

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketaset 100 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1 ml contains:

Ketamine 100 mg/ml (equivalent to Ketamine hydrochloride 115.36 mg/ml) with 0.01% benzethonium chloride as a preservative.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml

50 ml

5. TARGET SPECIES

Cats, dogs, horses, and sub-human primates.

6. INDICATION(S)

An anaesthetic agent for cats, dogs, horses, and sub-human primates.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

See package leaflet.

8. WITHDRAWAL PERIOD

Not to be used in animals intended for human consumption. Treated horses must never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

Consult the enclosed package leaflet for details of dosage and administration, contra-indications, warnings, etc.

Do not mix Ketaset with other products, with the exception of Domitor™ and Torbugesic®.

10. EXPIRY DATE

Use before:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light. Retain vial and package leaflet in this carton.

Following withdrawal of the first dose use the product within 28 days.

Discard unused material.

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

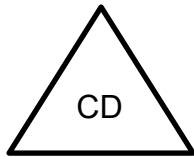
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13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

POM-V

For animal treatment only. To be supplied only on veterinary prescription.



14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of reach and sight 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 42058/4074

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS

{Vial Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketaset 100 mg/ml Solution for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 1 ml contains: Ketamine 100 mg/ml (equivalent to Ketamine hydrochloride 115.36 mg/ml) with 0.01% be-nzethonium chloride as a preservative.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

50 ml

4. ROUTE(S) OF ADMINISTRATION

Consult the enclosed package leaflet for details of dosage and administration, contra-indications, warnings, etc.

An anaesthetic agent for cats, dogs, horses and sub-human primates.

5. SPECIAL WARNINGS

Do not mix Ketaset with other products, with the exception of Domitor™ and Torbugesic®.

Do not store above 25°C. Protect from light. Keep out of reach and sight of children.

Keep container in outer carton.

6. BATCH NUMBER

Batch No.:

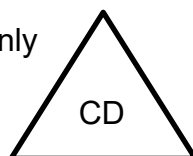
7. EXPIRY DATE

Use before:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

POM-V



To be supplied only on veterinary prescription.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

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

Vm 42058/4074

PACKAGE LEAFLET FOR:

Ketaset 100 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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketaset 100 mg/ml Solution for Injection

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

Ketaset Injection is a colourless solution containing Ketamine 100 mg/ml (equivalent to Ketamine hydrochloride 115.36 mg/ml) with benzethonium chloride 0.01% as a preservative.

4. INDICATION(S)

Ketaset is a dissociative anaesthetic agent for use by intramuscular, subcutaneous or intravenous injection.

Ketaset induces a state of catalepsy with amnesia and analgesia; muscle tone is maintained including the pharyngeal and laryngeal reflexes. The heart rate, blood pressure and cardiac output are increased; respiratory depression is not a noticeable feature. All these characteristics may be modified if Ketaset is used in combination with other agents. Ketaset may be used as a sole agent for restraint and minor surgical procedures where muscle relaxation is not required in the domestic cat and sub-human primates.

Ketaset may also be used to induce anaesthesia:

- a) in conjunction with butorphanol (Torbugesic® Injection) and medetomidine (Domitor™) in the dog and cat,
- b) in conjunction with xylazine in the dog, cat and horse,
- c) in conjunction with detomidine (Domosedan™) in the horse,

d) in conjunction with romifidine (Sedivet™) in the horse.

5. CONTRAINDICATIONS

Before using any combinations consult the contra-indications and warnings that appear on the other products' data sheets.

6. ADVERSE REACTIONS

7. TARGET SPECIES

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

It should be noted that dosage and routes of administration vary widely between species.

DOG - XYLAZINE/KETASET

Dosage and administration: Administer xylazine (2% solution) at a dose rate of 0.5ml/10kg bodyweight (equivalent to 1mg xylazine/kg) by intramuscular injection. Immediately administer Ketaset at a dose rate of 1.5ml/10kg bodyweight (equivalent to 15mg ketamine/kg) by intramuscular injection.

Dogs become recumbent in approximately 3 minutes and lose their pedal reflex in approximately 7 minutes. Duration of anaesthesia is approximately 24 minutes, the pedal reflex returning about 31 minutes following administration of the Ketaset Injection.

