ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ButorVet 10 mg/ml Solution for Injection
Kipurgesic 10 mg/ml Solution for Injection (FI)
Kipurgesic Vet 10 mg/ml Solution for Injection (SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Butorphanol 10 mg
(as tartrate)
(Equivalent to 14.58 mg of butorphanol tartrate.)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzethonium chloride	0.1 mg
Citric acid monohydrate	
Sodium Citrate	
Sodium Chloride	
Water for injections	

Clear, colourless to almost colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses, dogs and cats.

3.2 Indications for use for each target species

HORSE

As an analgesic:
Relief of abdominal pain caused by colic of gastrointestinal origin.

As a sedative (in combination)
For sedation in combination with certain α2-adrenoceptor agonists (detomidine, romifidine). For therapeutic and diagnostic measures such as minor surgical procedures on the standing horse.

DOG

As an analgesic
Relief of mild to moderate visceral pain and mild to moderate pain after soft tissue surgery.

As a sedative (in combination)
For deep sedation in combination with medetomidine.

As a pre-anaesthetic
Pre-anaesthetic use of the product has resulted in a dose related reduction in the dose of induction of anaesthetic agents.

As an anaesthetic (in combination)
As part of anaesthesia in combination with medetomidine and ketamine.

CAT

As an analgesic
To alleviate moderate postoperative pain after soft tissue surgery and minor surgical procedures.

As a sedative (in combination)
For deep sedation in combination with medetomidine.

As an anaesthetic (in combination)
As part of anaesthesia in combination with medetomidine and ketamine.

3.3 Contraindications

All target species
Do not use in cases hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of severe dysfunction of liver or/and kidney.
Do not use in cases of cerebral injury or organic brain lesions as well in animals with obstructive respiratory disease, heart dysfunction or spastic conditions.

HORSE
Butorphanol/detomidine hydrochloride combination:
Do not use in horses with a pre-existing cardiac dysrhythmia or bradycardia.
Do not use in cases of colic associated with impaction as the combination will cause a reduction in gastrointestinal motility.
Do not use in horses with emphysema due to a possible depressive effect on the respiratory system.

See also section 3.7.

3.4 Special warnings

Butorphanol is intended for use in situations where short-lasting analgesia (horse, dog) or a short to medium persistence of analgesia (cat) is required.

The response to butorphanol may vary individually in cats. In case of lack of proper analgesic effect another analgesic should be used.

Increasing of the dose may not increase the intensity or the duration of analgesia in cats

3.5 Special precautions for use

Special precautions for safe use in the target species:
The safety of the product in puppies, kitten and foals has not been established. Therefore, in these animals the product should only be used according to a benefit-risk assessment by the responsible veterinarian.

Due to its antitussive properties, butorphanol may lead to an accumulation of mucous in the respiratory tract (see section 3.8). Therefore, in animals with respiratory diseases associated with increased mucous production, butorphanol should only be used after benefit-risk assessment by the responsible veterinary surgeon.

Routine cardiac auscultation should be performed prior to use in combination with α2-adrenoceptor agonists. The combination of butorphanol and α2-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 combination of butorphanol and an α2-adrenoceptor agonist should be used with caution in animals with mild to moderate dysfunction of the liver or the kidney.
Take care when administering butorphanol to animals concomitantly treated with central nervous depressants (see section 3.8).

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

DOG
When administering as an intravenous injection, do not inject rapidly as a bolus.
In dogs with MDR1 mutation reduce dose by 25-50%.

CAT
Cats should be weighed to ensure that the correct dose is calculated. Use of either insulin syringes or 1 ml graduated syringes is recommended.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Butorphanol has opioid-like activity. The most frequent adverse effects of butorphanol in humans are drowsiness, sweating, nausea, dizziness and vertigo and these may occur following unintended self-injection.
Precautions should be taken to avoid accidental self-injection with this potent veterinary medicinal product. If accidental self-injection occurs, seek immediate medical attention showing a copy of the package leaflet or the label to the physician. DO NOT DRIVE, since sedation, dizziness and confusion may occur. Effects can be reversed by the administration of an opioid antagonist (e.g. naloxone).

Accidental spillage on the skin and eyes should be washed immediately with water.

