PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Torbugesic 10 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains butorphanol 10 mg/ml. Also contains 0.1 mg/ml benzethonium chloride.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

10 ml
50 ml

5. TARGET SPECIES

Horse, dog and cat

6. INDICATION(S)

For use as an analgesic/sedative in the cat, dog and horse.

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

-

8. WITHDRAWAL PERIOD

Withdrawal period: horses (meat & offal): zero days.

9. SPECIAL WARNING(S), IF NECESSARY

-

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Shelf-life after first opening the immediate packaging: 28 days.

Do not store above 25°C. Protect from light.

Keep the container in the outer carton.

Date opened:

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

-

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4154

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Torbugesic 10 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance:
Butorphanol 10 mg (as butorphanol tartrate 14.58 mg/ml).
Excipients:
Benzethonium chloride 0.1 mg (antimicrobial preservative).

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

10 ml
50 ml

5. TARGET SPECIES

Horse, dog and cat

6. INDICATION(S)

For use as an analgesic/sedative in the cat, dog and horse.

For full indications, user warnings and disposal advice: read the package leaflet carefully before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

-

8. WITHDRAWAL PERIOD

Withdrawal period: horses (meat & offal): zero days.

9. SPECIAL WARNING(S), IF NECESSARY

-

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Shelf-life after first opening the immediate packaging: 28 days.

Do not store above 25°C. Protect from light.

Keep the container in the outer carton.

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

-

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4154

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PACKAGE LEAFLET FOR: Torbugesic® 10 mg/ml Solution for Injection

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

MA Holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodon s/n "La Riba"
17813 Vall de Bianya, Girona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Torbugesic® 10 mg/ml Solution for Injection

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

Torbugesic Injection is a clear colourless, sterile solution.
Each ml contains:
Active substance: Butorphanol 10 mg (as butorphanol tartrate 14.58 mg/ml).
Excipients: Benzethonium chloride 0.1 mg (antimicrobial preservative).

4. INDICATION(S)

HORSE

As an analgesic:
Torbugesic Injection is a centrally acting analgesic and may be used for the relief of moderate to severe pain in the horse. Clinical studies in the horse have shown that Torbugesic Injection alleviates abdominal pain associated with torsion, impaction, intussusception, parturition and spasmodic and tympanic colic.

As a sedative:
When given after the administration of detomidine hydrochloride: Clinical studies have shown that this combination achieved a profound sedation in the horse. The degree of sedation achieved, rendered horses unaff ected by sound, tactile stimuli or any surrounding activity.

The sedative combination of Torbugesic Injection and detomidine hydrochloride has been successfully used for the following procedures: radiography, clipping, wound suturing, dentistry, standing castration, hoof care, rectal examination and passing a stomach tube.

Profound sedation is also achieved using Torbugesic after the adminstration of romifidine.

DOG

As an analgesic:

For the relief of moderate to severe pain in dogs. Clinical studies have shown that Torbugesic Injection can provide suitable analgesia after a variety of surgical procedures such as orthopaedic and soft tissue surgery.

As a sedative in combination with medetomidine hydrochloride:

For sedation in conjunction with medetomidine hydrochloride. Although sedation can occur with Torbugesic Injection alone, clinical studies have verified that deep to profound sedation is achieved by using Torbugesic Injection in conjunction with a dose range of medetomidine making it suitable for a range of procedures including ear cleaning, wound management, anal gland flush, cast application, radiography and (at the higher dose rate) as a premedicant to ketamine anaesthesia (see below).

As a pre-anaesthetic:

It has also been shown that pre-anaesthetic use of Torbugesic Injection has resulted in a dose-related reduction in the dose of thiopental sodium needed to induce anaesthesia, which will also reduce the risk of anaesthetic respiratory depression.

Clinical studies have verified that the use of Torbugesic Injection in conjunction with acepromazine provides a suitable analgesic and sedative premedicant to general anaesthesia. The dose of the Torbugesic can be adjusted according to the level of analgesia required. The use of the combination has resulted in a dose related reduction in the dose of either thiopental sodium or propofol needed to induce anaesthesia.