Xylazine and Ketaset Canine Anaesthesia – (IM)

Weight of Dog in kgs:-	1	3	5	10	15	20	25	30	40
Dose of *xylazine (2% soln) – mls:-	0.0 5	0.1 5	0.2 5	0.5 0	0.7 5	1.0 0	1.2 5	1.5 0	2.0 0
Dose of **Ketaset (100mg/ml) – mls:-	0.1 5	0.4 5	0.7 5	1.5 0	2.2 5	3.0 0	3.7 5	4.5 0	6.0 0

* Based on a dose rate of 1mg xylazine/kg bodyweight

** Based on a dose rate of 15mg ketamine/kg bodyweight

DOG - MEDETOMIDINE/KETASET

Dosage and administration: Administer Medetomidine (Domitor) at a dose rate of 0.40ml/10kg bodyweight (equivalent to 40µg medetomidine/kg) and Ketaset at 0.5-0.75ml/10kg bodyweight (equivalent to 5.0-7.5mg ketamine/kg), depending on duration of anaesthesia required, by intramuscular injection.

The combination may be administered in the same syringe, however the vials should have separate needles inserted for withdrawal, to minimise the risk of cross contamination.

Loss of pedal reflex occurs approximately 11 minutes following injection at 5mg/kg and 7 minutes following injection at 7.5mg/kg. Duration of anaesthesia is approximately 30 and 50 minutes respectively.

Medetomidine and Ketaset Canine Anaesthesia – (IM)

Dosage chart for 5mg ketamine/kg (duration of anaesthesia approximately 30 minutes)

Weight of Dog in kgs:-	1	3	5	10	15	20	25	30	40
Dose of *Medetomidine (Domitor) (1mg/ml) – mls:-	0.0 4	0.1 2	0.2 0	0.4 0	0.6 0	0.8 0	1.0 0	1.2 0	1.6 0
Dose of **Ketaset (100mg/ml) – mls:-	0.0 5	0.1 5	0.2 5	0.5 0	0.7 5	1.0 0	1.2 5	1.5 0	2.0 0

* Based on a dose rate of 40µg medetomidine/kg bodyweight

** Based on a dose rate of 5mg ketamine/kg bodyweight

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

Medetomidine and Ketaset Canine Anaesthesia – (IM)

Dosage chart for 7.5mg ketamine/kg (duration of anaesthesia approximately 50 minutes)

Weight of Dog in kgs:-	1	3	5	10	15	20	25	30	40
Dose of *Domitor (1mg/ml) – mls:-	0.0 4	0.1 2	0.2 0	0.4 0	0.6 0	0.8 0	1.0 0	1.2 0	1.6 0
Dose of **Ketaset (100mg/ml) – mls:-	0.0 8	0.2 3	0.3 8	0.7 5	1.1 3	1.5 0	1.8 8	2.2 5	3.0 0

* Based on a dose rate of 40µg medetomidine/kg bodyweight

** Based on a dose rate of 7.5mg ketamine/kg bodyweight

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

DOG - BUTORPHANOL/MEDETOMIDINE/KETASET

Dosage and administration: Administer Torbugesic at 0.1mg butorphanol/kg and Domitor at 25µg medetomidine/kg by intramuscular injection.

The combination may be 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.

Ketaset Injection should be administered 15 minutes following the first injection at a dose rate of 0.5ml/10kg bodyweight (equivalent to 5mg ketamine/kg) by intramuscular injection.

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

Torbugesic, medetomidine, and Ketaset Canine Anaesthesia - (IM)

Weight of Dog in kgs:-	1	3	5	10	15	20	25	30	40
Dose of *Torbugesic (10mg/ml) – mls:-	0.0 1	0.0 3	0.0 5	0.1 0	0.1 5	0.2 0	0.2 5	0.3 0	0.4 0
Dose of **Medetomidine (Domitor) (1mg/ml) – mls:-	0.0 3	0.0 8	0.1 3	0.2 5	0.3 8	0.5 0	0.6 3	0.7 5	1.0 0
ADMINISTER TORBUGESIC AND DOMITOR BY INTRAMUSCULAR INJECTION AT THE ABOVE DOSE RATES									
WAIT 15 MINUTES BEFORE ADMINISTERING THE KETASET BY IM INJECTION AT THE DOSE RATES BELOW									
Dose of ***Ketaset (100mg/ml) - mls	0.0 5	0.1 5	0.2 5	0.5 0	0.7 5	1.0 0	1.2 5	1.5 0	2.0 0

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

** Based on a dose rate of 25µg medetomidine/kg bodyweight

*** Based on a dose rate of 5 mg ketamine/kg bodyweight

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

CAT - KETASET AS A SOLE AGENT

Dosage and administration: Ketaset on its own may be used by intravenous or subcutaneous injection, but intramuscular injection is the recommended route. The dose is 11-33mg ketamine/kg depending on the degree of restraint or surgical interference that is intended.