3.6 Adverse events
Horses, dogs, cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain[1]

[1] Following intramuscular injection

Horses:

Very common (>1 animal / 10 animals treated):	Ataxia[2,3]
Common (1 to 10 animals / 100 animals treated):	Sedation (mild)[4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorder NOS[5] Pacing[6] Cardiac depression[7]

[1] Following intramuscular injection
[2] Mild; may persist for 3 to 10 minutes.
[3] Mild to severe ataxia may be encountered in combination with detomidine, but clinical studies have shown that horses are unlikely to collapse. Normal precautions should be observed to prevent self-injury.

[4] Following the administration of the product as a sole agent, may occur in approximately 15% of horses
[5] may also have adverse effects on gastrointestinal tract motility in horses, although there is no decrease in gastrointestinal transit time. These effects are dose-related and generally minor and transient.
[6] may cause excitatory locomotor effects (pacing)
[7] When used in combination with α2-adrenoceptor agonists, cardiopulmonary system depression may occur very rarely. In these cases, fatality may occur rarely.

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Anorexia[8] Ataxia[8] Diarrhoea[8]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Respiratory depression[9] Cardiac depression[9] Reduction in gastrointestinal motility

[8] Transient
[9] a decrease in respiratory rate, development of bradycardia and a decrease in diastolic pressure) may occur. The degree of depression is dose dependent.

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Excitation Anxiety Disorientation Dysphoria Mydriasis Respiratory depression

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

The use of butorphanol is not recommended during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

When butorphanol is used in combination with particular sedatives such as adrenergic α2-agonists (romifidine or detomidine in horses, medetomidine in dogs and cats) synergistic effects occur which require a reduction in butorphanol dose (see section 3.9).

Butorphanol has antitussive properties and should not be used in combination with an expectorant, as this can lead to accumulation of mucus in the respiratory tract.

Butorphanol has antagonistic properties towards mu opiate receptors (μ) and can remove the analgesic effect of pure μ-opioid agonists (e.g. morphine / oxymorphine) in animals that have already received these agents.

The concomitant use of other central nervous system sedatives is expected to potentiate the effects of butorphanol, so that these drugs should be used with caution. A reduced dose of butorphanol should be given when these agents are administered simultaneously.

See also section 3.5.

3.9 Administration routes and dosage

Horse: intravenous use (IV).
Dog and Cat: intravenous use (IV), subcutaneous use (SC) and intramuscular use(IM).
When administering as an intravenous injection, do not inject as a bolus.
If repeat SC or IM administrations are required, use different injection sites.
The closures should not be punctured more than 30 times.

HORSE

As an analgesic
Monotherapy:
0.1 mg of butorphanol/kg bodyweight i.e. 1 ml of product/100 kg bw IV. The dose may be repeated as required. Analgesic effects are seen within 15 minutes of injection.

As a sedative
With detomidine:
Detomidine hydrochloride: 0.012 mg/kg bw IV, followed within 5 minutes by
Butorphanol: 0.025 mg/kg bw i.e. 0.25 ml/100 kg bw IV

With romifidine:
Romifidine: 0.04 - 0.12 mg/kg bw IV, followed within 5 minutes by
Butorphanol: 0.02 mg/kg bw i.e. 0.2 ml/100 kg bw IV.

DOG

As an analgesic
Monotherapy:
0.2-0.3 mg butorphanol/kg bw i.e. 0.02-0.03 ml of product/kg bw IV, IM or SC injection.
Administer 15 minutes before terminating anaesthesia to provide analgesia in the recovery phase.
Repeat dose as required.

As a sedative
With medetomidine:
Butorphanol: 0.1 mg/kg bw i.e. 0.01 ml/kg bw IV or IM
Medetomidine: 0.01-0.025 mg/kg bw IV or IM.
Allow 20 minutes for sedation to develop before commencing the procedure.

As a pre-anaesthetic
Monotherapy for canine analgesia:
0.1-0.2 mg butorphanol/kg bw i.e. 0.01-0.02 ml of product/kg bw IV, IM or SC given 15 minutes prior to induction.

As an anaesthetic
In combination with medetomidine and ketamine:
Butorphanol: 0.1 mg/kg bw i.e. 0.01 ml/kg bw IM
Medetomidine: 0.025 mg/kg bw IM, followed after 15 minutes by
Ketamine: 5 mg/kg bw IM.
It is not advisable to reverse this combination in the dog with atipamezole.

