1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buprecare Multidose 0.3 mg/ml Solution for Injection for Dogs and Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Buprenorphine (as buprenorphine hydrochloride) 0.3 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorocresol	1.35 mg
Glucose, anhydrous	
Hydrochloric acid (for pH adjustment)	
Water for injection	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

DOGS
Post-operative analgesia.
Potentiation of the sedative effects of centrally-acting agents.

CATS
Post-operative analgesia.

3.3 Contraindications

Do not administer by the intrathecal or peridural route.
Do not use pre-operatively for caesarean section (see Section 3.7).
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species

Use of the veterinary medicinal product in the below circumstances should only be in accordance with the benefit/risk assessment by the responsible veterinarian.

Buprenorphine may occasionally cause significant respiratory depression and, as with other opioid drugs, care should be taken when treating animals with impaired respiratory function or animals that are receiving drugs that can cause respiratory depression.

Buprenorphine should be used with caution in animals with impaired liver function, especially biliary tract disease, as the substance is metabolised by the liver and its intensity and duration of action may be affected in some animals.

In cases of renal, cardiac or hepatic dysfunction, or shock, there may be greater risk associated with the use of the product. Safety has not been fully evaluated in clinically compromised cats.

The safety of buprenorphine has not been demonstrated in animals less than 7 weeks of age.

Repeated administration earlier than the recommended repeat interval suggested in Section 3.9 is not recommended.

Long-term safety of buprenorphine in cats has not been investigated beyond 5 consecutive days of administration.

The effect of an opioid on head injury is dependent on the type and severity of the injury and the respiratory support supplied.

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

Wash hands/affected area thoroughly after any accidental spillage.

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypertension Tachycardia Sedation[1]
Undetermined frequency (cannot be	Hypersalivation

estimated from the available data):	Bradycardia Hypothermia Agitation Dehydration Miosis Respiratory depression[2]

[1] May occur when used to provide analgesia at dose levels higher than those recommended.
[2] Significant, see section 3.5.

Cats:

Common (1 to 10 animals / 100 animals treated):	Mydriasis Euphoria (excessive purring, pacing, rubbing)[1]
Rare (1 to 10 animals / 10,000 animals treated):	Sedation[2]
Undetermined frequency (cannot be estimated from the available data):	Respiratory depression[3]

[1] Usually resolve within 24 hours.
[2] May occur when used to provide analgesia at dose levels higher than those recommended.
[3] Significant, see section 3.5.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Laboratory studies in rats have not produced any evidence of a teratogenic effect. However, these studies have shown post-implantation losses and early foetal deaths. Although post-implantation losses and early peri-natal deaths were observed, these may have resulted from a reduction in parental body condition during gestation and in post-natal care owing to sedation of the mothers. As reproductive toxicity studies have not been conducted in the target species, use only according to the benefit/risk assessment by the responsible veterinarian.

The veterinary medicinal product should not be used pre-operatively in cases of caesarean section, due to the risk of respiratory depression in the offspring periparturiently and should only be used post-operatively with special care (see section on lactation below).

Lactation:
Studies in lactating rats have shown that, after intramuscular administration of buprenorphine, concentrations of unchanged buprenorphine in the milk equalled or exceeded that in the plasma. It is likely that buprenorphine will be excreted in the milk of other species: Use only according to the benefit/risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Buprenorphine may cause some drowsiness, which may be potentiated by other centrally-acting agents,

including tranquillisers, sedatives and hypnotics.

There is evidence in humans to indicate that therapeutic doses of buprenorphine do not reduce the analgesic efficacy of standard doses of an opioid agonist, and that when buprenorphine is employed within the normal therapeutic range, standard doses of opioid agonist may be administered before the effects of the former have ended without compromising analgesia. However, it is recommended that buprenorphine is not used in conjunction with morphine or other opioid-type analgesics, e.g. etorphine, fentanyl, pethidine, methadone, papaveretum or butorphanol.

Buprenorphine has been used with acepromazine, alphaxalone/alphadalone, atropine, dexmedetomidine, halothane, isoflurane, ketamine, medetomidine, propofol, sevoflurane, thiopentone and xylazine. When used in combination with sedatives, depressive effects on heart rate and respiration may be augmented.

3.9 Administration routes and dosage

Administration: Intramuscular or intravenous use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Species	Post-Operative Analgesia	Potentiation of Sedation
Dogs	10–20 µg per kg (0.3–0.6 ml per 10 kg) For further pain relief, repeat if necessary after 3–4 hours with 10 µg per kg or 5–6 hours with 20 µg per kg.	10–20 µg per kg (0.3–0.6 ml per 10 kg).
Cats	10–20 µg per kg (0.3–0.6 ml per 10 kg), repeated if necessary, once, after 1-2 hours.	-

While sedative effects are present by 15 minutes after administration, analgesic activity becomes apparent after approximately 30 minutes. To ensure that analgesia is present during surgery and immediately on recovery, the product should be administered pre-operatively 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. The reduction will depend on the degree of sedation required, the individual animal, the type of other agents included in premedication and how anaesthesia is to be induced and maintained. It may also be possible to reduce the amount of inhalational anaesthetic used.