The following dosages are indicated as a guide but may need to be adjusted depending on the physical condition of the patient and the usage of sedatives and premedicants.

<i>Dose mg/kg</i>	<i>Clinical procedures</i>
11 (0.11ml/kg)	Minor restraint
22-33 (0.22-0.33ml/kg)	Minor surgery and restraint of fractious cats

Duration of Ketaset anaesthesia is 20-40 minutes and recovery takes place over a 1-4 hour period.

For major surgery, Ketaset should be used in conjunction with supplemental sedatives or anaesthetics. Dosage varies from 1.25-22mg/kg (0.06-1.1ml/5kg) depending on the combination and route of administration used.

Vomiting is unlikely to occur when Ketaset is used alone, however cats should be starved for several hours prior to anaesthesia where possible. Induction and recovery should be allowed to occur in quiet and calm surroundings.

Ketaset supplementary combinations in the cat: Atropine premedication is generally recommended at 0.05mg/kg to reduce salivation. Endotracheal intubation can be achieved during Ketaset anaesthesia. Inhalation anaesthesia may be maintained by suitable combinations of methoxyflurane, halothane, nitrous oxide and oxygen.

CAT - ACEPROMAZINE/KETASET

Dosage and administration: Administer acepromazine (0.2% solution) at a dose rate of 0.28ml/5kg bodyweight (equivalent to 0.11mg acepromazine/kg) and atropine (0.06% solution) at a dose rate of 0.42 ml/5kg bodyweight (equivalent to 0.05mg/kg) by intramuscular injection, as a premedicant.

Alternatively, administer simultaneously with Ketaset using separate needles and syringes.

CAT - XYLAZINE/KETASET

Dosage and administration: Administer xylazine (2% solution) at a dose rate of 0.28mls/5kg bodyweight (equivalent to 1.1mg xylazine/kg) and atropine (0.06% solution) at a dose rate of 0.25mls/5kg bodyweight (equivalent to 0.03mg atropine/kg) by intramuscular injection. Wait 20 minutes and then administer Ketaset at a dose rate of 1.1ml/5kg bodyweight (equivalent to 22mg ketamine/kg), by intramuscular injection.

Xylazine may induce vomiting up to 20 minutes after administration.

Onset of anaesthesia after intramuscular injection of Ketaset takes some 3-6 minutes.

A xylazine/Ketaset combination produces a deeper anaesthesia with more pronounced respiratory and cardiac effects and a longer recovery period than acepromazine/Ketaset combinations.

Xylazine and Ketaset Feline Anaesthesia – (IM)

Weight of Cat in kgs:-	1.5	2	2.5	3	3.5	4	4.5	5
Dose of *xylazine (2% soln) – mls:-	0.08	0.11	0.14	0.17	0.19	0.22	0.25	0.28
Dose of **atropine (600µg/ml) – mls:-	0.08	0.10	0.13	0.15	0.18	0.20	0.23	0.25
WAIT 20 MINUTES								
Dose of ***Ketaset (100mg/ml) – mls:-	0.33	0.44	0.55	0.66	0.77	0.88	0.99	1.10

* Based on a dose rate of 1.1mg xylazine/kg bodyweight

** Based on a dose rate of 0.03mg atropine/kg bodyweight

*** Based on a dose rate of 22mg ketamine/kg bodyweight

CAT - MEDETOMIDINE/KETASET

Dosage and administration:

a) Intramuscular

Administer Medetomidine (Domitor) at a dose rate of 80µg medetomidine/kg by intramuscular injection. This should be followed immediately by the intramuscular injection of Ketaset at a dose rate of 0.12-0.38ml/5kg bodyweight (equivalent to 2.5mg up to a maximum of 7.5mg ketamine/kg). Ketaset and medetomidine 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.

Onset of anaesthesia is 3-4 minutes. The duration of surgical anaesthesia varies between 30-60 minutes and is related to the dose of Ketaset used. If required, anaesthesia may be prolonged with halothane and oxygen with or without nitrous oxide.