As a pre-anaesthetic
In combination with acepromazine:
Butorphanol: 0.1 – 0.2mg/kg bw i.e. 0.01-0.02ml/kg bw IM or IV
Acepromazine: 0.02mg/kg of bw
Allow at least 20 minutes for onset of action but the time between premedication and induction is flexible from 20-120 minutes..

CAT

As an analgesic
Pre-operative:
0.4 mg butorphanol/kg bw i.e. 0.04 ml of product/ kg bw IM or SC
Administer 15-30 minutes prior to the administration of IV induction with anaesthetic agents.
Administer 5 minutes before induction with IM induction anaesthetic agents such as combinations of IM acepromazine/ketamine or xylazine/ketamine. See also section 4.2 for duration of analgesia.

Post-operative:
Administer 15 minutes before terminating anaesthesia to provide analgesia in the recovery phase:
either 0.4 mg butorphanol/kg bw i.e. 0.04 ml of product /kg bw SC or IM
or 0.1 mg butorphanol /kg bw i.e. 0.01 ml of product /kg bw IV.

As a sedative
With medetomidine:
Butorphanol: 0.4 mg butorphanol/kg bw i.e. 0.04 ml/kg bw IM or SC.
Medetomidine: 0.05 mg/kg bw SC.
Additional local anaesthesia should be used for wound suturing.

As an anaesthetic
In combination with medetomidine and ketamine:

IM administration:
Butorphanol: 0.4 mg butorphanol/kg bw i.e. 0.04 ml/kg bw IM
Medetomidine: 0.08 mg/kg bw IM.
Ketamine: 5 mg/kg bw IM.

IV administration:
Butorphanol: 0.1 mg butorphanol/kg bw i.e. 0.01 ml/kg bw IV.
Medetomidine: 0.04 mg/kg bw IV.
Ketamine: 1.25-2.5 mg/kg bw IV (depending on depth of anaesthesia required).

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

The most important result of overdosage is respiratory depression. This can be reversed with naloxone. Other possible signs of overdose in horses include restlessness / excitability, muscle tremor, ataxia, hypersalivation, decreased gastrointestinal motility and convulsions. In cats, the main signs of overdose are disrupted coordination, salivation and mild convulsions. To reverse the effect of combinations, atipamezole may be used, except when a combination of butorphanol, medetomidine, and ketamine has been used intramuscularly to produce anaesthesia in the dog. In this case, atipamezole should not be used. See “Amounts to be administered and administration route” for details of doses.

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

Not applicable.

3.12 Withdrawal periods

Horses:
Meat and offal: Zero days.
Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QNO2AF01

4.2 Pharmacodynamics

Butorphanol tartrate is a centrally acting analgesic. Its action is agonist-antagonist at the opiate receptors in the central nervous system; agonist at the kappa (k) opioid receptor subtype and antagonist at the mu (μ) receptor subtype. The kappa (k) receptors control analgesia, sedation without depression of cardiopulmonary system and body temperature, whereas the mu (μ) receptors control supraspinal analgesia, sedation and depression of cardiopulmonary system and body temperature. The agonist component of butorphanol activity is ten times more potent than the antagonist component.

Onset and duration of analgesia:
Analgesia generally occurs within 15 minutes following administration in horse (DK/V/0124/001/DC), 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. 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.

4.3 Pharmacokinetics

In the horse, butorphanol has a high clearance (on average 1.3 L/h.kg) after intravenous administration. It has a short terminal half-life (mean < 1 hour), indicating that 97% of a dose will be eliminated after intravenous administration in, on average, less than 5 hours.
In the dog, butorphanol administered by the intramuscular route has a high clearance (around 3.5 L/h.kg). It has a short terminal half-life (mean < 2 hours), indicating that 97% of a dose will be eliminated after intramuscular administration in, on average, less than 10 hours. Repeated dose pharmacokinetics and the pharmacokinetics following intravenous administration have not been studied.
In the cat, butorphanol administered by the subcutaneous route has a low clearance (< 1.32 L/h.kg). It has a relatively long terminal half-life (around 6 hours) indicating that 97% of the dose will be eliminated in approximately 30 hours. Repeated dose pharmacokinetics have not been studied.
Butorphanol is metabolized extensively in the liver and excreted in the urine. The volume of distribution is large, suggesting wide distribution into tissue.

