ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recuvyra 50 mg/ml transdermal solution for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Fentanyl 50 mg/ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Transdermal solution.

Clear, colourless to light yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

For the control of post-operative pain associated with major orthopaedic and soft tissue surgery in dogs.

4.3 Contraindications

Do not administer to skin that does not have an intact *stratum corneum* due to injury or disease.

Do not administer to areas other than the dorsal scapular region.

Do not use in dogs with cardiac failure, hypotension, hypovolaemia, respiratory depression, hypertension, a history of epilepsy, non age related corneal pathology or those who have or are suspected of having a paralytic ileus.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Do not give a second dose of the veterinary medicinal product within 7 days. Accumulation of fentanyl following repeated administration could result in severe adverse reactions, including death. Do not give more than the recommended dose of the veterinary medicinal product.

Do not allow the dog or other animals to lick the site of application as oral bioavailability following licking is high in the first five minutes after application. Do not allow other animals contact with the application site for at least 72 hours after application. The veterinary medicinal product should not come into direct contact with the oral cavity or mucous membranes of dogs. Mild side effects such as sedation, may occur after a single accidental oral administration of more than 20 µg/kg of fentanyl (0.4 µl/kg Recuvyra). Higher oral doses may induce anaesthetic effects and cardiopulmonary depression.

Do not use the veterinary medicinal product in lactating or pregnant bitches or breeding animals (see section 4.7).

4.4 Special warnings

Recuvyra should only be used for major surgery that requires opiate analgesia for a duration of at least 4 days.

Only use the syringes provided. The use of syringes not supplied with this veterinary medicinal product, or storage of this veterinary medicinal product in a syringe may lead to dosing inaccuracy. Do not re-use syringes or applicator tips.

The use of the veterinary medicinal product is intended as a single application administered 2 to 4 hours prior to surgery to provide analgesia for at least 4 days. Should subsequent surgery be intended in a dog previously treated with the veterinary medicinal product, a minimum of a 7 day dosing interval must be observed before administering another dose

4.5 Special precautions for use

Special precautions for use in animals

The veterinary medicinal product is strictly limited for use in dogs. Dogs of more than 20 kg bodyweight should remain in the hospital for a minimum of 48 hours following application.

As a class, opioids, including this veterinary medicinal product, may cause low body temperature, slow respiratory rate, low blood pressure or slow heart rate. Therefore, dogs should be continuously monitored for rectal temperature, pulse rate, respiratory rate and heart rhythm during surgical anaesthesia. Facilities for the maintenance of a patent airway, intermittent positive pressure ventilation (IPPV) and oxygen supplementation should be available.

Additional class effects that may be observed following administration of fentanyl include dysphoria and urinary retention, therefore appropriate precautionary measures should be in place.

The use of the veterinary medicinal product may result in corneal drying during prolonged sedation. Appropriate eye lubrication should therefore be applied prior to and following surgery and continued until the dog resumes normal blinking function.

The veterinary medicinal product should not be used in animals with systemic illness.

The safety of the veterinary medicinal product in animals less than 6 months of age has not been established.

Before using the product it is recommended to consider the availability of an opiate antagonist, e.g. naloxone, in case reversal is required (see sections 4.6 and 4.10).

Dogs must not be discharged to owners until post-operative sedation is mild or absent and dogs are drinking water and eating voluntarily at an appropriate level for the condition that required surgery.

Dogs that are moderately sedated and not drinking water and eating voluntarily should be evaluated for dehydration and administered supplemental fluid and nutrition support as necessary. Gastrointestinal stasis can result in serious complications and consideration should be given to opiate reversal in case of excessive narcosis (see section 4.10).

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

The veterinary medicinal product should be administered with caution. Avoid contact with skin, as Recuvyra can be absorbed by human skin. Also, the veterinary medicinal product might cause skin irritation.
Personal protective equipment consisting of latex or nitrile gloves, eye protection and suitable protective clothing should be worn when handling this veterinary medicinal product. If there is a risk of contact with the application site, suitable protective gloves must be worn.

Do not use near a naked flame.

In case of accidental spillage onto **skin**, immediately flush the area with water, then wash the area with copious amounts of soap and water and seek prompt medical advice, showing the physician this warning, the package leaflet or the label.