Medetomidine and Ketaset Feline Anaesthesia – (IM)

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

* Based on a dose rate of 80µg medetomidine/kg bodyweight

** Based on a dose rate of 5mg ketamine/kg bodyweight

b) Intravenous

Medetomidine and Ketaset may be administered together by intravenous injection at the following dose rates; 40µg medetomidine/kg and 1.25mg ketamine/kg).

Clinical experience has shown that when ketamine and medetomidine have been used intravenously in cats and the need for anaesthesia has passed, administration of 100µg atipamezole/kg by intramuscular injection results in recovery to sternal recumbency in approximately 10 minutes and to standing in approximately 14 minutes.

Medetomidine and Ketaset Feline Anaesthesia – (IV)

Weight of Cat in kgs:-	1.5	2	2.5	3	3.5	4	4.5	5
Dose of * Medetomidine (Domitor) (1mg/ml) – mls:-	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
Dose of **Ketaset (100mg/ml) – mls:-	0.02	0.03	0.03	0.04	0.05	0.05	0.06	0.06

* Based on a dose rate of 40µg medetomidine/kg bodyweight

** Based on a dose rate of 1.25mg ketamine/kg bodyweight

Atropine is not normally necessary when using a medetomidine / Ketaset combination.

Use of either insulin syringes or 1ml graduated syringes is recommended to ensure accurate dosing.

CAT - TORBUGESIC/MEDETOMIDINE/KETASET

Dosage and administration:

a) Intramuscular

Administer Torbugesic at a dose rate of 0.4mg butorphanol/kg, Domitor at a dose rate of 80µg medetomidine/kg and Ketaset at a dose rate of 0.25ml/5kg bodyweight (equivalent to 5mg ketamine/kg) by intramuscular injection.

All neurological agents 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 pedal reflex occurs 3 minutes post injection. At 45 minutes post induction, reversal with 200µg atipamezole/kg results in return of pedal reflex 2 minutes later, sternal recumbency 6 minutes later and standing 31 minutes later.

Torbugesic, medetomidine, and Ketaset Feline Anaesthesia - (IM)

Weight of Cat in kgs:-	1.5	2	2.5	3	3.5	4	4.5	5
Dose of *Torbugesic (10mg/ml) – mls:-	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
Dose of ** Medetomidine (Domitor) (1mg/ml) – mls:-	0.12	0.16	0.20	0.24	0.28	0.32	0.36	0.40
Dose of ***Ketaset (100mg/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 bodyweight

** Based on a dose rate of 80µg medetomidine/kg bodyweight

*** Based on a dose rate of 5 mg ketamine/kg bodyweight

b) Intravenous

Administer Torbugesic at a dose rate of 0.1mg butorphanol/kg, Domitor at a dose rate of 40µg medetomidine/kg and Ketaset, depending on depth of anaesthesia required, at a dose rate of 0.06- 0.13ml/5kg bodyweight (equivalent to 1.25-2.5mg ketamine/kg) by intravenous injection.

All neurological agents 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.

Ketaset*	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 40µg/kg

Clinical experience has shown that reversal, at any stage, with 100µg atipamezole/kg results in return of the pedal reflex 4 minutes later, sternal recumbency 7 minutes later and standing 18 minutes later.

Torbugesic, medetomidine, and Ketaset Feline Anaesthesia - (IV)

Dosage chart for 2.5 mg ketamine/kg (duration of anaesthesia approximately 28 minutes).

Weight of Cat in kgs:-	1.5	2	2.5	3	3.5	4	4.5	5
Dose of *Torbugesic (10mg/ml) – mls:-	0.02	0.02	0.03	0.03	0.04	0.04	0.05	0.05
Dose of ** Medetomidine (Domitor) (1mg/ml) – mls:-	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
Dose of ***Ketaset (100mg/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 40µg medetomidine/kg bodyweight

*** Based on a dose rate of 2.5 mg ketamine/kg bodyweight

HORSE

For the production of short-term anaesthesia suitable for minor surgical interference's or for induction prior to inhalation anaesthesia. When romifidine or detomidine are used as the premedicant, anaesthesia may also be maintained with a 'top-up' combination of either romifidine and Ketaset or detomidine and Ketaset at regular 8 - 10 minute intervals. Ketaset should never be used as a sole anaesthetic agent.