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: 4 years
Shelf-life after first opening the immediate packaging: 30 days.

5.3 Special precautions for storage

Keep the container in the outer carton.

5.4 Nature and composition of immediate packaging

Type I amber glass multi-dose vials, with chlorobutyl rubber stoppers secured with an aluminium cap.

Package sizes:
Cardboard box containing 1 vial of 10 ml.
Cardboard box containing 1 vial of 20 ml.

Not all pack sizes may be marketed.

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. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing ltd.,

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

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 BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ButorVet 10 mg/ml Solution for Injection
Kipurgesic 10 mg/ml Solution for Injection (FI)
Kipurgesic Vet 10 mg/ml Solution for Injection (SE)

2. STATEMENT OF ACTIVE SUBSTANCES

Butorphanol 10 mg/ml

3. PACKAGE SIZE

10 ml
20 ml

4. TARGET SPECIES

Horses, dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Horses: Intravenous use
Dogs/cats: intravenous, intramuscular, or subcutaneous use

7. WITHDRAWAL PERIODS

Withdrawal period:
Horses:
Meat and offal: Zero days.
Milk: Zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 30 days.

9. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton.

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

Chanelle Pharmaceuticals Manufacturing ltd.,

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ButorVet 10 mg/ml Solution for Injection
Kipurgesic 10 mg/ml Solution for Injection (FI)
Kipurgesic Vet 10 mg/ml Solution for Injection (SE)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Butorphanol 10 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use by……

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ButorVet 10 mg/ml Solution for Injection
Kipurgesic 10 mg/ml Solution for Injection (FI)
Kipurgesic Vet 10 mg/ml Solution for Injection (SE)

2. Composition

Each ml contains:

Active substance
Butorphanol 10 mg
(as tartrate)
(Equivalent to 14.58 mg of butorphanol tartrate.)
Excipient:
Benzethonium chloride 0.1 mg

Clear, colourless to almost colourless solution.

3. Target species

Horses, dogs and cats.

4. Indications for use

HORSE

As an analgesic
Relief of abdominal pain caused by colic of gastrointestinal origin.

As a sedative (in combination)
For sedation in combination with certain α2-adrenoceptor agonists (detomidine, romifidine). For therapeutic and diagnostic measures such as minor surgical procedures on the standing horse.

DOG

As an analgesic
Relief of mild to moderate visceral pain and mild to moderate pain after soft tissue surgery.

As a sedative (in combination)
For deep sedation in combination with medetomidine.

As a pre-anaesthetic
Pre-anaesthetic use of the product has resulted in a dose related reduction in the dose of induction of anaesthetic agents.

As an anaesthetic (in combination)
As part of anaesthesia in combination with medetomidine and ketamine.

CAT

As an analgesic
To alleviate moderate postoperative pain after soft tissue surgery and minor surgical procedures.

As a sedative (in combination)
For deep sedation in combination with medetomidine.

As an anaesthetic (in combination)
As part of anaesthesia in combination with medetomidine and ketamine.

5. Contraindications

All target species
Do not use in cases hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of severe dysfunction of liver or/and kidney.
Do not use in cases of cerebral injury or organic brain lesions as well in animals with obstructive respiratory disease, heart dysfunction or spastic conditions.

HORSE
Butorphanol/detomidine hydrochloride combination:
Do not use in horses with a pre-existing cardiac dysrhythmia or bradycardia.
Do not use in cases of colic associated with impaction as the combination will cause a reduction in gastrointestinal motility.
Do not use in horses with emphysema due to a possible depressive effect on the respiratory system.

See also section 6

6. Special warnings

Special warnings:
Butorphanol is intended for use in situations where short-lasting analgesia (horse, dog) or a short to medium persistence of analgesia (cat) is required.

The response to butorphanol may vary individually in cats. In case of lack of proper analgesic effect another analgesic should be used.
Increasing of the dose may not increase the intensity or the duration of analgesia in cats.

Special precautions for safe use in the target species:
Before using any combinations consult the contraindications, withdrawal periods and warnings that appear on the other products' SPCs.

The safety of the product in puppies, kitten and foals has not been established. Therefore, in these animals the product should only be used according to a benefit-risk assessment by the responsible veterinarian.