In case of accidental exposure of **protective clothing** to the veterinary medicinal product, immediately remove any contaminated clothing. Blot up any noticeable solution using an absorbent material such as paper tissues. The tissues should be discarded immediately following use. Thoroughly clean any contaminated clothing before reuse.

In case of accidental **eye** contact with the veterinary medicinal product, rinse with abundant quantities of water and seek medical advice immediately.

In case of **accidental ingestion** of the veterinary medicinal product, seek medical advice immediately.

If symptoms develop following exposure to the veterinary medicinal product such as erythema, confusion, nausea or vomiting, medical advice should be sought immediately. The most common symptoms associated with fentanyl overdose in people include respiratory depression, sedation and myosis. At a high dose, fentanyl is known to cause a potentially fatal respiratory depression. This depression may be reversed by use of a suitable reversal agent, such as naloxone.

Following application to dogs, do not touch the site for 5 minutes.
As a precaution, RECUVYRA should not be administered by pregnant women.
This product should only be administered by a veterinary surgeon.

For the attention of dog owner
After the application site is dry, direct contact to the application site should not pose a risk to adults. However, for small children (15 kg) such contact might still result in serious exposure to fentanyl. Therefore, treated dogs of more than 20 kg body weight have to be kept at the hospital for 48 hours post-application. SMALL CHILDREN SHOULD NOT TOUCH THE DOG FOR 72 HOURS (3 days) AFTER RECUVYRA IS APPLIED TO THE DOG.
If a small child touches the application site within 72 hours of application, the child's skin that touched the dog (for example, fingers) should not contact the child's mouth, and the skin should be washed with soap and water. If a child orally contacts the application site within 72 hours of application, medical attention should be sought immediately.

4.6 Adverse reactions (frequency and seriousness)

Fentanyl very commonly causes dose-dependent sedation in dogs which is associated with potential decreased food and water intake, decreased stool production and transient weight loss. Sedation may persist beyond 24 hours after application.

Mild reductions in body temperature and heart and respiratory rates for up to 3 days following use are common. Vomiting and diarrhoea are also common adverse reactions. In rare cases, dysphoria and urinary retention have also been observed.

In field trials, 2 % of dogs treated with the veterinary medicinal product required reversal of adverse opiate effects with naloxone. See section 4.10.

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).

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use the veterinary medicinal product in lactating or pregnant bitches or breeding animals.

Fertility:
Laboratory studies conducted in rats have not shown any evidence of teratogenic effect, or any adverse effect on fertility or embryo-foetal development.

4.8 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 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, α_2-adrenergic agonists should be used with caution in animals dosed with the veterinary medicinal product due to potentially additive or synergistic effects.

4.9 Amounts to be administered and administration route

For transdermal use.

A single topical application provides pain relief for at least 4 days. Once applied to the skin, the veterinary medicinal product rapidly dries resulting in percutaneous absorption of fentanyl.

The recommended dose is 2.6 mg fentanyl/kg bodyweight (i.e. 0.052 ml/kg bw), applied topically to the dorsal scapular area 2 to 4 hours prior to surgery and according to the dosing table below.

The veterinary medicinal product has a narrow margin of safety and it is important to measure the dose accurately to avoid over-dosing. Do not blow out any residual volume in the syringe or applicator tip as this has been accounted for in the dosing table. Only up to 0.5 ml can be applied to one area of skin.

Apply up to 0.5 ml onto the skin without moving the applicator tip. If the volume to be administered is greater than 0.5 ml, move the applicator tip at least 2.5 cm from the initial site and apply up to 0.5 ml. Repeat until the entire calculated volume has been applied to the dog.

It is imperative that the veterinary medicinal product is not applied to any other site on the body than the dorsal scapular area, as absorption has been shown to vary between different locations of skin. The product should only be applied by a veterinarian.

Do not give a second dose of the veterinary medicinal product. Accumulation of fentanyl following repeated administration could result in severe adverse reactions, including death. Do not give more than the recommended dose of the veterinary medicinal product. Should subsequent surgery be intended in a dog previously treated with the veterinary medicinal product, a minimum of a 7 day dosing interval must be observed before administering another dose.