It is generally accepted as good anaesthetic practice to starve animals for a period prior to anaesthesia where possible.

To achieve the best results, it is important the horses are not stressed before the anaesthetic. It is equally important that the whole procedure, from induction to recovery, should take place in quiet and calm surroundings.

For horses that are stressed before the procedure, the use of 0.03mg/kg acepromazine 45 minutes prior to administration of either Detomidine(Domosedan) or Romifidine(Sedivet)facilitates handling and placement of an intravenous catheter.

If the horse fails to become sedated following the injection of either xylazine, detomidine or romifidine, then Ketaset should not be injected and the anaesthetic procedure should be abandoned. The situation should be assessed to establish why

the horse failed to respond, and then the environment and/or the drugs should be adjusted as necessary, before trying again the following day.

When using a total intravenous technique and for safe and effective use of a top-up regime, the use of an intravenous catheter is strongly advised.

During castration it has been noted that the use of 10mls lidocaine divided between the testicles eliminates the possible response to ligation of the testicular cord and minimises the number of top-ups required.

HORSE - XYLAZINE/KETASET

Dosage and administration: Xylazine (10% solution) should be administered by slow intravenous injection at a dose rate of 1.1ml/100kg bodyweight (equivalent to 1.1mg xylazine/kg). The horse should appear sedated by 2 minutes post injection.

Injection of Ketaset should be administered at this stage. It is recommended not to delay the Ketaset injection longer than 5 minutes after xylazine administration.

Ketaset should be administered as an intravenous bolus at a dose rate of 2.2ml/100kg bodyweight (equivalent to 2.2mg ketamine/kg).

Induction and recumbency take some 1-2 minutes. Muscle jerking may occur in the first minutes, but this usually subsides.

Anaesthesia is variable in duration, lasting between 10-30 minutes, but usually less than 20 minutes. Horses invariably stand 25-45 minutes after induction. Recovery is generally quiet, but may occur suddenly. It is important therefore that short duration interferences only are attempted, or arrangements to prolong anaesthesia are made. For longer periods of anaesthesia, intubation and maintenance by inhalation anaesthesia can be used.

Xylazine and Ketaset Equine Anaesthesia – (IV)

Weight of Horse in kgs:-	50	100	150	200	250	300	400	500	600
+ Dose of *xylazine (10% soln) – mls:-	0.60	1.10	1.70	2.20	2.80	3.30	4.40	5.50	6.60
WAIT 2 MINUTES									
Dose of **Ketaset (100mg/ml) – mls:-	1.10	2.20	3.30	4.40	5.50	6.60	8.80	11.00	13.20

+ Administer xylazine, wait 2 minutes before administering Ketaset

* Based on a dose rate of 1.1mg xylazine/kg bodyweight

** Based on a dose rate of 2.2mg ketamine/kg bodyweight

HORSE - DETOMIDINE/KETASET

Dosage and administration: Domosedan™ should be administered by intravenous injection at a dose rate of 20µg detomidine/kg. The horse should appear sedated by five minutes post injection. At this stage Ketaset should be administered at a dose rate of 2.2ml/100kg bodyweight (equivalent to 2.2mg ketamine/kg) as an intravenous bolus.

Onset of anaesthesia is gradual; most horses take approximately 1 minute to become recumbent. Large, fit horses may take up to 3 minutes for recumbency. Anaesthesia continues to deepen for a further 1-2 minutes and during this time the horse should be left quietly.

Horses regain sternal recumbency approximately 20 minutes post Ketaset injection giving a surgical anaesthesia duration of 10-15 minutes.

Maintenance of surgical anaesthesia

Should it become necessary to prolong anaesthesia, either of the following regimes may be used:

i) Thiopental sodium

Thiopental sodium may be administered intravenously in boluses of 1mg/kg as required. Total doses of 5mg/kg (five 1mg/kg increments) have been given. Total doses greater than this may reduce the quality of recovery. Thiopental sodium can also be administered in increments if sufficient depth of anaesthesia is not achieved. The horse may be ataxic if encouraged to stand prematurely and so should be left to stand in its own time.

ii) Detomidine/Ketaset

Administer 10µg detomidine/kg i.e. ½ the initial premedication dose by intravenous injection, followed immediately by 1.1mg ketamine/kg i.e. ½ the initial induction dose by intravenous injection. This will provide approximately 10 minutes additional surgical anaesthesia, which can be repeated at regular 10 minute intervals (up to 5 times) without compromising recovery.

