on the duration of analgesia that can be expected following treatment (see section 'Dosage for each species, routes and method of administration').

Horses:

For relief of pain associated with colic of gastrointestinal tract origin

For sedation in combination with certain α_2 -adrenoceptor agonists (see section 'Dosage for each species, routes and method of administration')

Dogs:

For relief of moderate visceral pain

For sedation in combination with certain α_2 -adrenoceptor agonists (see section 'Dosage for each species, routes and method of administration')

Cats:

For the relief of moderate pain associated with soft tissue surgery.

5. Contraindications

Do not use in animals with a history of liver or kidney disease.

Do not use in cases of hypersensitivity to the active ingredient or to any of the

excipients.

Butorphanol/detomidine combination:

The combination should not be used in horses with a pre-existing cardiac dysrhythmia or bradycardia.

The combination will cause a reduction in gastrointestinal motility and consequently should not be used in cases of colic associated with impaction.

6. Special warnings

Special warnings:

In cats, individual response to butorphanol may be variable. In the absence of an adequate analgesic response, an alternative analgesic agent should be used (see section 'Dosage for each species, routes and method of administration').

Increasing of the dose may not increase the intensity or duration of analgesia.

Special precautions for safe use in the target species:

Butorphanol is a morphinan derivative and therefore possesses opioid activity.

Horses:

The use of the veterinary medicinal product at the recommended dose may lead to transient ataxia and/or excitement. Therefore, to prevent injuries in patient and people when treating horses, the location for the treatment should be chosen carefully.

Horses, dogs, and cats:

Due to its anti-tussive properties, butorphanol may lead to an accumulation of mucous in the respiratory tract. Therefore, in animals with respiratory diseases associated with increased mucous production or in animals that are being treated with expectorants, butorphanol should only be used on the basis of a benefit-risk analysis by the responsible veterinarian.

The concomitant use of other central nervous depressants would be expected to potentiate the effects of butorphanol, and such drugs should be used with caution. A reduced dose should be used when administering these agents concurrently.

The combination of butorphanol and α_2 -adrenoceptor agonists should be used with caution in animals with cardiovascular disease. The concurrent use of anticholinergic drugs, e.g. atropine should be considered.

The safety of the veterinary medicinal product in young puppies, kittens and foals has not been established. Use of the product in these groups should be on the basis of a benefit-risk analysis by the responsible veterinarian.

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

Precautions should be taken to avoid accidental injection/self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive. The effects of butorphanol include sedation, dizziness and confusion. Effects can be reversed with an opioid antagonist such as naloxone.

Wash splashes from skin and eyes immediately.

Pregnancy and lactation:

The safety of this veterinary medicinal product has not been established in the target species during pregnancy and lactation. The use of the veterinary medicinal product during pregnancy and lactation is not recommended.

Interaction with other medicinal products and other forms of interaction:

Butorphanol may be used in combination with other sedatives such as α 2-adrenoceptor agonists (e.g., romifidine or detomidine in horses, medetomidine in dogs) where synergistic effects can be expected. Therefore, an appropriate reduction in dose is necessary when used concomitantly with such agent (see dosage).

Because of its antagonist properties at the opiate mu (μ) receptor, butorphanol may remove the analgesic effect in animals, which have already received pure opioid mu (μ) agonists (morphine/oxymorphone).

Overdose:

The main sign of overdose is respiratory depression, which, if severe, can be reversed with an opioid antagonist (e.g., naloxone).

Other possible signs of overdose in the horse include restlessness/excitability, muscle tremor, ataxia, hypersalivation, decrease of gastrointestinal motility and seizure. In the cat, the main sign of overdose are incoordination, salivation, and mild convulsion.

Major incompatibilities:

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

7. Adverse events

Horses, dogs, cats.

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):

Pacing¹; Ataxia (incoordination), Sedation; Digestive tract hypomotility (slow movement); Cardiac depression.