Dose (ml)	**Bodyweight (kilograms)**
0.2	3.0 to 4.2
0.3	4.3 to 6.1
0.4	6.2 to 8.0
0.5	8.1 to 9.9
0.6	10.0 to 11.7
0.7	11.8 to 13.6
0.8	13.7 to 15.5
0.9	15.6 to 17.4
1.0	17.5 to 19.3
1.1	19.4 to 21.2
1.2	21.3 to 23.1
1.3	23.2 to 25.0
1.4	25.1 to 26.9
1.5	27.0 to 28.8
1.6	28.9 to 30.6
1.7	30.7 to 32.5
1.8	32.6 to 34.4
1.9	34.5 to 36.3
2.0	36.4 to 38.2
2.1	38.3 to 40.1
2.2	40.2 to 42.0
2.3	42.1 to 43.9
2.4	44.0 to 45.8
2.5	45.9 to 47.7
2.6	47.8 to 49.6
2.7	49.7 to 51.4
2.8	51.5 to 53.3
2.9	53.4 to 55.2
3.0	55.3 to 57.0

Instructions for use:

Attaching adaptor (see Figure 1):

1. Remove the plastic protective cover from the top of the glass vial. The vial must be placed upright on a firm, stable surface during placement and application of the adaptor.

2. Centre the adaptor directly over the top of the vial. Applying gentle, even pressure, press the adaptor onto the vial until it is seated. Once seated, do not remove the adaptor. Store vial upright with the adaptor attached.

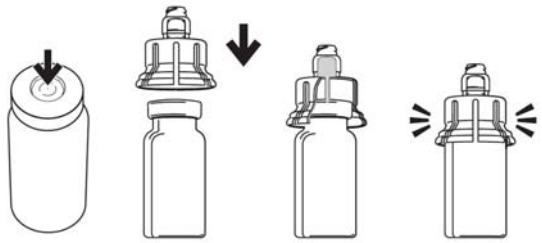

Figure 1. Attaching the adaptor

Withdrawing the solution from the vial (see Figure 2):

1. Only use the syringes provided. Do not re-use syringes.

2. To withdraw the solution from the vial, press the provided syringe tip into the centre of the adaptor and gently turn the syringe approximately ¼ turn clockwise until fully seated.

3. Invert vial and pull back on the syringe plunger until the appropriate volume is withdrawn. It may be necessary to evacuate air from the syringe back into the vial.

4. To accurately withdraw the correct amount, align the top of the O-ring on the syringe plunger with the appropriate tick mark on the syringe barrel.

5. Turn the vial into the upright position, grasp the adaptor, turn the syringe ¼ turn anti-clockwise and remove the syringe.

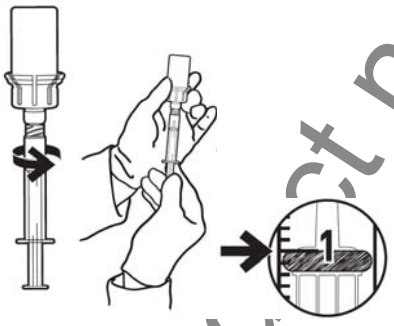

Figure 2. Withdrawing the solution from the vial

Attaching the applicator tip (see Figure 3):

1. Attach the applicator tip to the syringe by turning the applicator tip 1/3 turn clockwise

2. Do no re-use the applicator tip. Store the broached vial with the adaptor in an upright position.

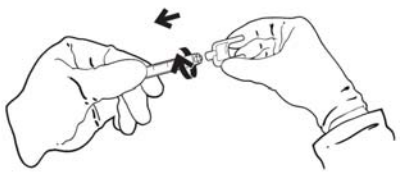

Figure 3. Attaching the Applicator Tip

Site preparation: It is not necessary to clip the hair over the application site. However, in dogs with thick hair coats, it is advisable to clip the hair prior to application to assure direct contact of the

veterinary medicinal product with the skin. The application site should be clean and free of any surface matter.

Product Application (see Figure 4):

1. Place applicator tip at an approximate 45º angle directly onto the skin in the dorsal scapular region. It is important that both tips make direct contact with the skin.

2. Apply up to 0.5 ml onto the skin without moving the applicator tip. If the volume to be administered is greater than 0.5 ml, move the applicator tip at least 2.5 cm from the initial site and apply up to 0.5 ml. Repeat until the entire calculated volume has been applied to the dog.

3. Restrain the dog for approximately 2 minutes and avoid contact with the application site for 5 minutes to allow complete drying of the solution.

4. Do not blow out any residual volume in the syringe or applicator tip as this has been accounted for in the dosing table.