As an anaesthetic in combination with medetomidine and ketamine:

Torbugesic Injection may be used as a triple anaesthetic combination with medetomidine and ketamine.

This provides surgical anaesthesia suitable for a range of procedures including castrations and spays.

CAT

As an analgesic:

Torbugesic Injection may be used for the relief of pain in the cat. Pre-operative use of Torbugesic Injection can provide analgesia during surgery. Clinical studies have

demonstrated that Torbugesic Injection can provide analgesia after a variety of surgical procedures such as spays, orthopaedic and soft tissue surgery.

As a sedative in combination with medetomidine hydrochloride:
Although no sedation occurs when using Torbugesic Injection alone in the cat, clinical studies have verified that profound sedation is achieved by using Torbugesic Injection in conjunction with medetomidine, making it suitable for radiography, fracture examination/casting, dematting, ear cleaning, wound management and other minor procedures.

As an anaesthetic in combination with medetomidine and ketamine:
Torbugesic Injection may be used as a triple anaesthetic combination with medetomidine and ketamine. This provides surgical anaesthesia suitable for a range of procedures including castrations and spays.

5. CONTRAINDICATIONS

Before using any combinations consult the contra-indications, withdrawal periods and warnings that appear on the other products' SPCs.

HORSE
Torbugesic:
Do not use in horses with a history of liver disease. The most commonly observed side-effect is slight ataxia which may persist for 3-10 minutes. Mild sedation may occur in approximately 15% of horses.

Torbugesic/detomidine hydrochloride combination:
Do not use in horses with a history of liver disease. Do not use in pregnant mares. Do not use in horses suffering from colic, or in horses with a pre-existing cardiac dysrhythmia or bradycardia. Routine cardiac auscultation should be performed prior to use of this combination. Mild to severe ataxia may be encountered but clinical studies have shown that horses are unlikely to collapse. Normal precautions should be observed to prevent patient self-injury.

Torbugesic/romifidine combination:
Do not use in horses with a history of liver disease. Do not use during the last month of pregnancy.

DOG
If respiratory depression occurs, naloxone may be used as an antidote. Do not use in dogs with a history of liver disease. Transient ataxia, anorexia and diarrhoea have been reported as occurring rarely. When using Torbugesic as a pre-anaesthesia the use of an anti-cholinergic, such as atropine will protect the heart against possible narcotic-induced bradycardia. When administering as an intravenous injection do not inject as a bolus.

CAT
If respiratory depression occurs, naloxone may be used as an antidote. Do not use in cats with a history of liver disease. Cats should be weighed to ensure that the correct dose is calculated. Use of either insulin syringes or 1 ml graduated syringes is recommended.

Marked sedation does not occur in cats when Torbugesic Injection is used as a sole agent.

Mydriasis is likely to occur.

6. ADVERSE REACTIONS

There may be some pain on intramuscular injection.

7. TARGET SPECIES

Horse, dog, cat

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

HORSE
For analgesia:
Dose rate: 5 ml/500 kg (equivalent to 0.1 mg butorphanol/kg) bodyweight, by intravenous injection.

The dose may be repeated as required. Analgesic effects are seen within 15 minutes of injection.

Torbugesic for Equine Analgesia - (IV)

Weight of Horse - kgs:	50	100	150	200	250	300	350	400	450	500	550
Dose of Torbugesic (10 mg/ml) - mls:	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5

For sedation in combination with detomidine hydrochloride:
A dose rate of 0.1 ml Domosedan™/100 kg (equivalent to 0.012 mg/kg detomidine hydrochloride) should be given intravenously followed within 5 minutes by a dose rate of 0.25 ml Torbugesic Injection/100 kg (equivalent to 0.025 mg/kg butorphanol) intravenously.

Clinical experience has shown that a total dose 0.5 ml Domosedan and 1.0 ml Torbugesic Injection affords effective, safe sedation in horses above 200 kg bodyweight.

