SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Torbugesic 10 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance

Butorphanol 10 mg
(as butorphanol tartrate 14.58 mg/ml)

Excipient

Benzethonium chloride 0.1mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear, colourless liquid

4. CLINICAL PARTICULARS

4.1 Target species

Horse, dog, cat

4.2 Indications for use, specifying the target species

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 produces a profound sedation in the horse. The degree of sedation achieved rendered horses unaffected 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 administration 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 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 thiopentone 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 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 thiopentone 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 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 hydrochloride 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.

4.3 Contraindications

HORSE
As a sole agent and in any combination:
Do not use in horses with a history of liver disease.

Torbugesic/detomidine hydrochloride combination:
Do not use in horses suffering from colic.
Do not use in horses with a pre-existing cardiac dysrhythmia or bradycardia.
Do not use in pregnant mares.

Torbugesic/romifidine combination
Do not use during the last month of pregnancy.

DOG & CAT
Do not use in dogs and cats with a history of liver disease.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

i) Special precautions for use in animals

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

HORSE
Torbugesic/detomidine hydrochloride combination:
Routine cardiac auscultation should be performed prior to use in combination with detomidine.

DOG
If respiratory depression occurs, naloxone may be used as an antidote.
When using Torbugesic Injection as a pre-anaesthetic, the use of an anticholinergic, 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. Cats should be weighed to ensure that the correct dose is calculated. Use of either insulin syringes or 1 ml graduated syringes is recommended.

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

Butorphanol has opioid-like activity. Precautions should be taken to avoid accidental injection or 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 included sedation, dizziness and confusion. Effects can be reversed with an opioid antagonist.

Wash splashes from skin and eyes immediately.

4.6 Adverse reactions (frequency and seriousness)

There may be some pain on intramuscular injection.

HORSE

The most commonly observed side effect is slight ataxia which may persist for 3-10 minutes. 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 patient self-injury.

Mild sedation may occur in approximately 15% of horses following the administration of Torbugesic Injection as a sole agent.

DOG

Respiratory depression may occur.
Transient ataxia, anorexia, and diarrhoea have been reported as occurring rarely.

CAT

Respiratory depression may occur.
Mydriasis is likely to occur.

4.7 Use during pregnancy, lactation or lay

See section 4.3.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

HORSE

For analgesia:
For use at a dose rate of 5 ml per 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 – kg	50	100	150	200	250	300	350	400	450	500	550
Dose of Torbugesic (10 mg/ml) – mls	0.50	1.00	1.50	2.00	2.50	3.00	3.50	4.00	4.50	5.00	5.50

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 0.025 mg/kg butorphanol intravenously (equivalent to 0.25 ml Torbugesic Injection/100 kg).
Clinical experience has shown that a total dose rate of 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 – kg	50	100	150	200	250	300	350	400	450	500	550
Dose of detomidine (10 mg/ml) – mls	0.05	0.10	0.20	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	1.00	1.00	1.00	1.00	1.00	1.00	1.00

NB. 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™ per 100 kg bodyweight (equivalent to 40-120 µg romifidine/kg) followed by 0.2 ml Torbugesic per 100 kg bodyweight (equivalent to 20 µg butorphanol/kg) should be administered intravenously.

Torbugesic and romifidine Combination for Equine Sedation - (IV)

Weight of horse - kg	50	100	150	200	250	300	350	400	450	500	550
*Dose of romifidine (10 mg/ml) - mls	0.30	0.60	0.90	1.20	1.50	1.80	2.10	2.40	2.70	3.00	3.30
Dose of Torbugesic (10 mg/ml) - mls	0.10	0.20	0.30	0.40	0.50	0.60	0.70	0.80	0.90	1.00	1.10

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

DOG

For analgesia:

Administer by intravenous, intramuscular, or subcutaneous injection 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 per 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 - kg	1	3	5	10	15	20	25	30	40
# Dose of Torbugesic (10 mg/ml) - mls	0.03	0.07	0.10	0.30	0.40	0.50	0.60	0.80	1.00

Based on a 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 intramuscular or intravenous injection. Allow 20 minutes for profound sedation to develop before commencing the procedure.
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.
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 - kg	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 - kg	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 - kg	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 in 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 - kg	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 reflex in approximately 14 minutes.
Ketamine (100 mg/ml) should be administered 15 minutes following the first injection at 0.5 ml/10 kg (equivalent to 5 mg ketamine/kg) by intramuscular injection.
The pedal reflex 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 - kg	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 AND MEDETOMIDINE BY INTRAMUSCULAR INJECTION AT THE ABOVE DOSE RATES									
WAIT 15 MINUTES BEFORE ADMINISTERING THE KETAMINE BY IM 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/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/5 kg bodyweight (equivalent to 0.4 mg butorphanol/kg), should be administered by either subcutaneous or intramuscular injection 15 minutes prior to recovery. Alternatively, 0.05 ml per 5 kg (equivalent to 0.1 mg butorphanol/kg), by intravenous injection can be used.

Torbugesic for Feline Analgesia

Weight of cat - kg	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 - kg	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	0.05	0.08	0.10	0.13	0.15	0.18	0.20	0.23	0.25

(1 mg/ml) - mls									

* 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:
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 reflex occurs 3 minutes post-injection.

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

Weight of cat - kg	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.

Intravenous

Administer Torbugesic Injection at 0.05 ml/5 kg (equivalent to 0.1 mg butorphanol/kg), 0.2 ml Domitor/5 kg (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 bodyweight (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
2.50	22 secs	39 secs	28 mins	62 mins	83mins

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

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.

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

The most important result of overdosage is respiratory depression. This can be reversed with naloxone. 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.

4.11 Withdrawal period(s)

Horse (Meat & Offal): Zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Analgesics, Opioids, Morphinan derivatives

ATCvet Code: QNO2AF01

Torbugesic Injection contains butorphanol, a centrally acting analgesic showing opioid -agonist and -antagonist activity. Its analgesic activity is about 4-7 times that of morphine, and its narcotic antagonist activity about 1/40 that of naloxone. Analgesic effects are dose-related, and in the horse last 15-90 minutes. Butorphanol assists in the production of profound sedation in combination with detomidine, medetomidine, or romifidine; in the production of sedation and analgesia in combination with acepromazine as a premedicant to general anaesthesia; pre-operative analgesia prior to induction of anaesthesia with a variety of agents. In high doses, respiratory depression followed by cardiovascular depression can occur.

5.2 Pharmacokinetic particulars

After intravenous injection in horses of butorphanol at 0.1 mg/kg, the elimination half-life is brief with a C_{max} of 680.6±568.5 ng/ml at 5 minutes post-treatment. A mean plasmatic butorphanol concentration of about 5 ng/ml three hours post injection is observed. It is metabolized in the liver and eliminated by the urine.
Preclinical studies and clinical experience have shown that analgesic effects are seen within 15 minutes of injection and last approximately 2 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzethonium Chloride
Citric Acid Monohydrate
Sodium Citrate Dihydrate
Sodium Chloride
Water for Injections

6.2 Incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

10 and 50 ml amber glass type I vials, with grey rubber chlorobutyl bungs and aluminium overseals, containing a clear, colourless sterile aqueous solution.

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4154

9. DATE OF FIRST AUTHORISATION

15 May 1991

10. DATE OF REVISION OF THE TEXT

November 2020

Approved: 28/10/21

D Austin