

**LABELLING AND PACKAGE LEAFLET**  
**(REFERENCE MEMBER STATE: CZECH REPUBLIC)**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARDBOARD BOX (1x1ml only)**  
**PLASTIC BOX**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Versiguard Rabies, suspension for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

One dose (1 ml) contains:  
Inactivated rabies virus min. 2 IU

**3. PHARMACEUTICAL FORM**

Suspension for injection

**4. PACKAGE SIZE**

1 x 1 ml  
10 x 1 ml  
10 x 10 ml

**5. TARGET SPECIES**

Dogs, cats, cattle, pigs, sheep, goats, horses and ferrets

**6. INDICATION(S)**

Read the package leaflet before use.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

Dogs: SC.  
Cats, ferrets, cattle, pigs, sheep, goats, horses: SC or IM.

**8. WITHDRAWAL PERIOD(S)**

Dogs, cats, ferrets: Not applicable.  
Withdrawal period for cattle, pigs, sheep, goats, horses: Zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Accidental self-injection is dangerous.

**10. EXPIRY DATE**

EXP 00 (month) / 0000 (year)

Once broached use within 10 hours.

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator.

Do not freeze

Protect from light.

**12. SPECIFIC 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. To be supplied only on veterinary prescription.

**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**

*To be completed nationally.*

**16. MARKETING AUTHORISATION NUMBER(S)**

*To be completed nationally.*

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS****GLASS VIALS (1 ml)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Versiguard Rabies, suspension for injection

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Inactivated rabies virus min. 2 IU/ml

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

1 ml

**4. ROUTE(S) OF ADMINISTRATION**

SC/IM (dogs SC)

**5. WITHDRAWAL PERIOD(S)****6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP 00 (month) / 0000 (year)

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**GLASS VIALS (10 ml)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Versiguard Rabies, suspension for injection

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Inactivated rabies virus min. 2 IU/ml, aluminium hydroxide 2.0 mg/ml, thiomersal 0.1 mg/ml

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

10 ml

**4. ROUTE(S) OF ADMINISTRATION**

Dogs: SC.

Other species: SC / IM.

**5. WITHDRAWAL PERIOD(S)**

Dogs, cats, ferrets: Not applicable.

Withdrawal period for cattle, pigs, sheep, goats, horses: Zero days.

**6. BATCH NUMBER**

Lot{number}

**7. EXPIRY DATE**

EXP 00 (month) / 0000 (year)

Once broached use within 10 hours.

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