Torbugesic and detomidine Combination for Equine Sedation - (IV)

Weight of Horse - kgs:	50	100	150	200	250	300	350	400	450	500	550
Dose of detomidine (10 mg/ml) – mls:	0.05	0.1	0.2	0.25	0.50	0.50	0.50	0.50	0.50	0.50	0.50
Dose of Torbugesic (10 mg/ml) - mls:	0.10	0.25	0.40	0.50	1.0	1.0	1.0	1.0	1.0	1.0	1.0

N.B. Detomidine should be administered up to 5 minutes before the Torbugesic dose.

For sedation in combination with romifidine:
A dose of 0.4 - 1.2 ml Sedivet™/100 kg bodyweight (equivalent to 40-120 µg romifidine/kg) followed by 0.2 ml Torbugesic Injection/100 kg bodyweight (equivalent to 20 µg butorphanol/kg) should be administered intravenously.

Torbugesic and romifidine Combination for Equine Sedation - (IV)

Weight of Horse - kgs:	50	100	150	200	250	300	350	400	450	500	550
*Dose of romifidine (10 mg/ml) – mls:	0.3	0.6	0.9	1.2	1.5	1.8	2.1	2.4	2.7	3.0	3.3
*Dose of Torbugesic (10 mg/ml) - mls:	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1

* Above example based on a dose rate of 60 µg romifi dine/kg bodyweight.
N.B. Romifidine should be administered up to 5 minutes before the Torbugesic dose.

DOG

For analgesia:

Administer by intravenous, intramuscular or subcutaneous injection routes using aseptic technique.

Rapid IV injection should be avoided.

Dose rate: 0.2-0.3 ml/10 kg (equivalent to 0.2-0.3 mg butorphanol/kg) bodyweight. Torbugesic 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.

Torbugesic for Canine Analgesia - (IV, IM or SC)

Weight of Dog - kgs:	1	3	5	10	15	20	25	30	40
*Dose of Torbugesic (10 mg/ml) - mls:	0.03	0.07	0.1	0.3	0.4	0.5	0.6	0.8	1.0

* Based on mean dose rate of 0.25 mg butorphanol/kg.

For sedation in combination with medetomidine hydrochloride:

Torbugesic Injection should be administered at 0.1 ml/10 kg bodyweight (equivalent to 0.1 mg butorphanol/kg) together with 0.1-0.25 ml Domitor™/10 kg bodyweight (equivalent to 10-25 µg medetomidine/kg) depending on degree of sedation required, both by either intramuscular or intravenous injection. Domitor and Torbugesic may be combined and administered in the same syringe. However the vials should have separate needles inserted for withdrawal to minimise the risk of cross contamination.

Allow 20 minutes for profound sedation to develop before commencing the procedure.

Reversal with 0.1-0.25 ml Antisedan™/10 kg bodyweight (equivalent to 50-125 µg atipamezole/kg) results in sternal recumbency approximately 5 minutes later and standing approximately a further 2 minutes later.

Torbugesic and medetomidine Combination for Canine Sedation - (IM or IV)

For sedation and as a premedicant to barbiturate anaesthesia.

Weight of Dog - kgs:	1	3	5	10	15	20	25	30	40

*Dose of Torbugesic (10 mg/ml) - mls:	0.01	0.03	0.05	0.10	0.15	0.20	0.25	0.30	0.40
*Dose of medetomidine (1 mg/ml) – mls:	0.01	0.03	0.05	0.10	0.15	0.20	0.25	0.30	0.40

* Based on a dose rate of 0.1 mg butorphanol/kg and 10 µg medetomidine/kg.

Torbugesic and medetomidine Combination for Canine Sedation - (IM or IV)
For profound sedation and as a premedicant to ketamine anaesthesia.

