PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

OUTER CARTON: 5/10/20/25/30/50/100 ml
LABEL: 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fentadon 50 microgram/ml, solution for injection for dogs
Fentanyl

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance:
Fentanyl 50 microgram (equivalent to fentanyl citrate 78.5 microgram)

Excipients:

Methyl parahydroxybenzoate (E218)	1.6 mg
Propyl parahydroxybenzoate	0.2 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

5/10/20/25/30/50/100 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use by …./…./….

11. SPECIAL STORAGE CONDITIONS

Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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, IF APPLICABLE

For animal treatment only.
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

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 16849/4031

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL/5/10/20/25/30/50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fentadon 50 microgram/ml, solution for injection for dogs
Fentanyl

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml contains:
Active substance:
Fentanyl 50 microgram (equivalent to fentanyl citrate 78.5 microgram)

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

5/10/20/25/30/50 ml

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use by…./…./….

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET
Fentadon 50 microgram/ml, solution for injection for dogs

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

Marketing authorisation holder and manufacturer responsible for batch release:
Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fentadon 50 microgram/ml, solution for injection for dogs
Fentanyl

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 ml contains:
Active substance:
Fentanyl 50 microgram (equivalent to fentanyl citrate 78.5 microgram)

Excipients:

Methyl parahydroxybenzoate (E218)	1.6 mg
Propyl parahydroxybenzoate	0.2 mg

Clear, colourless solution

4. INDICATION(S)

For intra-operative analgesia during surgical procedures such as soft tissue and orthopaedic surgery.
For the control of post-operative pain associated with major orthopaedic and soft tissue surgery.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance, or to any of the excipients.
Do not use in dogs with cardiac failure, hypotension, hypovolaemia, obstructive airway disease, respiratory depression, hypertension or with a history of epilepsy.
Do not use in animals with severe liver or renal dysfunction.
Refer to section 'Special Warnings'.

6. ADVERSE REACTIONS

In analogy with other narcotic analgesics, common serious adverse reactions with fentanyl are respiratory depression and bradycardia. Bradycardia may occur due to increased cardiac vagal stimulation. The respiratory depressant effects can be of long duration and may exhibit a biphasic pattern.

Also common is a transient fall in blood pressure following intravenous administration of fentanyl citrate injection even at doses of 2.5 - 5 µg/kg. Hypothermia may occur. Lowered nociceptive thresholds in dogs when the effects of the drug dissipate have been described.

The following adverse reactions have been observed during studies with the product and occur very commonly:
Rapid breathing, panting, urination, defecation, vocalization, tongue protrusion, overactivity, irritability, body tremors, vomiting, scratching and sedation.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

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

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intravenous administration. The weight of the animal to be treated should be accurately determined before the administration of the product. Onset of action is seen within 5 minutes. The duration of the analgesic effect is 20 (lowest recommended dose) to 40 minutes (highest recommended dose).

Fentanyl can be administered according to the following dosage regimen:

Analgesia by Continuous Rate Infusion (CRI)

- 5 – 10 µg/kg (0.1 -0.2 ml/kg) IV as a bolus followed by 12 – 24 µg/kg/hr (0.24 – 0.48 ml/kg/hr) IV for intra-operative analgesia as CRI.
- 6 – 10 µg/kg/hr (0.12 – 0.2 ml/kg/hr) IV for subsequent post-operative analgesia as CRI in sedated animals. During post-operative CRI administration of fentanyl, animals should be monitored carefully.

Chemical-physical compatibility has only been demonstrated for dilutions 1:5 with the following solutions for infusion: sodium chloride 0.9%, Ringer solution, and glucose 5%.

This veterinary medicinal product has a narrow margin of safety and it is important to measure the dose accurately to avoid overdosing.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not freeze
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days
Chemical and physical stability of the dilutions has been demonstrated for 4 hours at 25°C. From a microbiological point of view the dilutions should be used immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:
The use of the medicine must be preceded by a thorough clinical examination.
Atropine may be used to block the vagal effects.