Animals administered opioids possessing sedative and analgesic properties may show variable responses. Therefore, the responses of individual animals should be monitored and subsequent doses should be adjusted accordingly. In some cases repeat doses may fail to provide additional analgesia. In these cases, consideration should be given to using a suitable injectable NSAID.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

The vial seal may be punctured up to a maximum of 30 times.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of over dosage, supportive measures should be instituted and if appropriate, naloxone or respiratory stimulants may be used.

When administered at overdose to dogs, buprenorphine may cause lethargy. At very high doses, bradycardia and miosis may be observed.

In toxicological studies of buprenorphine hydrochloride in dogs, biliary hyperplasia was observed after oral administration for one year at dose levels of 3.5 mg/kg/day and above. Biliary hyperplasia was not observed following daily intramuscular injection of dose levels up to 2.5 mg/kg/day for 3 months. This is well in excess of any clinical dose regimen in the dog.

Naloxone may be of benefit in reversing reduced respiratory rate and respiratory stimulants such as doxapram are also effective in man. 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. Volunteer studies in man have indicated that opiate antagonists may not fully reverse the effects of buprenorphine.

Please also refer to sections 3.5 and 3.6 of this SPC.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

3.12 Withdrawal period(s)

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code QN02AE01

4.2 Pharmacodynamics

In summary buprenorphine is a potent, long-acting analgesic acting at opiate receptors in the central nervous system. Buprenorphine can potentiate the effects of other centrally-acting agents, but unlike most opiates, buprenorphine has, at clinical doses, only a limited sedative effect of its own.

Buprenorphine exerts its analgesic effect via high affinity binding to various subclasses of opiate receptors, particularly μ, in the central nervous system. At clinical dose levels for analgesia, buprenorphine binds to opiate receptors with high affinity and high receptor avidity, such that its dissociation from the receptor site is slow, as demonstrated in *in vitro* studies. This property of buprenorphine could account for its longer duration of activity when compared to morphine. In circumstances where excessive opiate agonist is already bound to opiate receptors, buprenorphine can exert a narcotic antagonistic activity as a consequence of its high-affinity opiate receptor binding, such that an antagonistic effect on morphine equivalent to naloxone has been demonstrated.

Buprenorphine has little effect on gastro-intestinal motility.

4.3 Pharmacokinetics

When given parenterally, the product may be administered by intramuscular or intravenous injection.

Buprenorphine is rapidly absorbed after intramuscular injection in various animal species and man. The substance is highly lipophilic and the volume of distribution in body compartments is large. Pharmacological effects (e.g. mydriasis) may occur within minutes of administration and signs of sedation normally appear by 15 minutes. Analgesic effects appear around 30 minutes after injection with peak effects usually being observed at about 1–1.5 hours.

Following intramuscular administration to cats, the mean terminal half-life was 6.3 hours and the clearance was 23 ml/kg/min, however, there was considerable inter-cat variability in pharmacokinetic parameters.

Following intravenous administration to dogs at a 20 µg/kg dose, the mean terminal half-life was 9 hours and the mean clearance was 24 ml/kg/min, however there is considerable inter-dog variability in pharmacokinetic parameters.

Combined pharmacokinetic and pharmacodynamic studies have demonstrated a marked delay between plasma concentrations and analgesic effect. Plasma concentrations of buprenorphine should not be used to formulate individual animal dosage regimens, which should be determined by monitoring of the patient's response.

The major route of excretion in all species except the rabbit (where urinary excretion predominates) is the faeces. Buprenorphine undergoes N-dealkylation and glucuronide conjugation by the intestinal wall and the liver and its metabolites are excreted via the bile into the gastro-intestinal tract.

In tissue distribution studies carried out in rats and rhesus monkeys, the highest concentrations of drug-related material were observed in liver, lung and brain. Peak levels occurred rapidly and declined to low levels by 24 hours after dosing.

Protein binding studies in rats have shown that buprenorphine is highly bound to plasma proteins, principally to alpha and beta globulins.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25°C.
Keep the vial in the outer carton in order to protect from light.
Do not refrigerate or freeze.

5.4 Nature and composition of immediate packaging

Presented in a 10 ml amber Type I glass vial with a bromobutyl rubber stopper and flip-off aluminium cap and a carton box.