Weight of Dog - kgs:	1	3	5	10	15	20	25	30	40
*Dose of Torbugesic (10 mg/ml) - mls:	0.01	0.03	0.05	0.10	0.15	0.20	0.25	0.30	0.40
*Dose of medetomidine (1 mg/ml) – mls:	0.03	0.08	0.13	0.25	0.38	0.50	0.63	0.75	1.00

* Based on a dose rate of 0.1 mg butorphanol/kg and 25 µg medetomidine/kg.

For use as a pre-anaesthetic:
Used as a pre-anaesthetic, the Torbugesic Injection dose should be reduced to 0.1-0.2 ml/10 kg (0.1-0.2 mg butorphanol/kg), given 15 minutes prior to induction.

Torbugesic for Canine Analgesia Pre-Anaesthetic - (IV, IM or SC)

Weight of Dog - kgs:	1	3	5	10	15	20	25	30	40
*Dose of Torbugesic (10 mg/ml) - mls:	0.01	0.03	0.05	0.10	0.15	0.20	0.25	0.30	0.40

* Pre-anaesthetic doses:- Based on a dose rate of 0.10 mg butorphanol/kg.

For use as a pre-anaesthetic combination with acepromazine:
Torbugesic Injection should be administered at 0.1 ml/10 kg bodyweight (equivalent to 0.1 mg butorphanol/kg) together with 0.1 ml of 2 mg/ml acepromazine/10 kg bodyweight (equivalent to 0.02 mg acepromazine/kg) by intramuscular or intravenous injection.

Torbugesic and acepromazine may be combined and administered in the same syringe. However the vials should have separate needles inserted for withdrawal to minimise the risk of cross contamination.

Allow at least 20 minutes for onset of action but the time between premedication and induction is flexible from 20-120 minutes.

The dose of butorphanol may be increased to 0.2 mg/kg (equivalent to 0.2 ml Torbugesic/10 kg bodyweight) if the animal is already experiencing pain before the procedure commences, or if a higher plane of analgesia is required during surgery.

Torbugesic and acepromazine Combination for Canine Analgesia and Sedation Pre-Anaesthetic - (IM or IV)

Weight of Dog - kgs:	1	3	5	10	15	20	25	30	40
*Dose of Torbugesic (10 mg/ml) - mls:	0.01	0.03	0.05	0.10	0.15	0.20	0.25	0.30	0.40
**Dose of acepromazine (2 mg/ml) – mls:	0.01	0.03	0.05	0.10	0.15	0.20	0.25	0.30	0.40

* Based on a dose rate of 0.1 mg butorphanol/kg bodyweight.
**Based on a dose rate of 0.02 mg acepromazine/kg bodyweight.

For anaesthesia in combination with medetomidine and ketamine:
Administer Torbugesic Injection at 0.1 ml/10 kg (equivalent to 0.1 mg butorphanol/kg) and Domitor at 0.25 ml/10 kg (equivalent to 25 µg medetomidine/kg) by intramuscular injection.

Domitor and Torbugesic may be combined and administered in the same syringe. However, the vials should have separate needles inserted for withdrawal to minimise the risk of cross-contamination.

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

Ketamine (100 mg/ml) should be administered 15 minutes following the fi rst injection at 0.5 ml/10 kg (equivalent to 5 mg ketamine/kg) by intramuscular injection. The pedal refl ex returns approximately 53 minutes following administration of the ketamine injection. Sternal recumbency is attained approximately 35 minutes later followed by standing a further 36 minutes later.

Torbugesic, medetomidine and ketamine for Canine Anaesthesia - (IM)

Weight of Dog - kgs:	1	3	5	10	15	20	25	30	40
*Dose of Torbugesic (10 mg/ml) - mls:	0.01	0.03	0.05	0.10	0.15	0.20	0.25	0.30	0.40
**Dose of medetomidine (1 mg/ml) – mls:	0.03	0.08	0.13	0.25	0.38	0.50	0.63	0.75	1.00
ADMINISTER TORBUGESIC & MEDETOMIDINE BY INTRAMUSCULAR INJECTION AT THE ABOVE DOSE RATES									
WAIT 15 MINUTES BEFORE ADMINISTERING THE KETAMINE BY INTRAMUSCULAR INJECTION AT THE DOSE RATES BELOW									
*** Dose of ketamine (100 mg/ml) - mls:	0.05	0.15	0.25	0.50	0.75	1.00	1.25	1.50	2.00

* Based on a dose rate of 0.1 mg butorphanol/kg.
** Based on a dose rate of 25 µg medetomidine/kg.
*** Based on a dose rate of 5 mg ketamine/kg.

