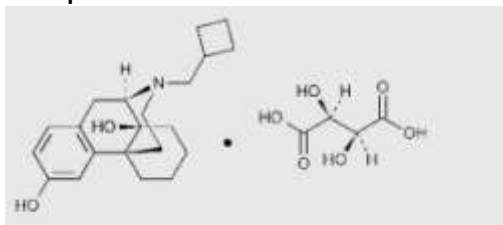


## ILIMUM BUTORGESIC INJECTION

### Description:

Ilium Butorgesic Injection is a clear colourless solution containing butorphanol tartrate as the active constituent. Butorphanol tartrate is a synthetically derived opioid agonist-antagonist analgesic of the phenanthrene series. The label claim of the Ilium Butorgesic Injection is as the free base. One milligram of the salt is equivalent to 0.686mg of the free base.

### Butorphanol tartrate



<b>IUPAC Name</b>	morphinan-3,14-diol, 17-(cyclobutylmethyl)-, (-)-, [S-(R*,R*)]-2,3-dihydroxybutanedioate (1:1) salt
<b>Molecular Formula</b>	C <sub>21</sub> H <sub>29</sub> N <sub>2</sub> O <sub>2</sub> ·C <sub>4</sub> H <sub>6</sub> O <sub>6</sub>
<b>Molecular Weight</b>	477.55
<b>Appearance</b>	Butorphanol tartrate is a white crystalline substance.

### Indications:

**HORSE** - As an analgesic: Ilium Butorgesic Injection is a centrally acting analgesic and may be used for the relief of pain in adult horses and yearlings. Clinical studies have shown that butorphanol tartrate alleviates abdominal pain associated with torsion, impaction, intussusceptions, spasmodic, and tympanic and postpartum pain.

**DOG AND CAT** – As an analgesic: Ilium Butorgesic Injection is indicated for the relief of moderate to severe pain in dogs and cats. Clinical studies have shown the butorphanol tartrate can provide suitable analgesia after a variety of surgical procedures e.g. orthopaedic and soft tissue surgery. Administered pre-operatively, Ilium Butorgesic Injection will reduce the amount of analgesia required post-operatively.

As a sedative: In cats, sedation does not occur with Ilium Butorgesic Injection alone, but can occur in dogs alone. In both species, profound sedation is achieved when Ilium Butorgesic Injection is used in conjunction with

medetomidine hydrochloride; making it suitable for radiography, fracture examination or casting, dematting, ear cleaning, wound management, anal gland flush and other minor procedures.

As a pre-anaesthetic: The use of butorphanol tartrate as a pre-anaesthetic in dogs has resulted in a dose-related reduction in the dose of thiopentone sodium needed to induce anaesthesia, which may reduce the risk of anaesthetic respiratory depression. Pre-anaesthetic use in cats provides improved analgesia. Intravenous induction agents should be given to effect

As an anaesthetic: Ilium Butorgesic Injection may be used in combination with medetomidine hydrochloride and ketamine hydrochloride as a triple anaesthetic.

### Direction for Use:

#### RESTRAINTS

NOT TO BE USED in food producing animals.

NOT TO BE USED in horses intended for human consumption.

### Contraindications:

Contraindicated for use in horses with a history of liver disease. The safety of Ilium Butorgesic Injection in breeding horses, weanlings or foals has not been established, and is therefore not recommended for use in these classes of horse. When used in combination with detomidine hydrochloride, this product is contraindicated for use in pregnant animals and animals suffering from colic. Routine cardiac auscultation should be performed prior to use of this combination. Do not use this combination in horses with pre-existing cardiac dysrhythmia or bradycardia

Contraindicated for use in dogs with a history of liver disease.

Contraindicated for INTRAVENOUS ADMINISTRATION in cats under 5kg body weight.

### Precautions:

Use with caution with other sedative or analgesic drugs as these are likely to produce additive effects. Transient pain may occur with intramuscular injections. Ilium Butorgesic Injection should not be mixed with any other

## ILIUM BUTORGESIC INJECTION (CONT)

product in the same syringe. As alpha-2-agonists and butorphanol both cause bradycardia, use of combination of alpha-2-agonists and butorphanol are very likely to produce additive effects.

### Side Effects:

#### Horse

It has been reported that rapid intravenous administration of butorphanol at a dosage of 2.0mg/kg (20 times the recommended dose) to a previously unmedicated horse resulted in a brief episode of inability to stand, muscle fasciculation, and a convulsive seizure of 6 seconds duration and recovery within 3 minutes. The same dosage administered after 10 successive daily 1.0mg/kg dosages of butorphanol resulted only in transient sedative effects. Transient behavioural changes typical of narcotic agonist activity were also reported. These included muscle fasciculation about the head and neck, dysphoria, lateral nystagmus, ataxia and salivation. Repeated administration of butorphanol at 1.0mg/kg (10 times the recommended dose) every four hours for 48 hours caused constipation in one of the two horses.