Pack size: 1 vial with 10 ml solution for injection.

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

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. MARKETING AUTHORISATION HOLDER

Ecuphar NV

7. MARKETING AUTHORISATION NUMBER

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF PRODUCT CHARACTERISTICS

MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buprecare Multidose 0.3 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Buprenorphine (as buprenorphine hydrochloride) 0.3 mg/ml.

3. PACKAGE SIZE

10 ml

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intramuscular or intravenous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp: {mm/yyyy}
Once broached, use within 28 days

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Keep the vial in the outer carton in order to protect from light.
Do not refrigerate or freeze.

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

Ecuphar
An Animalcare Company

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Buprecare Multidose

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Buprenorphine (as buprenorphine hydrochloride) 0.3 mg/ml.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Buprecare Multidose 0.3 mg/ml Solution for Injection for Dogs and Cats

2. Composition

Each ml contains:

Active substance:
Buprenorphine 0.3 mg (as buprenorphine hydrochloride).

Excipient:
Chlorocresol 1.35 mg

Clear, colourless solution.

3. Target species

Dogs and cats.

4. Indications for use

DOGS:
Post-operative analgesia.
Potentiation of the sedative effects of centrally- acting agents.

CATS:
Post-operative analgesia.

5. Contraindications

Do not administer by the intrathecal or peridural route.
Do not use pre-operatively for caesarean section. Please refer to section "Special warnings, pregnancy and lactation".
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:

Use of the veterinary medicinal product in the below circumstances should only be in accordance with the benefit/risk assessment by the responsible veterinarian.

Buprenorphine may occasionally cause significant respiratory depression and, as with other opioid drugs, care should be taken when treating animals with impaired respiratory function or animals that are receiving drugs that can cause respiratory depression.

Buprenorphine should be used with caution in animals with impaired liver function, especially biliary tract disease, as the substance is metabolised by the liver and its intensity and duration of action may be affected in some animals.

In cases of renal, cardiac or hepatic dysfunction, or shock, there may be greater risk associated with the use of the product. Safety has not been fully evaluated in clinically compromised cats.
The safety of buprenorphine has not been demonstrated in animals less than 7 weeks of age.

Repeated administration earlier than the recommended repeat interval suggested in Section "Dosage for each species, routes and method of administration" is not recommended.

Long-term safety of buprenorphine in cats has not been investigated beyond 5 consecutive days of administration.

The effect of an opioid on head injury is dependent on the type and severity of the injury and the respiratory support supplied.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands/affected area thoroughly after any accidental spillage.

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.

Pregnancy and lactation:
Laboratory studies in rats have not produced any evidence of a teratogenic effect. However, these studies have shown post-implantation losses and early foetal deaths. Although post-implantation losses and early peri-natal deaths were observed, these may have resulted from a reduction in parental body condition during gestation and in post-natal care owing to sedation of the mothers. As reproductive toxicity studies have not been conducted in the target species, use only according to the benefit-risk assessment by the responsible veterinarian.

The product should not be used pre-operatively in cases of caesarean section, due to the risk of respiratory depression in the offspring periparturiently and should only be used post-operatively with special care (see section on lactation below).

Studies in lactating rats have shown that, after intramuscular administration of buprenorphine, concentrations of unchanged buprenorphine in the milk equalled or exceeded that in the plasma. It is likely that buprenorphine will be excreted in the milk of other species: Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Buprenorphine may cause some drowsiness, which may be potentiated by other centrally-acting agents, including tranquillisers, sedatives and hypnotics.

There is evidence in humans to indicate that therapeutic doses of buprenorphine do not reduce the analgesic efficacy of standard doses of an opioid agonist, and that when buprenorphine is employed within the normal therapeutic range, standard doses of opioid agonist may be administered before the effects of the former have ended without compromising analgesia. However, it is recommended that buprenorphine is not used in conjunction with morphine or other opioid-type analgesics, e.g. etorphine, fentanyl, pethidine, methadone, papaveretum or butorphanol.

Buprenorphine has been used with acepromazine, alphaxalone/alphadalone, atropine, dexmedetomidine, halothane, isoflurane, ketamine, medetomidine, propofol, sevoflurane, thiopentone and xylazine. When used in combination with sedatives, depressive effects on heart rate and respiration may be augmented.

Overdose:
In case of overdosage, supportive measures should be instituted and if appropriate, naloxone or respiratory stimulants may be used.

When administered at overdose to dogs, buprenorphine may cause lethargy. At very high doses, bradycardia and miosis may be observed.

In toxicological studies of buprenorphine hydrochloride in dogs, biliary hyperplasia was observed after oral administration for one year at dose levels of 3.5 mg/kg/day and above. Biliary hyperplasia was not observed following daily intramuscular injection of dose levels up to 2.5 mg/kg/day for 3 months. This is well in excess of any clinical dose regimen in the dog.