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

CAT

For pre-operative analgesia:
0.2 ml Torbugesic Injection/5 kg bodyweight (equivalent to 0.4 mg butorphanol/kg), should be administered either by subcutaneous or intramuscular injection.

Clinical studies have shown that administering the butorphanol 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, butorphanol should be administered 15-30 minutes prior to administration of the anaesthetic.

For post-operative analgesia:
0.2 ml Torbugesic Injection/5kg bodyweight (equivalent to 0.4mg butorphanol/kg), should be administered by either subcutaneous or intramuscular injection 15 minutes prior to recovery.

Alternatively, 0.05 ml Torbugesic Injection/5 kg (equivalent to 0.1 mg butorphanol/kg), by intravenous injection can be used.

Torbugesic for Feline Analgesia

Bodyweight	1	1.5	2	2.5	3	3.5	4	4.5	5
IM or SC Dose (ml) §									
Torbugesic Injection (10 mg/ml)	0.04	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
IV Dose (ml) §§									
Torbugesic Injection (10 mg/ml)	0.01	0.02	0.02	0.03	0.03	0.04	0.04	0.05	0.05

§ Based on a mean dose rate of 0.4 mg butorphanol/kg.
§§ Based on a mean dose rate of 0.1 mg butorphanol/kg.

For sedation in combination with medetomidine hydrochloride:
Torbugesic Injection should be administered at 0.2 ml/5 kg bodyweight (equivalent to 0.4 mg butorphanol/kg) together with 0.25 ml Domitor/5 kg bodyweight (equivalent to 50 µg medetomidine/kg) both by either intramuscular or subcutaneous injection.

Domitor and Torbugesic may be combined and administered in the same syringe. However, the vials should have separate needles inserted for withdrawal to minimise the risk of cross-contamination.

Local anaesthetic infiltration should be used for wound suturing. Reversal with 0.125 ml Antisedan/5 kg bodyweight (equivalent to 125 µg atipamezole/kg) results in sternal recumbency approximately 4 minutes later and standing 1 minute later.

Torbugesic and medetomidine Combination for Feline Sedation - (IM or SC)

Weight of Cat – kgs:	1	1.5	2	2.5	3	3.5	4	4.5	5
*Dose of Torbugesic (10 mg/ml) - mls:	0.04	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
**Dose of medetomidine (1 mg/ml) – mls:	0.05	0.08	0.10	0.13	0.15	0.18	0.20	0.23	0.25

* Based on a dose rate of 0.4 mg butorphanol/kg.
** Based on a dose rate of 50 µg medetomidine/kg.

For anaesthesia in combination with medetomidine and ketamine:
a) Intramuscular

Administer Torbugesic Injection at 0.2 ml/5 kg (equivalent to 0.4 mg butorphanol/kg), 0.4 ml Domitor/5 kg (equivalent to 80 µg medetomidine/kg) and ketamine (100 mg/ml) at 0.25 ml/5 kg (equivalent to 5 mg ketamine/kg). Domitor and Torbugesic (and *Ketaset® - where registered) may be combined and administered in the same syringe. However, the vials should have separate needles inserted for withdrawal to minimise the risk of cross-contamination. Cats become recumbent in 2-3 minutes following injection. Loss of the pedal refl ex occurs 3 minutes post-injection.