Due to its antitussive properties, butorphanol may lead to an accumulation of mucous in the respiratory tract (see section 3.8). Therefore, in animals with respiratory diseases associated with increased mucous production, butorphanol should only be used after benefit-risk assessment by the responsible veterinary surgeon.

Routine cardiac auscultation should be performed prior to use in combination with α2-adrenoceptor agonists. The combination of butorphanol and α2-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 combination of butorphanol and an α2-adrenoceptor agonist should be used with caution in animals with mild to moderate dysfunction of the liver or the kidney.
Take care when administering butorphanol to animals concomitantly treated with central nervous depressants.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Butorphanol has opioid-like activity. The most frequent adverse effects of butorphanol in humans are drowsiness, sweating, nausea, dizziness and vertigo and these may occur following unintended self-injection.
Precautions should be taken to avoid accidental self-injection with this potent veterinary medicinal product. If accidental self-injection occurs, seek immediate medical attention showing a copy of the package leaflet or the label to the physician. DO NOT DRIVE, since sedation, dizziness and confusion may occur. Effects can be reversed by the administration of an opioid antagonist (e.g. naloxone).

Accidental spillage on the skin and eyes should be washed immediately with water.

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

Interaction with other medicinal products and other forms of interaction:
When butorphanol is used in combination with particular sedatives such as adrenergic α2-agonists (romifidine or detomidine in horses, medetomidine in dogs and cats) synergistic effects occur which require a reduction in butorphanol dose (see section 3.9).

Butorphanol has antitussive properties and should not be used in combination with an expectorant, as this can lead to accumulation of mucus in the respiratory tract.

Butorphanol has antagonistic properties towards mu opiate receptors (μ) and can remove the analgesic effect of pure μ-opioid agonists (e.g. morphine / oxymorphine) in animals that have already received these agents.

The concomitant use of other central nervous system sedatives is expected to potentiate the effects of butorphanol, so that these drugs should be used with caution. A reduced dose of butorphanol should be given when these agents are administered simultaneously.

Overdose:
The most important result of overdosage is respiratory depression. This can be reversed with naloxone. Other possible signs of overdose in horses include restlessness / excitability, muscle tremor, ataxia, hypersalivation, decreased gastrointestinal motility and convulsions. In cats, the main signs of overdose are disrupted coordination, salivation and mild convulsions. To reverse the effect of combinations, atipamezole may be used, except when a combination of butorphanol, medetomidine, and ketamine has been used intramuscularly to produce anaesthesia in the dog. In this case, atipamezole should not be used. See “Amounts to be administered and administration route” for details of doses.

Special restrictions for use and special conditions for use:
Not applicable.

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:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain[1]

[1] Following intramuscular injection

Horses:

Very common (>1 animal / 10 animals treated):	Ataxia[2,3]
Common (1 to 10 animals / 100 animals treated):	Sedation (mild)[4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastrointestinal tract motility[5] Pacing[6] Cardiac depression [7]

[1] Following intramuscular injection
[2] Mild; may persist for 3 to 10 minutes.
[3] Mild to severe ataxia may be encountered in combination with detomidine, but clinical studies have shown that horses are unlikely to collapse. Normal precautions should be observed to prevent self-injury.
[4] Following the administration of the product as a sole agent, may occur in approximately 15% of horses
[5] may also have adverse effects on gastrointestinal tract motility in horses, although there is no decrease in gastrointestinal transit time. These effects are dose-related and generally minor and transient.
[6] may cause excitatory locomotor effects (pacing)
[7] When used in combination with α2-adrenoceptor agonists, cardiopulmonary system depression may occur very rarely. In these cases, fatality may occur rarely.

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Anorexia[8] Ataxia[8] Diarrhoea[8]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Respiratory depression[9] Cardiac depression[9] Reduction in gastrointestinal motility

[8] Transient
[9] a decrease in respiratory rate, development of bradycardia and a decrease in diastolic pressure) may occur. The degree of depression is dose dependent.

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Excitation Anxiety Disorientation Dysphoria Mydriasis Respiratory depression

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

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

Horse: intravenous use (IV).
Dog and Cat: intravenous use (IV), subcutaneous use (SC) and intramuscular use(IM).
When administering as an intravenous injection, do not inject as a bolus.
If repeat SC or IM administrations are required, use different injection sites.
The closures should not be punctured more than 30 times.