Detomidine and Ketaset Equine Anaesthesia – (IV)

Premedication and Induction of Anaesthesia

Weight of Horse in kgs:-	50	100	150	200	250	300	400	500	600
Dose of *Detomidine (10mg/ml) – mls:-	0.10	0.20	0.30	0.40	0.50	0.60	0.80	1.00	1.20
WAIT 5 MINUTES									
Dose of **Ketaset (100mg/ml) – mls:-	1.10	2.20	3.30	4.40	5.50	6.60	8.80	11.00	13.20

Induction – administer Detomidine IV, wait 5 minutes before administering Ketaset IV

* Based on a dose rate of 20µg detomidine/kg bodyweight

** Based on a dose rate of 2.2mg ketamine/kg bodyweight

Top-up (Maintenance) dose at 10 minute intervals

Weight of Horse in kgs:-	50	100	150	200	250	300	400	500	600
Dose of ~Detomidine(10mg/ml) – mls:-	0.05	0.10	0.15	0.20	0.25	0.30	0.40	0.50	0.60
Dose of ~~ Ketaset (100mg/ml) – mls:-	0.55	1.10	1.65	2.20	2.75	3.30	4.40	5.50	6.60

Maintenance - administer Detomidine IV, immediately followed by Ketaset IV

~ Based on a dose rate of 10µg detomidine/kg bodyweight

~~ Based on a dose rate of 1.1mg ketamine/kg bodyweight

HORSE - ROMIFIDINE/KETASET

Dosage and administration: Romifidine should be administered by intravenous injection at a dose rate of 100µg romifidine/kg. The horse should appear sedated by five to ten minutes post injection. At this stage Ketaset should be administered at a dose rate of 2.2ml/100kg (equivalent to 2.2mg ketamine/kg) as an intravenous bolus. Sedation should be apparent before the induction of anaesthesia.

Maintenance of surgical anaesthesia

Should it become necessary to prolong anaesthesia, either of the following regimes may be used:

i) Thiopental sodium

Thiopental sodium may be administered intravenously in boluses of 2.5mg/kg when signs of returning consciousness appear. This can be repeated up to 3 times after induction. Total doses greater than this may reduce the quality of recovery. The horse may be ataxic if encouraged to stand prematurely and so should be left to stand in its own time.

ii) Romifidine/Ketaset

Depending on depth and duration of anaesthesia required, administer romifidine intravenously within the dose range of 25-50µg/kg bodyweight i.e. ¼-½ the initial premedication dose followed immediately by ketamine intravenously at a dose rate of 1.1mg/kg bodyweight i.e. ½ the initial induction dose). Each top-up lasts

approximately 8-10 minutes and can be repeated at regular 8-10 minute intervals (up to 5 times) without compromising recovery.

Romifidine and Ketaset Equine Anaesthesia – (IV)

Premedication and Induction of Anaesthesia

Weight of Horse in kgs:-	50	100	150	200	250	300	400	500	600
Dose of * Romifidine (10mg/ml) – mls:-	0.50	1.00	1.50	2.00	2.50	3.00	4.00	5.00	6.00
WAIT 5-10 MINUTES									
Dose of **Ketaset (100mg/ml) – mls:-	1.10	2.20	3.30	4.40	5.50	6.60	8.80	11.00	13.20

Induction - administer Romifidine IV, wait 5-10 minutes before administering Ketaset IV

* Based on a dose rate of 100µg romifidine/kg bodyweight

** Based on a dose rate of 2.2mg ketamine/kg bodyweight

Top-up (Maintenance) dose at 8-10 minute intervals

Weight of Horse in kgs:-	50	100	150	200	250	300	400	500	600
~ Dose of Romifidine (10mg/ml) – mls:-	0.25	0.50	0.75	1.00	1.25	1.5	2.00	2.5	3.00
~~ Dose of Ketaset (100mg/ml) – mls:-	0.55	1.10	1.65	2.20	2.75	3.30	4.40	5.50	6.60

Maintenance – administer Romifidine IV, immediately followed by Ketaset IV

~ Based on a dose rate of 50µg romifidine/kg bodyweight

~~ Based on a dose rate of 1.1mg ketamine/kg bodyweight

SUB-HUMAN PRIMATES

The usual therapeutic dose for restraint and minor surgical procedures in primates is 3-15mg/kg administered intramuscularly. Ketaset (11mg/kg or 1.1ml/10kg) and acepromazine (0.55mg/kg or 2.8ml/10kg) administered intramuscularly to rhesus monkeys results in a smooth induction with anaesthesia attained in less than 5 minutes. The average duration of anaesthesia is just under one hour. Information on dosage rates for individual species can be obtained from the Marketing Authorisation Holder.