5. Dispose of the used syringe/applicator tip as a unit in an appropriate container.

Figure 4. Product Application

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In the event that any of the following observations are made following the application/overdose of the veterinary medicinal product, reversal should be initiated: severe sedation, unconsciousness, seizures, laboured or abdominal breathing or severe hypotension.

Severe overdose may result in renal failure secondary to hypotension produced by gastrointestinal hypomobility.

Administration of naloxone at 0.04 mg/kg may be used to reverse adverse reactions associated with topical fentanyl. Reversal should occur rapidly within 1-2 minutes. The duration of action of naloxone ranges between 45 minutes and 3 hours in the dog. The effects of transdermal fentanyl could last longer than the effects of the opioid reversal agent. If needed, re-administer naloxone.

Dogs that are moderately sedated, and are not drinking water and eating voluntarily at an appropriate level for the condition that required surgery, should be evaluated for dehydration and administered supplemental fluid and nutrition support as necessary.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Analgesic, opioid, phenylpiperidene derivative.

ATCvet code: QN02AB03

5.1 Pharmacodynamic properties

Fentanyl exerts its analgesic action by binding to and activating μ (*mu*) opioid receptors that are predominantly found in the pain regulating areas of the brain and spinal cord. The analgesic effects of the veterinary medicinal product are related to the resulting fentanyl blood concentration achieved following application.

5.2 Pharmacokinetic particulars

The mean plasma fentanyl concentration from time 0 through 96 hours post-dose administration is approximately 1.32 ng/ml. The ranges (90% interval) of pharmacokinetic parameters in dogs are given below:

Terminal half-life (hrs)	**Time to 1.0 ng/ml (hrs)**	**C_{max} (ng/ml)**	**t_{max} (hrs)**	**t_{lag} (hrs)**
68.7 – 79.8	1.3 – Not Reached	0.7 – 4.7	10.3 – 17.9	0.4 – 0.8

Following application to the skin, fentanyl is rapidly absorbed into the skin. At the moment of drying, approximately 2 to 5 minutes after application, fentanyl and octyl salicylate are absorbed into the stratum corneum. Fentanyl partitions from the stratum corneum through the deeper skin layers and into the systemic circulation over a period of days. The maximum plasma fentanyl concentrations of 0.7 to 4.7 ng/ml are reached within 10 to 18 hours of dose administration. Plasma fentanyl concentrations reach 1.0 ng/ml, (which is generally considered analgesic) in more than 60% of dogs within 4 hours of administration. The systemic bioavailability of the veterinary medicinal product is approximately 40%. The pharmacokinetic profile of the veterinary medicinal product is primarily characterised by the long period of systemic absorption. Fentanyl is highly lipid soluble and distributes rapidly into a variety of tissues readily crossing the blood-brain barrier in the dog. Fentanyl plasma protein binding is estimated at approximately 60% in dogs.

Fentanyl is extensively metabolised and excreted into the urine. The clearance of fentanyl ranges from 1.7 to 4.7 l/h/kg in dogs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Octyl salicylate
Isopropyl alcohol

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first broaching the vial: 30 days.

6.4. Special precautions for storage

The unbroached vial does not require any special storage conditions.
Do not store or use near a naked flame.
Store the broached vial with the adaptor in an upright position.
Store the vial together with the Summary of Product Characteristics (SPC).

When the vial is broached for the first time, the date on which any product remaining in the vial should be discarded should be written in the space provided on the label, using the in-use shelf-life.

6.5 Nature and composition of immediate packaging

Vial:

Type I amber glass vial containing 10 ml solution, closed with a grey butyl rubber stopper sealed with a two piece aluminium seal with a grey flip-off plastic disc.

Dosing device:

- A polycarbonate Robertsite vial adaptor (allowing needleless luer connection to the vial).
- A 2-pronged polycarbonate applicator tip.
- A 3 ml polypropylene syringe with a silicone O-ring fitted to the plunger.

Each pack is supplied with one vial adaptor, 15 syringes and 15 applicator tips, as well as 15 package leaflets for animal owners, and 1 SPC (for the veterinarian).

