LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dolorex 10mg/ml solution for injection for horse, dog, and cat.
Butorphanol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance:
Butorphanol 10 mg (equivalent to butorphanol tartrate 14.6 mg).
Excipients:
Benzethonium chloride 0.1 mg.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

10 ml glass vial
50 ml glass vial

5. TARGET SPECIES

/

6. INDICATION(S)

/

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Horse: Intravenous
Dog: Intravenous
Cat: Subcutaneous

8. WITHDRAWAL PERIOD

Horse:
Meat and offal zero days

Milk	zero hours

9. SPECIAL WARNING(S), IF NECESSARY

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10. EXPIRY DATE

<EXP {month/year}>
Once open, use by ….

11. SPECIAL STORAGE CONDITIONS

Protect from light
Do not refrigerate or freeze.

12. SPECIFIC 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.

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

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

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/5111

17. MANUFACTURER'S 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 10mg/ml solution for injection for horse, dog, and cat
Butorphanol

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains:
Active substance:
Butorphanol 10 mg (equivalent to butorphanol tartrate 14.6 mg).
Excipients:
Benzethonium chloride 0.1 mg.

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

10ml glass vial
50ml glass vial

4. ROUTE(S) OF ADMINISTRATION

Horse: Intravenous
Dog: Intravenous
Cat: Subcutaneous

5. WITHDRAWAL PERIOD

Horse:
Meat and offal: zero days
Milk: zero hours

6. BATCH NUMBER

<Lot> {number}

7. EXPIRY DATE

<EXP {month/year}>
Once open, use by ….

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Dolorex 10mg/ml solution for injection for horse, dog and cat

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

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International GmbH
Feldstrasse 1a, 85716 Unterschleissheim
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dolorex 10mg/ml solution for injection for horse, dog, and cat
Butorphanol

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:
Butorphanol 10 mg (equivalent to butorphanol tartrate 14.6 mg).

Excipients:
Benzethonium chloride 0.1 mg.
Sodium citrate
Sodium chloride
Citric acid monohydrate
Water for injections

Aqueous colourless solution

4. INDICATIONS

Butorphanol is intended for use where short (horse and dog) or short to medium (cat) duration analgesia is required. For information on the duration of analgesia that can be expected following treatment (see section 8).

Horse:
For relief of pain associated with colic of gastrointestinal tract origin

For sedation in combination with certain α2-adrenoceptor agonists (see section 8)

Dog:
For relief of moderate visceral pain
For sedation in combination with certain α2-adrenoceptor agonists (see section 8)

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

6. ADVERSE REACTIONS

Butorphanol may cause the following side effects:

Horse, dog, and cat:
- Sedation may be noted in treated animals.

Horse:
- Excitatory locomotor effects (pacing)
- Ataxia
- Reduction in gastrointestinal motility
- Depression of the cardiovascular system.

Dog:
- Depression of the respiratory and cardiovascular system
- Anorexia and diarrhoea
- Reduction in gastrointestinal motility
- Local pain associated with intramuscular injection

Cat:
- Mydriasis
- Disorientation
- Possible irritation at the injection site in case of repeated administrations
- Mild agitation
- Dysphoria
- Pain on injection

If respiratory depression occurs, naloxone may be used as an antidote.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horse, Dog, Cat

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

For analgesia:
Horse: 0.05 to 0.1 mg/kg, intravenous route
(*i.e.* 2.5 to 5 ml for 500 kg bw)

Dog: 0.2 to 0.4mg/kg, intravenous route
(*i.e.* 0.2 to 0.4 ml/10kg bw)
Rapid intravenous injection should be avoided.

Cat: 0.4 mg/kg, subcutaneous route
(*i.e.* 0.2 mL/5 kg bw)

Butorphanol is intended for use where short (horse and dog) or short to medium (cat) 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 α2–adrenoceptor agonist (*e.g.* (me)detomidine, or romifidine). Adjustment of the dose will be then necessary according to the following recommendations.

Horse: Detomidine: 0.01 - 0.02 mg/kg intravenous route
Butorphanol: 0.01 - 0.02 mg/kg intravenous route
Detomidine should be administered up to 5 min before butorphanol

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

Dog: Medetomidine: 0.01 – 0.03 mg/kg intramuscular route
Butorphanol: 0.1 – 0.2 mg/kg intramuscular route
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 PERIOD

Horse:

Meat and offal	zero days
Milk	zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Protect from light.
Do not refrigerate or freeze.
Do not use after the expiry date which is stated on the carton and the bottle.
Shelf-life after first opening the container: 28 days.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the carton/label.

12. SPECIAL WARNINGS

Special precautions for use in animals

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

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

Horse:
The use of the 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.

Horse, dog, and cat:
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 risk-benefit analysis by the responsible veterinarian.

Sedation may be noted in treated animals.

In cats, if respiratory depression occurs, naloxone may be used as an antidote.

Butorphanol is a morphinan derivative and therefore possesses opioid activity

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.

Butorphanol may be used in combination with other sedatives such as α2-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). This combination should be used with caution in animals with cardiovascular disease. The concurrent use of anticholinergic drugs, e.g atropine, should be considered.

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/oxymorphine).

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

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.

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. If accidental self-injection occurs, 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.

Incompatibilities

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

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

August 2020

15. OTHER INFORMATION

10 ml vial
50 ml vial
Not all pack sizes may be marketed

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

Veterinary medicinal product to be supplied only on veterinary prescription.