Torbugesic, medetomidine and ketamine Combination for Feline Anaesthesia - (IM)

Weight of Cat – kgs:	1.5	2	2.5	3	3.5	4	4.5	5
*Dose of Torbugesic (10 mg/ml) - mls:	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
**Dose of medetomidine (1 mg/ml) – mls:	0.12	0.16	0.20	0.24	0.28	0.32	0.36	0.40
***Dose of ketamine (100 mg/ml) - mls:	0.08	0.10	0.13	0.15	0.18	0.20	0.23	0.25

* Based on a dose rate of 0.4 mg butorphanol/kg.
** Based on a dose rate of 80 µg medetomidine/kg.
*** Based on a dose rate of 5 mg ketamine/kg.

Reversal with 0.2 ml Antisedan/5 kg (equivalent to 200 µg atipamezole/kg) results in return of the pedal reflex 2 minutes later, sternal recumbency 6 minutes later and standing 31 minutes later.

b) Intravenous
Administer Torbugesic Injection at 0.05 ml/5 kg bodyweight (equivalent to 0.1 mg butorphanol/kg), 0.2 ml Domitor/5 kg bodyweight (equivalent to 40 µg medetomidine/kg) and ketamine (100 mg/ml), depending on depth of anaesthesia required, at a dose rate of 0.06-0.13 ml/5 kg (equivalent to 1.25-2.5 mg ketamine/kg) by intravenous injection. Domitor and Torbugesic (and *Ketaset® - where registered) may be combined and administered in the same syringe. However, the vials should have separate needles inserted for withdrawal to minimise the risk of cross-contamination.

Approximate time scales when using the triple combination intravenously.

Ketamine* Dose mg/kg	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 secs	62 secs	26 mins	54 mins	74 mins
2.5	22 secs	39 secs	28 mins	62 mins	83 mins

* In conjunction with butorphanol at 0.1 mg/kg and medetomidine at 40 µg/kg.

Torbugesic, medetomidine and ketamine for Feline Anaesthesia - (IV)
Dosage chart for 2.5 mg ketamine/kg (duration of anaesthesia approximately 28 minutes)

Weight of Cat – kgs:	1.5	2	2.5	3	3.5	4	4.5	5
*Dose of Torbugesic (10 mg/ml) - mls:	0.02	0.02	0.03	0.03	0.04	0.04	0.05	0.05
**Dose of medetomidine (1 mg/ml) – mls:	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
***Dose of ketamine (100 mg/ml) - mls:	0.04	0.05	0.06	0.08	0.09	0.10	0.11	0.13

* Based on a dose rate of 0.1 mg butorphanol/kg bodyweight.
** Based on a dose rate of 40 µg medetomidine/kg bodyweight.
*** Based on a dose rate of 2.5 mg ketamine/kg bodyweight.

Reversal with 0.1 ml Antisedan/5 kg (equivalent to 100 µg atipamezole/kg) results in return of the pedal reflex 4 minutes later, sternal recumbency 7 minutes later and standing 18 minutes later.

9. ADVICE ON CORRECT ADMINISTRATION

Torbugesic Injection must not be mixed with other products with the exception of the following combinations:

i) Torbugesic and Domitor
ii) Torbugesic, Domitor and *Ketaset (where registered)
iii) Torbugesic and acepromazine

10. WITHDRAWAL PERIOD(S)

Horse (meat & off al): Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light. Keep the container in the outer carton.

Shelf life after first opening the immediate packaging: 28 days.

When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

12. SPECIAL WARNING(S)

Operator Warning
Butorphanol has opioid-like activity. Precautions should be taken to avoid accidental injection/self-injection with this potent drug.

If accidental self-injection occurs, seek immediate medical attention showing a copy of the product literature. Do not drive. The effects of butorphanol include sedation, dizziness and confusion. Effects can be reversed with an opioid antagonist. Wash splashes from skin and eyes immediately.

For animal treatment only.

Keep out of the sight and reach of children.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2020

15. OTHER INFORMATION

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4154

10 ml and 50 ml amber glass vials. Not all pack sizes may be marketed.

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* Ketaset does not have a Marketing Authorisation in Ireland. Reference to Ketaset is applicable to the UK only.

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