

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX OF 10 ml
CARDBOARD BOX OF 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AT, CZ, DE, ES, PT, RO

Ketaset 100 mg/ml solution for injection for dogs, cats and horses
Ketamine hydrochloride

UK, CY, EL, IE

Ketavet 100 mg/ml solution for injection for dogs, cats and horses
Ketamine hydrochloride

IT

Ketastesic Vet 100 mg/ml solution for injection for dogs, cats and horses
Ketamine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Ketamine:	100 mg
(Equivalent to ketamine hydrochloride)	115.35 mg

3. PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless solution, free from visible evidence of contamination

4. PACKAGE SIZE

10 ml

50 ml

5. TARGET SPECIES

Dogs, cats and horses.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Horses (meat and offal): 1 day
(milk): 24 hours

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP { DD/MMM/YYYY}
Shelf life after first opening the vial: 28 days.
Once broached, use by _____.

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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

Disposal: read package leaflet.

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

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 subsidiaries in the concerned European Union Member States

16. MARKETING AUTHORISATION NUMBER(S)

TBA

17. MANUFACTURER’S BATCH NUMBER

<Batch> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AT, CZ, DE, ES, PL, PT, RO

Ketaset 100 mg/ml solution for injection for dogs, cats and, horses.
Ketamine hydrochloride

UK, CY, EL, IE

Ketavet 100 mg/ml solution for injection for dogs, cats and, horses.
Ketamine hydrochloride

IT

Ketastesic Vet 100 mg/ml solution for injection for dogs, cats and, horses.
Ketamine hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains:

Active substance:

Ketamine 100mg

(as ketamine hydrochloride: 115.35mg)

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

10 mL

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Horses (meat and offal): 1 day
(milk): -24 hours

6. BATCH NUMBER

<Batch> {number}

7. EXPIRY DATE

EXP { DD/MMM/YYYY }

Shelf life after first opening the vial: 28 days.

Once broached, use by _____.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AT, CZ, DE, ES, PT, RO

Ketaset 100 mg/ml solution for injection for dogs, cats and, horses.
Ketamine hydrochloride

UK, CY, EL, IE

Ketavet 100 mg/ml solution for injection for dogs, cats and, horses.
Ketamine hydrochloride

IT

Ketastesic Vet 100 mg/ml solution for injection for dogs, cats and, horses.
Ketamine hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains:

Active substance:

Ketamine 100mg

(as ketamine hydrochloride: 115.35mg)

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

50 mL

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Horses (meat and offal): 1 day
(milk): 24 hours

6. BATCH NUMBER

<Batch> {number}

7. EXPIRY DATE

EXP { DD/MMM/YYYY}

Shelf life after first opening the vial: 28 days.

Once broached, use by _____.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.