Occasional, slight transient ataxia has been reported in horses dosed at 0.5mg/kg IV every four hours for 48 hours followed by once daily injections for a total of 21 days. No clinical, laboratory, or gross or histopathologic evidence of any butorphanol-related toxicity was encountered in the horses.

#### Dog

If respiratory depression occurs, nalorphine may be used as an antidote. (NB nalorphine is a first schedule prescription human medicine, not a registered veterinary medicine). Transient ataxia, anorexia and diarrhoea have been reported as occurring rarely.

#### Cat

If respiratory depression occurs, nalorphine may be used as an antidote. Marked sedation does not occur in cats when Ilium Butorgesic Injection is used as a sole agent. Mydriasis is likely to occur. Anorexia, diarrhoea and constipation are side effects seen among both dogs and cats.

### Reproduction

Studies reported in mice and rabbits revealed no evidence of impaired fertility or harm to the foetus due to butorphanol tartrate. In the female rat, parenteral administration was associated with increased nervousness and decreased care for the new-born,

resulting in decreased survival rate of the new-born. The nervousness was seen only in rat species.

### Dosage and Administration:

Use the contents within 90 days of first broaching the vial. Discard the unused portion.

#### Horse

For analgesia: the recommended dosage is 0.1mg of butorphanol per kilogram of bodyweight administered by intravenous injection. This is equivalent to 1mL of Ilium Butorgesic Injection for each 100kg of body weight. Analgesic effects will be evident within 15 minutes following injection and persist for about 4 hours. The dose may be repeated as required. Butorphanol use should not exceed 48 hours in any one treatment episode.

#### Ilium Butorgesic Injection (10mg/mL) for equine analgesia (IV)

Weight of Horse - kg	50	100	150	200	250	300	350	400	450	500	550
Dose of Butorphanol - mg	5.0	10.0	15.0	20.0	25.0	30.0	35.0	40.0	45.0	50.0	55.0
Dose of Butorgesic - mL	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5

Dose of Ilium Butorgesic Injection based on a dose rate of 0.1mg butorphanol per kg bodyweight.

#### Dog

When administering intravenously, inject slowly: do not inject as a bolus.

For dogs weighing less than or equal to 10kg, administration by insulin syringe is recommended to ensure accurate dosing. Due to the low volumes involved, great care should be taken when administering Ilium Butorgesic Injection to animals weighing less than 5kg.

For Analgesia: Administer by intravenous, intramuscular or subcutaneous injection routes using aseptic technique. Dose rate: 0.2-0.3mg butorphanol per kg (equivalent to 0.2-0.3mL per 10kg) bodyweight. Ilium Butorgesic Injection should be administered before terminating anaesthesia to provide analgesia in the recovery phase. Analgesic effects are seen within 15 minutes. For continuous analgesia the dose may be repeated as required.

#### Ilium Butorgesic Injection (10mg/mL) for canine analgesia (IV, IM or SC)

Weight of Dog - kg	5	10	15	20	25	30	40
Dose of Butorphanol - mg	1.25	2.5	3.75	5.0	6.25	7.5	10.0
Dose of Butorgesic <sup>1</sup> - mL	0.1 <sup>1</sup>	0.3	0.4	0.5	0.6	0.8	1.0

Ilium Butorgesic Injection dose based on mean dose rate of 0.25mg butorphanol per kg bodyweight.

## ILIMUM BUTORGESIC INJECTION (CONT)

### For sedation in combination with medetomidine hydrochloride:

Ilium Butorgesic Injection should be administered at 0.1mg butorphanol per kg (equivalent to 0.1mL per 10kg) together with 10-25µg (0.01-0.025mg) medetomidine hydrochloride per kg of bodyweight depending on the degree of sedation required, both by intramuscular or intravenous injection. Allow 20 minutes for profound sedation to develop before commencing procedure.

Reversal with 50-100µg (0.05-0.1mg) atipamezole per kg bodyweight, results in sternal recumbency approximately 5 minutes later and standing approximately further 2 minutes later.