9. ADVICE ON CORRECT ADMINISTRATION

Ketaset must not be mixed with other products, with the exception of Domitor and Torbugesic.

10. WITHDRAWAL PERIOD(S)

Not to be used in animals intended for human consumption. Treated horses must never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Keep container in outer carton.

Protect from light.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

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 Warnings

1. This is a potent drug - particular care should be taken to avoid accidental self-administration. Preferably use a guarded needle until the moment of injection.
2. Wash off splashes from the skin and eyes immediately.
3. In the event of accidental self-administration - seek urgent medical attention and show this package leaflet to the doctor.
4. Advice to doctor: Do not leave patient unattended. Maintain airways and give symptomatic and supportive treatment.

General

Ketaset is metabolised by the liver and excreted via the kidney and hence should not be used in animals with hepatic or renal failure.

A small proportion of animals have been reported to be unresponsive to Ketaset as an anaesthetic agent at normal doses.

Care should be taken when using Ketaset-halothane combinations since the half-life of ketamine is prolonged.

For Animal Treatment Only

DOG

Xylazine should not be used in the latter stages of pregnancy. Medetomidine is not recommended in pregnant animals. Use of premedicants should be followed by a suitable reduction in Ketaset dosage. In the dog, the eyes remain open and pupils dilated. The eyes may be protected by covering with a damp gauze swab.

Torbugesic/medetomidine/Ketaset combination:

Consult the contra-indications that appear on the Torbugesic Injection and Domitor data sheets. There may be some pain on intramuscular injection.

CAT

Xylazine should not be used in the latter stages of pregnancy. Medetomidine is not recommended in pregnant cats. Use of premedicants should be followed by a suitable reduction in Ketaset dosage. Ketaset may cause salivation in cats. Atropine premedication may reduce this side effect. Muscular twitching and mild tonic convulsions have been recorded in the cat at recommended dose rates. These subside spontaneously but may be prevented by use of acepromazine or xylazine premedication, or controlled by use of acepromazine or ultra-short acting barbiturates in low doses. In the cat, the eyes remain open and pupils dilated. The eyes may be protected by covering with a damp gauze swab.

Torbugesic/medetomidine/Ketaset combination:

Consult the contra-indications that appear on the Torbugesic Injection and Domitor data sheets. There may be some pain on intramuscular injection.

HORSE

Do not use Ketaset as a sole agent in the horse. Xylazine should not be used in the latter stages of pregnancy. Detomidine should not be used in the last month of pregnancy. Romifidine should not be used in the last month of pregnancy.

In some horses, a mild, reversible heart block has been observed following premedication with detomidine.

Overdosage: If necessary, suitable artificial aids to maintain ventilation and cardiac output should be used until sufficient detoxification has taken place to enable a return to adequate spontaneous ventilation and cardiac activity. Pharmacological cardiac stimulants are not recommended, unless no other supportive measures are available.

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

Dispose of any unused product or containers in accordance with guidance from your local waste regulation authority.

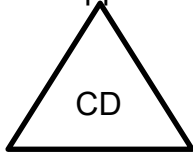
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

POM-V

To be supplied only on veterinary prescription.



Schedule 4, Part I

Package Quantities

10 ml and 50 ml multi-dose glass vials. Not all pack sizes may be marketed.

Further Information

Ketaset has been used in conjunction with xylazine in the donkey (Fisher R. J. 1984 E.V.J. 16(3) 176-179) and in mules (data on file) at the same dosages and route as the horse.

Further data on the use of ketamine in primates is available in the following reference:

Booth and McDonald 1988 Veterinary Pharmacology and Therapeutics 6th Edition, Published Ames Iowa State University Press 253-259.

Vm 04258/4074

Approved 28 August 2020

A handwritten signature in black ink that reads 'A. Hunter.' with a stylized initial 'A'.