HORSE

As an analgesic
Monotherapy:
0.1 mg of butorphanol/kg bodyweight i.e. 1 ml of product/100 kg bw IV. The dose may be repeated as required. Analgesic effects are seen within 15 minutes of injection.

As a sedative
With detomidine:
Detomidine hydrochloride: 0.012 mg/kg bw IV, followed within 5 minutes by
Butorphanol: 0.025 mg/kg bw i.e. 0.25 ml/100 kg bw IV

With romifidine:
Romifidine: 0.04 - 0.12 mg/kg bw IV, followed within 5 minutes by
Butorphanol: 0.02 mg/kg bw i.e. 0.2 ml/100 kg bw IV.

DOG

As an analgesic
Monotherapy:
0.2-0.3 mg butorphanol/kg bw i.e. 0.02-0.03 ml of product/kg bw IV, IM or SC injection.
Administer 15 minutes before terminating anaesthesia to provide analgesia in the recovery phase.
Repeat dose as required.

As a sedative
With medetomidine:
Butorphanol: 0.1 mg/kg bw i.e. 0.01 ml/kg bw IV or IM
Medetomidine: 0.01-0.025 mg/kg bw IV or IM.
Allow 20 minutes for sedation to develop before commencing the procedure.

As a pre-anaesthetic
Monotherapy for canine analgesia:
0.1-0.2 mg butorphanol/kg bw i.e. 0.01-0.02 ml of product/kg bw IV, IM or SC given 15 minutes prior to induction.

As an anaesthetic
In combination with medetomidine and ketamine:
Butorphanol: 0.1 mg/kg bw i.e. 0.01 ml/kg bw IM
Medetomidine: 0.025 mg/kg bw IM, followed after 15 minutes by
Ketamine: 5 mg/kg bw IM.
It is not advisable to reverse this combination in the dog with atipamezole.

As a pre-anaesthetic
In combination with acepromazine:
Butorphanol: 0.1 – 0.2mg/kg bw i.e. 0.01-0.02ml/kg bw IM or IV
Acepromazine: 0.02mg/kg of bw
Allow at least 20 minutes for onset of action but the time between premedication and induction is flexible from 20-120 minutes.

CAT

As an analgesic
Pre-operative:
0.4 mg butorphanol/kg bw i.e. 0.04 ml of product/ kg bw IM or SC
Administer 15-30 minutes prior to the administration of IV induction with anaesthetic agents.
Administer 5 minutes before induction with IM induction anaesthetic agents such as combinations of IM acepromazine/ketamine or xylazine/ketamine. See also section 4.2 for duration of analgesia.

Post-operative:
Administer 15 minutes before terminating anaesthesia to provide analgesia in the recovery phase:
either 0.4 mg butorphanol/kg bw i.e. 0.04 ml of product /kg bw SC or IM
or 0.1 mg butorphanol /kg bw i.e. 0.01 ml of product /kg bw IV.

As a sedative
With medetomidine:
Butorphanol: 0.4 mg butorphanol/kg bw i.e. 0.04 ml/kg bw IM or SC.
Medetomidine: 0.05 mg/kg bw SC.
Additional local anaesthesia should be used for wound suturing.

As an anaesthetic
In combination with medetomidine and ketamine:

IM administration:
Butorphanol: 0.4 mg butorphanol/kg bw i.e. 0.04 ml/kg bw IM
Medetomidine: 0.08 mg/kg bw IM.
Ketamine: 5 mg/kg bw IM.

IV administration:
Butorphanol: 0.1 mg butorphanol/kg bw i.e. 0.01 ml/kg bw IV.
Medetomidine: 0.04 mg/kg bw IV.
Ketamine: 1.25-2.5 mg/kg bw IV (depending on depth of anaesthesia required).

9. Advice on correct administration

Dogs: When administering as an intravenous injection, do not inject as a bolus.

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.

Keep the container in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 30 days

12. Special precautions for disposal

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

Package sizes:
Cardboard box containing 1 vial of 10 ml.
Cardboard box containing 1 vial of 20 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Chanelle Pharmaceuticals Manufacturing ltd.,
Loughrea,
Co. Galway,
Ireland
Telephone: +353 (0)91 841788
vetpharmacoviggroup@chanellegroup.ie

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

17. Other information

Not applicable