### Ilium Butorgesic Injection (10mg/mL) and medetomidine hydrochloride (1mg/mL) combination for canine sedation (IM or IV)

For sedation and as a premedicant to barbiturate anaesthesia

Weight of Dog - kg	5	10	15	20	25	30	40
Dose of Butorphanol - mg	0.5	1.0	1.5	2.0	2.5	3.0	4.0
Dose of Butorgesic <sup>1</sup> - mL	0.05 <sup>1</sup>	0.10 <sup>1</sup>	0.15	0.20	0.25	0.30	0.40
Dose of medetomidine hydrochloride - mg	0.05	0.1	0.15	0.20	0.25	0.30	0.40
Dose of medetomidine hydrochloride <sup>2</sup> - mL	0.05 <sup>2</sup>	0.10 <sup>2</sup>	0.15	0.20	0.25	0.30	0.40

Based on dose rates of 0.1mg butorphanol per kg and 10µg (0.01mg) medetomidine hydrochloride per kg respectively.

For profound sedation and as a premedicant to ketamine anaesthesia.

Weight of Dog - kg	5	10	15	20	25	30	40
Dose of Butorphanol - mg	0.5	1.0	1.5	2.0	2.5	3.0	4.0
Dose of Butorgesic <sup>1</sup> - mL	0.05 <sup>1</sup>	0.10 <sup>1</sup>	0.15 <sup>1</sup>	0.20 <sup>1</sup>	0.25	0.30	0.40
Dose of medetomidine hydrochloride - mg	0.13	0.25	0.38	0.50	0.63	0.75	1.00
Dose of medetomidine hydrochloride <sup>2</sup> - mL	0.13 <sup>2</sup>	0.25	0.38	0.50	0.63	0.75	1.00

Based on dose rates of 0.1mg butorphanol per kg and 25µg (0.025mg) medetomidine per kg respectively.

### For use as a pre-anaesthetic

Used as a pre-anaesthetic, the Ilium Butorgesic Injection dose should be reduced to 0.1-0.2mg butorphanol per kg (0.1-0.2mL per 10kg), given 15 minutes prior to induction.

### Ilium Butorgesic Injection (10mg/mL) for canine analgesia pre-anaesthetic (IV, IM or SC)

Weight of Dog - kg	5	10	15	20	25	30	40
Dose of Butorphanol - mg	0.5	1.0	1.5	2.0	2.5	3.0	4.0
Dose of Butorgesic <sup>1</sup> - mL	0.05 <sup>1</sup>	0.10 <sup>1</sup>	0.15 <sup>1</sup>	0.20 <sup>1</sup>	0.25	0.30	0.40

Based on dose rate of 0.1mg butorphanol per kg.

For anaesthesia in combination with medetomidine hydrochloride and ketamine:

Administer Ilium Butorgesic Injection at 0.1mg butorphanol per kg (equivalent to 1.0mL per 10kg) and 25µg (0.025mg) medetomidine hydrochloride per kg bodyweight by intramuscular injection.

Dogs become recumbent in approximately 6 minutes and lose their pedal reflex in approximately 14 minutes.

Ketamine should be administered 15 minutes following the first injection at 5mg ketamine per kg by intramuscular injection.

The pedal reflex returns approximately 53 minutes following the administration of the ketamine injection. Sternal recumbency is attained approximately 35 minutes later followed by standing a further 36 minutes later.

### Ilium Butorgesic Injection (10mg/mL), medetomidine hydrochloride (1mg/mL) for canine anaesthesia (IM)

Weight of Dog - kg	5	10	15	20	25	30	40
Dose of Butorphanol - mg	0.5	1.0	1.5	2.0	2.5	3.0	4.0
Dose of Butorgesic <sup>1</sup> - mL	0.05 <sup>1</sup>	0.10 <sup>1</sup>	0.15 <sup>1</sup>	0.20 <sup>1</sup>	0.25	0.30	0.40
Dose of medetomidine hydrochloride - mg	0.13	0.25	0.38	0.50	0.63	0.75	1.00
Dose of medetomidine hydrochloride <sup>2</sup> - mL	0.13 <sup>2</sup>	0.25	0.38	0.50	0.63	0.75	1.00
<b>WAIT 15 MINUTES AFTER FIRST INJECTION BEFORE ADMINISTERING KETAMINE</b>							
Dose of Ketamine - mg	25	50	75	100	125	150	200
Dose of Ketamine - mL	0.25	0.50	0.75	1.0	1.25	1.50	2.0

Based on dose rates of 0.1µg butorphanol, 25µg (0.025mg) medetomidine hydrochloride and 5mg ketamine per kg bodyweight, respectively.

Note: It is NOT advisable to reverse this combination in the dog with atipamezole.

### Cat

Cats should be weighed to ensure the correct dose is calculated.

