

**ANNEX III**  
**LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

1 x 5 doses / carton

2 x 1 dose, 5 x 1 dose, 10 x 1 dose, 10 x 5 doses / plastic box

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

EquiShield EHV, emulsion for injection for horses

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

One dose (1 ml) contains:

**Active substance:**

Inactivated equine herpes virus type 1, (Bio 82: EHV – 1)

Min. 2.1 log<sub>10</sub> VNI

**Adjuvant:**

Montanide ISA 35 VG

**Excipient:**

Thiomersal

**3. PHARMACEUTICAL FORM**

Emulsion for injection.

**4. PACKAGE SIZE**

2 x 1 dose / 5 x 1 dose / 10 x 1 dose / 1 x 5 doses / 10 x 5 doses

**5. TARGET SPECIES**

Horses

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

Intramuscular use.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

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

Read the package leaflet before use.

Accidental injection is dangerous.

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

**10. EXPIRY DATE**

EXP {month/year}

Once opened use by 10 hours.

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator.

Protect from light.

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

Dispose of waste material in accordance with local requirements.

**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**

Dechra Limited  
Snaygill Industrial Estate  
Skipton  
North Yorkshire  
BD23 2RW  
United Kingdom of Great Britain and Northern Ireland

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

**17. MANUFACTURER’S BATCH NUMBER**

Batch {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

{1 dose; 5 doses / glass vial}

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

EquiShield EHV, emulsion for injection for horses

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

Inactivated equine herpes virus type 1, (Bio 82: EHV-1)

Min. 2.1 log<sub>10</sub> VNI

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

1 dose / 5 doses

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

i.m.

**5. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

**6. BATCH NUMBER**

Batch {number}

**7. EXPIRY DATE**

EXP {month/year}

Once opened use by 10 hours.

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

For animal treatment only.