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Eli Lilly & Company Ltd
Elanco Animal Health
Lilly House
Priestley Road
Basingstoke,
Hampshire RG24 9NL
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/127/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

{06/10/2011}

10 DATE OF REVISION OF THE TEXT

{MM/YYYY}

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

D. STATEMENT OF THE MRLs

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

McGregor Cory
Cherwell 2
Middleton Close
Banbury, Oxfordshire, OX16 4RS
United Kingdom.

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary prescription.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT

To address the safety concerns remaining in relation to the novel type of product, and the uncertainty about possible interactions of concomitantly used products during the operation and in the post-operative period, the marketing authorisation holder should arrange for collation and assessment of detailed data on the clinical safety of the product in a representative sample of dogs. Such data should be submitted to the Agency together with the periodic safety update reports.

D. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Outer

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recuvyra 50 mg/ml transdermal solution for dogs.
Fentanyl

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Fentanyl 50 mg/ml

3. PHARMACEUTICAL FORM

Transdermal solution.

4. PACKAGE SIZE

1 vial (10 ml)
1 vial adaptor
15 syringes
15 applicator tips

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For the control of post-operative pain associated with major orthopaedic and soft tissue surgery in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For transdermal use.
Read the Summary of Product Characteristics before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental administration is dangerous – see Summary of Product Characteristics before use

10. EXPIRY DATE

EXP: MM/YYYY
Once broached, use within 30 days.

11. SPECIAL STORAGE CONDITIONS

Store the broached vial with the adaptor in an upright position.

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

Dispose of waste material 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eli Lilly & Company Ltd
Elanco Animal Health
Lilly House
Priestley Road
Basingstoke,
Hampshire RG24 9NL
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/127/001

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recuvyra 50 mg/ml transdermal solution for dogs.
Fentanyl

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fentanyl 50 mg/ml

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

10 ml

4. ROUTE(S) OF ADMINISTRATION

For transdermal use.
Store the Summary of Product Characteristics together with the vial, and read before use

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP:MM/YYYY
Once broached, use by….

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Recuvyra 50 mg/ml transdermal solution 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:

Eli Lilly & Company Ltd
Elanco Animal Health
Lilly House
Priestley Road
Basingstoke,
Hampshire RG24 9NL
United Kingdom

Manufacturer for batch release:

McGregor Cory
Cherwell 2
Middleton Close
Banbury, Oxfordshire, OX16 4RS
United Kingdom.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recuvyra 50 mg/ml transdermal solution for dogs

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

Recuvyra is a clear, colourless to light yellow solution containing 50 mg of fentanyl (the active substance) per ml of solution. Recuvyra also contains octyl salicylate and isopropyl alcohol. Recuvyra is supplied to your veterinarian in an amber glass bottle containing 10 ml of product.

4. INDICATION(S)

Recuvyra controls pain in dogs that have undergone major orthopaedic or soft tissue surgery.

5. CONTRAINDICATIONS

Your dog should not be given Recuvyra if it:

- Has broken, damaged or diseased skin at the treatment site.
- Has heart failure, low or high blood pressure, low blood volume, impaired breathing, has a history of epilepsy, non-aged related corneal pathology or has or might have a partial or completely stationary bowel.
- Has an allergy to the active substance (fentanyl) or to any of the excipients.
- Is lactating, pregnant or a dog used for breeding.

Your veterinarian should not administer Recuvyra:

- Except as a single dose at the recommended dose rate.
- To anywhere except between your dogs shoulder blades.
- To your dog if it has already had a dose of Recuvyra within the last 7 days.

It is important that you do not allow any other dogs or pets you may have to lick or come into contact with the area between your dog's shoulder blades where your veterinarian has applied Recuvyra for at least 3 days (72 hours) following treatment, as this might cause adverse reactions in these animals.

6. ADVERSE REACTIONS

Recuvyra like any other medicine may cause adverse reactions. Your veterinarian can best describe these for you. It can cause:

Very commonly (i.e. in more than 10% of treated dogs)
- Mild sedation (sleepiness) for up to 24 hours after Recuvyra has been applied by your veterinarian.
- Loss of appetite or drinking less water.
- Decreased stool production and some temporary weight loss.

Commonly (i.e. in 1 to 10% of treated dogs)
- Your dog to feel cold when touched (for example the ears).
- Lowering of heart and breathing rates.
- Vomiting and diarrhoea.

Rarely (i.e. in 0,01 to 0,1% of treated dogs)
- Dysphoria and urinary retention.

The above side effects can occur up to 3 days (72 hours) after Recuvyra was given to your dog.

