

## **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**

Do not freeze.  
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

Ketastestic 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.