Naloxone may be of benefit in reversing reduced respiratory rate and respiratory stimulants such as doxapram are also effective in man. 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. Volunteer studies in man have indicated that opiate antagonists may not fully reverse the effects of buprenorphine. Please refer to "Special precautions for safe use in the target species" and to section "Adverse events".

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

Special restrictions for use and special conditions for use:

7. **Adverse events**

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypertension (high blood pressure) Tachycardia (rapid heart rate) Sedation[1]
Undetermined frequency (cannot be estimated from the available data):	Hypersalivation Bradycardia (slow heart rate) Hypothermia (low body temperature) Agitation Dehydration Miosis (constricted pupils) Respiratory depression[2]

[1] May occur when used to provide analgesia at dose levels higher than those recommended.
[2] Significant, see section "special warnings".

Cats:

Common (1 to 10 animals / 100 animals treated):	Mydriasis (dilated pupils) Euphoria (excessive purring, pacing, rubbing)[1]
Rare (1 to 10 animals / 10,000 animals	Sedation[2]

treated):	
Undetermined frequency (cannot be estimated from the available data):	Respiratory depression[3]

[1] Usually resolve within 24 hours.
[2] May occur when used to provide analgesia at dose levels higher than those recommended.
[3] Significant, see section "special warnings".

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

For intramuscular or intravenous use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Species	Post-Operative Analgesia	Potentiation of Sedation
Dogs	10–20 µg per kg (0.3–0.6 ml per 10 kg) For further pain relief, repeat if necessary after 3–4 hours with 10 µg per kg or 5–6 hours with 20 µg per kg.	10–20 µg per kg (0.3–0.6 ml per 10 kg).
Cats	10–20 µg per kg (0.3–0.6 ml per 10 kg), repeated if necessary, once, after 1-2 hours.	-

While sedative effects are present by 15 minutes after administration, analgesic activity becomes apparent after approximately 30 minutes. To ensure that analgesia is present during surgery and immediately on recovery, the product should be administered pre-operatively 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. The reduction will depend on the degree of sedation required, the individual animal, the type of other agents included in premedication and how anaesthesia is to be induced and maintained. It may also be possible to reduce the amount of inhalational anaesthetic used.

Animals administered opioids possessing sedative and analgesic properties may show variable responses. Therefore, the responses of individual animals should be monitored and subsequent doses should be adjusted accordingly. In some cases repeat doses may fail to provide additional analgesia. In these cases, consideration should be given to using a suitable injectable NSAID.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

The vial seal may be punctured up to a maximum of 30 times.

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 store above 25°C.
Keep the vial in the outer carton in order to protect from light.
Do not refrigerate or freeze.
Shelf life after first opening the immediate packaging: 28 days.
Do not use this veterinary medicinal product after the expiry date stated on the label and the carton after "Exp".
The expiry date refers to the last day of that month.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, 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 label.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack size:
1 vial with 10ml solution for injection.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:
Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

Manufacturer responsible for batch release:
Produlab Pharma BV
Forrellenweg 16
NL 4941-SJ Raamsdonksveer

The Netherlands

Local representatives and contact details to report suspected adverse events:

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

17. **Other information**

Buprenorphine is a potent long-acting analgesic acting at opioid receptor sites in the central nervous system (CNS). Buprenorphine can potentiate the effects of other centrally-acting agents, but unlike most opiates, buprenorphine has, at clinical doses, only a limited sedative effect of its own. Buprenorphine exerts its analgesic effect via high-affinity binding to various subclasses of opiate receptors, particularly μ, in the CNS.
At clinical dose levels for analgesia, buprenorphine binds to opiate receptors with high affinity and high receptor avidity, such that its dissociation from the receptor is slow, as demonstrated in *in vitro* studies. This property of buprenorphine could account for its longer duration of activity when compared to morphine. In circumstances where excessive opiate agonist is already bound to opiate receptors, buprenorphine can exert a narcotic antagonistic activity as a consequence of its high-affinity opiate receptor binding, such that an antagonistic effect on morphine equivalent to naloxone has been demonstrated.

Buprenorphine is rapidly absorbed after intra-muscular injection in various animal species and in man. Analgesic effects appear around 30 minutes after injection with peak effects usually being observed at about 1–1.5 hours.

Combined pharmacokinetic and pharmacodynamic studies in cats have demonstrated a marked delay between plasma concentrations and analgesic effect. Plasma concentrations of buprenorphine should not be used to formulate individual animal dosage regimes, which should be determined by monitoring of the patient's response.

Buprenorphine has little effect on gastro-intestinal motility.