For cats weighing less than or equal to 10kg, administration by insulin syringe is recommended to ensure accurate dosing. Due to low volumes involved, great care should be taken when administering Ilium Butorgesic Injection to animals weighing less than 5kg.

Not recommended for intravenous use in cats under 5kg bodyweight.

### For pre-operative analgesia

0.4mg Ilium Butorgesic Injection per kg bodyweight (equivalent to 0.2mL butorphanol per 5kg) should be

## ILIUM BUTORGESIC INJECTION (CONT)

administered either by subcutaneous or intramuscular injection. It is reported in clinical studies that administering the dose 5 minutes prior to induction with either acepromazine/ketamine or xylazine/ketamine given intramuscularly will provide analgesia when surgery commences. The arousal time will not be significantly altered. With intravenous induction agents, Ilium Butorgesic Injection should be administered 15-30 minutes prior to the administration of the anaesthetic.

### For post-operative analgesia

0.4mg Ilium Butorgesic Injection per kg bodyweight (equivalent to 0.2mL butorphanol per 5kg) should be administered either by subcutaneous or intramuscular injection 15 minutes prior to recovery.

### Ilium Butorgesic Injection (10mg/mL) for feline analgesia

Weight of Cat - kg	2.5	3.0	3.5	4.0	4.5	5.0
IM or SC Dose of Butorphanol - mg	1.0	1.2	1.4	1.6	1.8	2.0
IM or SC Dose of Butorgesic <sup>1</sup> - mL	0.10 <sup>1</sup>	0.12 <sup>1</sup>	0.14 <sup>1</sup>	0.16 <sup>1</sup>	0.18 <sup>1</sup>	0.20 <sup>1</sup>
IV Dose of Butorphanol - mg	Not Recommended					0.5
IV Dose of Butorgesic <sup>1</sup> - mL	Not Recommended					0.05 <sup>1</sup>

Based on a mean dose rate of 0.4mg butorphanol per kg for IM and SC use, and 0.1mg butorphanol per kg for IV use.

For sedation in combination with medetomidine hydrochloride:

Ilium Butorgesic Injection should be administered at 0.4mg per kg bodyweight (equivalent to 0.2mL butorphanol per 5kg), together with 50µg (0.05mg) medetomidine hydrochloride per kg of bodyweight, both by either intramuscular or subcutaneous injection.

Local anaesthetic infiltration should be used for wound suturing. Reversal with 125µg (0.125mg) atipamezole per kg bodyweight results in sternal recumbency approximately 4 minutes later and standing 1 minute later.

### Ilium Butorgesic Injection (10mg/mL) and medetomidine hydrochloride (1mg/mL) combination for feline sedation (IM or SC)

For sedation and as a premedicant to barbiturate anaesthesia.

Weight of Cat - kg	2.5	3.0	3.5	4.0	4.5	5.0
Dose of Butorphanol - mg	1.0	1.2	1.4	1.6	1.8	2.0
Dose of Butorgesic <sup>1</sup> - mL	0.10 <sup>1</sup>	0.12 <sup>1</sup>	0.14 <sup>1</sup>	0.16 <sup>1</sup>	0.18 <sup>1</sup>	0.20 <sup>1</sup>
Dose of medetomidine hydrochloride - mg	0.13	0.15	0.18	0.20	0.23	0.25
Dose of medetomidine hydrochloride <sup>1</sup> - mL	0.13 <sup>1</sup>	0.15 <sup>1</sup>	0.18 <sup>1</sup>	0.20 <sup>1</sup>	0.23	0.25

Based on dose rates of 0.4mg butorphanol per kg and 50µg (0.05mg) medetomidine hydrochloride per kg respectively.

### For anaesthesia in combination with medetomidine hydrochloride and ketamine:

Intramuscular administration

Administer Ilium Butorgesic Injection at 0.2mL per 5kg (equivalent to 0.4mg butorphanol per kg) and 80µg (0.08mg) medetomidine hydrochloride per kg bodyweight and ketamine 5mg per kg.

Cats become recumbent in approximately 2-3 minutes and lose their pedal reflex in approximately 3 minutes following injection.