Special precautions for use in animals:
This veterinary medicinal product should be titrated for the individual animal to an effective dose that provides adequate analgesia and minimises undesirable effects. Animals should be carefully monitored until an effective dose is reached. Due to individual differences in pain sensitivity, the effects of fentanyl may be variable. Older animals may tend to titrate to a lower effective dose than younger animals.
It is important when estimating the required dose for intra-operative analgesia to assess the likely degree of surgical stimulation, the effect of premedication drugs, whether supportive care like endotracheal intubation and ventilatory support may be required, and the duration of the procedure.
If other narcotic or CNS-depressant drugs (e.g. propofol, isoflurane, sevoflurane) are used concurrently with fentanyl the doses of these agents may need to be reduced.
When estimating the required dose for post-operative analgesia the degree of tissue damage has to be assessed.
As a class, opioids, including this veterinary medicinal product, may cause hypothermia with duration related to dose, bradypnea, hypotension and bradycardia. Therefore, animals should be continuously monitored for rectal temperature, pulse rate, respiratory rate and heart rhythm during surgical anaesthesia.
In case of renal, cardiac or hepatic dysfunction, hypovolaemia or shock, there may be greater risk associated with the use of the product. It is desirable to reduce dosage in case of hypothyroidism and in case of chronic hepatic or renal disease. As with all

narcotic analgesics, care should be taken when administering fentanyl to animals with myasthenia gravis.
Facilities for the maintenance of a patent airway, intermittent positive pressure ventilation (IPPV) and oxygen supplementation should be available. When respiratory depression occurs, controlled ventilation should be installed.
As with all potent opioids, profound analgesia is accompanied by respiratory depression, which may persist into or recur in the early post-operative period. The respiratory depressant effects may be more problematic in animals with pre-existing respiratory disease or increased intracranial pressure. The effect of an opioid on head injury is dependent on the type and severity of the injury and the respiratory support supplied. It is imperative to ensure that adequate spontaneous breathing has been established and maintained before discharge from the recovery area whenever large doses of infusions of fentanyl have been administered. The benefit/ risk ratio for using the product should be made by the attending vet. The pharmacological effects of fentanyl citrate can be reversed by naloxone.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Fentanyl, an opioid, may cause adverse effects after internal exposure, including respiratory depression or apnoea, sedation, hypotension and coma. The product may cause hypersensitivity reactions.
Avoid contact with the skin and eyes. Wear protective gloves when handling the product. Wash hands after use. Wash any splashes from skin and eyes immediately with large amounts of water. Remove contaminated clothes.
Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the doctor but DO NOT DRIVE as sedation may occur.
-Adverse effects on the foetus cannot be excluded. Pregnant women should avoid handling the product. In case of women who are breastfeeding being accidentally exposed, breastfeeding is discouraged for 24 hours, as fentanyl may transfer to breast milk.

ADVICE TO DOCTORS:
Fentanyl is an opioid whose toxicity may cause clinical effects including respiratory depression or apnoea, sedation, hypotension and coma. When respiratory depression occurs controlled ventilation should be installed. Administration of the opioid antagonist naloxone to reverse the symptoms is recommended.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. The use of the product is not recommended during pregnancy or lactation.
Laboratory studies in rats have not produced any evidence of a teratogenic, foetotoxic, or mutagenic effect. Placental transfer of fentanyl occurs. Administration during parturition may cause respiratory depression in the foetus.

Interaction with other medicinal products and other forms of interaction:
Fentanyl is a potent anaesthetic sparing substance. To avoid anaesthetic overdose in dogs treated with the veterinary medicinal product, anaesthetic agents should be administered only until the desired effect is produced.

The veterinary medicinal product should be used with caution in conjunction with morphine or other opioid type analgesics as the effects have not been studied.
The effects of the concomitant use of the veterinary medicinal product and α-adrenergic agonists have not been studied. Therefore, α2-adrenergic agonists should be used with caution in animals dosed with the veterinary medicinal product due to potentially additive or synergistic effects.

Overdose (symptoms, emergency procedures, antidotes):
A 2 fold overdose as a bolus injection resulted in the effects mentioned in the section 'Adverse reactions'. In the event that any of the following observations are made following the application/overdose of the product, reversal should be initiated: severe sedation, unconsciousness, seizures, laboured or abdominal breathing or severe hypotension. The specific narcotic antagonist naloxone hydrochloride can be used to counteract respiratory depression. A dose of 0.01 to 0.04 mg/kg is given intravenously and may be repeated at intervals of 2 to 3 minutes if necessary.

Incompatibilities:
Do not mix with any other veterinary medicinal product except the infusion solutions indicated in section 'Dosage, route and method of administration'.
The product is incompatible with injection fluids containing meloxicam or any other nonaqueous solution.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Month YYYY

15. OTHER INFORMATION

For animal treatment only
Vm 16849/4031
To be supplied only on veterinary prescription.
This product falls within the regime of controlled drugs Schedule II

Package sizes: 5/10/20/25/30/50/100 ml
Not all pack sizes may be marketed.

Approved: 24 March 2017