ANNEX I

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)

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 dihydrate	
Sodium chloride	
Benzethonium chloride Water for injection	

Clear, colourless liquid.

3. CLINICAL INFORMATION

3.1 Target species

Horses, dogs and cats.

3.2 Indications for use for each target species

HORSES

As an analgesic:
The veterinary medicinal product 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 the veterinary medicinal product 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 the veterinary medicinal product 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 the veterinary medicinal product after the administration of romifidine.

DOGS

As an analgesic:
For the relief of moderate to severe pain in dogs. Clinical studies have shown that the veterinary medicinal product 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 the veterinary medicinal product alone, clinical studies have verified that deep to profound sedation is achieved by the veterinary medicinal product 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 the veterinary medicinal product 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 the veterinary medicinal product in conjunction with acepromazine provides a suitable analgesic and sedative premedicant to general anaesthesia. The dose of the veterinary medicinal product 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:

The veterinary medicinal product 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.

CATS

As an analgesic:
The veterinary medicinal product may be used for the relief of pain in the cat. Pre-operative use of the veterinary medicinal product can provide analgesia during surgery. Clinical studies have demonstrated that the veterinary medicinal product 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 the veterinary medicinal product alone in the cat, clinical studies have verified that profound sedation is achieved by using the veterinary medicinal product 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: The veterinary medicinal product 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.

3.3 Contraindications

HORSES
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.

DOGS & CATS
Do not use in dogs and cats with a history of liver disease.

3.4 Special warnings

Marked sedation does not occur when the veterinary medicinal product is used as a sole agent in cats.

3.5 Special precautions for use

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.

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

DOGS
If respiratory depression occurs, naloxone may be used as an antidote.
When using the veterinary medicinal product 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.

CATS
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.

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. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician. **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.

Special precautions for the protection of the environment:

Not applicable.

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]

[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 Torbugesic Injection as a sole agent, may occur in approximately 15% of horses.

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Anorexia [5] Ataxia [5] Diarrhoea [5]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Respiratory depression

[5] Transient

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	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 the national competent authority via the national reporting system. See package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not use during the last month of pregnancy.
Do not use in pregnant mares.
The use is not recommended during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

HORSES

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

*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.

DOGS

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 anaesthesiaWeight 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.

CATS

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 (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: 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 Ketavet – 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 Ketavet – 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

* 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 - 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.

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. 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 'Administration routes and dosage ' 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

Horse:
Meat and offal: Zero days.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QNO2AF01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except other component following combinations:

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 36 months.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25 °C

Keep the vial in the outer carton.

Protect from light.

5.4 Nature and composition of immediate packaging

Amber glass type I vials, with a chlorobutyl stopper and aluminium overseal,.

Pack sizes:
Cardboard box containing 1 vial of 10 ml.
Cardboard box containing 1 vial of 50 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/079/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 01/10/2000

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

12/2022

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).