### Ilium Butorgesic Injection (10mg/mL), medetomidine hydrochloride (1mg/mL) and ketamine hydrochloride 100mg/mL for feline anaesthesia

Weight of Cat - kg	2.5	3.0	3.5	4.0	4.5	5.0
Dose of Butorphanol - mg	1.0	1.2	1.4	1.6	1.8	2.0
Dose of Butorgesic <sup>1</sup> - mL	0.10 <sup>1</sup>	0.12 <sup>1</sup>	0.14 <sup>1</sup>	0.16 <sup>1</sup>	0.18 <sup>1</sup>	0.20 <sup>1</sup>
Dose of medetomidine hydrochloride - mg	0.20	0.24	0.28	0.32	0.36	0.40
Dose of medetomidine hydrochloride <sup>1</sup> - mL	0.20 <sup>1</sup>	0.24	0.28	0.32	0.36	0.40
Dose of ketamine - mg	12.5	15.0	17.5	20.0	22.5	25.0
Dose of ketamine <sup>1</sup> - mL	0.13 <sup>1</sup>	0.15 <sup>1</sup>	0.18 <sup>1</sup>	0.20 <sup>1</sup>	0.23 <sup>1</sup>	0.25 <sup>1</sup>

Based on dose rates of 0.4mg butorphanol, 80µg (0.08mg) medetomidine hydrochloride and 5mg ketamine per kg bodyweight respectively.

Reversal with 200µg (0.2mg) atipamezole per kg bodyweight results in return of the pedal reflex 2 minutes later, sternal recumbency 6 minutes later and standing 31 minutes later.

### Intravenous Administration

Administer Ilium Butorgesic Injection at 0.05mL per 5kg (equivalent to 0.1mg butorphanol per kg), 40µg (0.04mg) medetomidine hydrochloride per kg bodyweight and ketamine. Depending on the depth of anaesthesia required. At a dose rate of 1.25-2.5mg ketamine per kg by intravenous injection. Do not physically mix products in the same syringe.

## ILIUM BUTORGESIC INJECTION (CONT)

Approximate time scales when using the triple combination intravenously.

Ketamine* Dose mg/kg bw	Time to Recumbency	Time to Loss of Pedal Reflex	Time to Return of Pedal Reflex	Time to Sternal Recumbency	Time to Standing
1.25	32 seconds	62 seconds	26 minutes	54 minutes	74 minutes
2.5	22 seconds	39 seconds	28 minutes	62 minutes	83 minutes

\*In conjunction with butorphanol tartrate at 0.1mg/kg bw and medetomidine hydrochloride at 40µg (0.04mg)/kg bodyweight.

### Ilium Butorgesic Injection (10mg/mL), medetomidine hydrochloride (1mg/mL) and ketamine hydrochloride (100mg/mL) for feline anaesthesia (IV)

Dosage chart for 2.5mg Ketamine per kg bodyweight (duration of anaesthesia approx. 28 minutes).

Weight of Cat - kg	2.5	3.0	3.5	4.0	4.5	5.0
Dose of Butorphanol - mg	Not recommended					0.50
Dose of Butorgesic <sup>1</sup> - mL	Not recommended					0.05 <sup>1</sup>
Dose of medetomidine hydrochloride - mg	Not applicable					0.20
Dose of medetomidine hydrochloride <sup>1</sup> - mL	Not applicable					0.20 <sup>1</sup>
Dose of ketamine - mg	Not applicable					12.5
Dose of ketamine <sup>1</sup> - mL	Not applicable					0.13 <sup>1</sup>

Based on dose rates of 0.1mg butorphanol tartrate, 40µg (0.04mg) medetomidine hydrochloride and 2.5mg ketamine per kg bodyweight, respectively.

Reversal with 100µg (.01mg) atipamezole per kg bodyweight results in return of the pedal reflex 4 minutes later, sternal recumbency 7 minutes later and standing 18 minutes later.

### Meat Withholding Period (Horses):

DO NOT USE in horses intended for human consumption.

### First Aid:

If poisoning occurs contact a doctor or Poisons Information Centre. Phone New Zealand 0800 764 766.

### Disposal:

Dispose of empty container by wrapping with paper and putting in garbage.

### Storage:

Store below 25°C (air conditioning). Protect from light.

Registered pursuant to the ACVM Act 1997, No A10454

### RESTRICTED VETERINARY MEDICINE

Ilium Butorgesic Injection  
For Animal Treatment Only

### References:

1. Pircio, A. W. et. Al. (1976) the pharmacology of butorphanol, Arch. Int. Pharmacodyn. Ther. 220(2), 231-257.
2. Dobkin, A. B. Et. Al. (1975) Butorphanol and Pentazocine in patients with severe postoperative pain. Clin. Pharmacol. Ther., 18, 547-553.

\*For animals weighing ≤10kg bodyweight, administration by insulin syringe is recommended. Due to the low volumes involved, great care should be taken when administering Ilium Butorgesic Injection to animals weighing under 5kg.