¹ Excitatory locomotor effects.

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):

Cardiac depression; Respiratory depression¹; Anorexia (loss of appetite); Diarrhoea, Digestive tract hypomotility (slow movement); Injection site pain²; Sedation

¹ Naloxone may be used as an antidote.

² Associated with intramuscular injection.

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):

Mydriasis (dilated pupils); Disorientation, Sedation; Injection site irritation¹, Immediate pain upon injection; Agitation²; Dysphoria (unsettled).

¹ In case of repeated administrations.

² Mild.

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

For analgesia:

Horses:

Intravenous use.

0.05 to 0.1 mg/kg

(i.e., 2.5 to 5 ml for 500 kg bw)

Dogs:

Intravenous use.

0.2 to 0.4mg/kg

(i.e., 0.2 to 0.4 ml/10kg bw)

Rapid intravenous injection should be avoided.

Cats:

Subcutaneous use.

0.4 mg/kg

(i.e., 0.2 ml/5 kg bw)

Butorphanol is intended for use where short (horses and dogs) or short to medium (cats) duration analgesia is required. Analgesia generally occurs within 15 minutes following administration in horse, dog and cat. After a single intravenous dose in the horse, analgesia usually lasts for 15 – 60 minutes. In the dog, it lasts for 15 – 30 minutes after a single intravenous administration.

However, repeat treatments of butorphanol may be administered. The need for, and timing of repeat treatment will be based on clinical response. For cases where longer duration analgesia is likely to be required, an alternative therapeutic agent should be used.

In cats with visceral pain, analgesic effect for 15 minutes up to 6 hours after butorphanol administration has been demonstrated. In cats with somatic pain, the

duration of analgesia has been considerably shorter. Depending on the clinical response, product administration may be repeated within six hours. In the absence of an adequate analgesic response, use of an alternative analgesic agent, such as another suitable opioid analgesic and/or a non-steroidal anti-inflammatory drug,

should be considered. Any alternative analgesia should take account of the action of butorphanol on opioid receptors,

For sedation:

Butorphanol can be used in combination with an α 2-adrenoceptor agonist (e.g. (me)detomidine, or romifidine). Adjustment of the dose will be then necessary according to the following recommendations.

Horses: Detomidine: 0.01 - 0.02 mg/kg intravenous use
Butorphanol: 0.01 - 0.02 mg/kg intravenous use
Detomidine should be administered up to 5 min before butorphanol.

Romifidine: 0.05 mg/kg intravenous use
Butorphanol: 0.02 mg/kg intravenous use
Romifidine can be administered concurrently or 4 min before butorphanol.

Dogs: Medetomidine: 0.01 – 0.03 mg/kg intramuscular use
Butorphanol: 0.1 – 0.2 mg/kg intramuscular use
Medetomidine and butorphanol can be administered concurrently.

The stopper should not be pierced more than 25 times.

9. Advice on correct administration

Cats should be weighed to ensure that the correct dose is calculated. An appropriate graduated syringe must be used to allow accurate administration of the required dose volume (e.g., insulin syringe or 1 ml graduated syringe). If repeated administration is required, use different injection sites.

10. Withdrawal periods

Horses:
Meat and offal zero days
Milk zero hours

11. Special storage precautions

Keep out of the sight and reach of children.

Do not refrigerate or freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after Exp. The expiry date refers to the last day of that

month.

Shelf-life after first opening the immediate packaging: 28 days.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01708/3041

10 ml vial

50 ml vial

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 contact details to report suspected adverse reactions:

MSD Animal Health UK Ltd
Walton Manor, Walton
Milton Keynes
MK7 7AJ, United Kingdom
Tel.: +44 (0)1908 685685

Manufacturer responsible for batch release:

Intervet International GmbH
Feldstraße 1a
Unterschleißheim, Bavaria, 85716
GERMANY

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall
Approved 03 April 2025