If necessary, your veterinarian may administer treatment to your dog (for example a reversal agent called naloxone which has a very rapid effect within 1 – 2 minutes). If needed, your veterinarian might administer more than one dose of naloxone to your dog.
If your dog is more than mildly sedated, or has decreased appetite or water intake, you should contact your veterinary surgeon for advice.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

Recuvyra is a solution designed to be carefully applied to your dog's skin **only by a veterinarian**.
Two to four hours before your dog has surgery, the recommended dose (2.6 mg fentanyl/kg bodyweight) of Recuvyra solution is applied directly on the skin between the dog's shoulder blades. Within 5 minutes, the product dries on the skin. Fentanyl gradually moves through the skin into your dog's bloodstream and then relieves pain. A single dose relieves pain for at least 4 days.

If your dog weighs more than 20 kg, then it will remain in hospital for at least 48 hours following application of Recuvyra. Application of Recuvyra will not cause your dog any pain and your veterinarian will use a dosing table and a specially designed applicator to carefully apply the product onto the skin surface without using any needles.

9. ADVICE ON CORRECT ADMINISTRATION

Recuvyra is a solution designed to be applied to the skin between the shoulder blades of your dog (see picture) **only by a veterinarian** using a specially designed single use applicator, which does not involve any needles. Unless your dog has thick hair it will not usually be necessary to clip/ shave your dog's hair between the shoulder blades for correct application.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

As Recuvyra contains fentanyl (the active substance), it will only ever be kept in a veterinarian's surgery under secure conditions. Your veterinarian will ensure the product is stored correctly and safely for up to 3 years, but the contents of a bottle should be used within 30 days of the first dose being withdrawn.

12. SPECIAL WARNING(S)

Recuvyra should only be used for dogs.

Recuvyra should not be used if your dog is pregnant, lactating or is used for breeding, or if your dog is less than 6 months old. You should tell your veterinarian if you know any of these applies about your dog before treatment is given.
Tell your veterinarian if your dog is sick or was recently ill, if it has ever had breathing, heart or blood pressure problems or epilepsy, if it has ever had bowel or kidney problems or problems with its eyes, and what medicines your dog has taken, especially within the last month.
Once Recuvyra has been administered, your veterinarian will carefully monitor your dog to ensure it responds safely to the product.
Your dog will only be allowed to go home once it has recovered from its surgery, and is drinking and eating normally.
Dogs weighing 20 kg or more will be kept at the veterinary clinic for at least 48 hours after treatment with Recuvyra.
Your veterinarian should use Recuvyra with caution in conjunction with other morphine or other opioid pain relievers, or α-adrenergic agonists because the possible side-effects have not been studied.

When using Recuvyra your veterinarian should use less anaesthetic agents and administer them only to achieve the desired effect.

After the application site is dry, direct contact to the application site should not pose a risk to adults. However, for children such contact might still result in serious exposure to fentanyl. Therefore, **special precautions should be taken by people whose dogs have been treated with Recuvyra.**

SMALL CHILDREN SHOULD NOT TOUCH THE DOG FOR 72 HOURS (3 days) AFTER RECUVYRA IS APPLIED TO THE DOG. If a small child touches the application site within 72 hours of application, the child's skin that touched the dog (for example, fingers) should not contact the child's mouth, and the skin should be washed with soap and water. If a child orally contacts the application site within 72 hours of application, medical attention should be sought immediately.

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

Any unused veterinary medicinal product or waste material 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

Detailed information on this product is available on the website of the European Medicines Agency (EMA) http://www.ema.europa.eu/.

15. OTHER INFORMATION

Recuvyra is a strong and long-lasting painkiller, and should only be used for major surgery that requires opiate analgesia for a duration of at least 4 days.
Should subsequent surgery be intended in a dog previously treated with Recuvyra, a minimum of a 7 day dosing interval must be observed before administering another dose.
Your veterinarian received a separate information sheet (summary of product characteristics) with more details on the correct and safe administration of Recuvyra.

To help you remember when your dog was given Recuvyra by your veterinarian and how long you should not let children touch your dog in the place where the product was applied, your veterinarian will make a note in the spaces provided below. Keep this package leaflet in a safe place.

This dog was treated on:

Date _____ Time _____

Children should not touch the dog before:

Date _____ Time _____

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

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