

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Box with vial of lyophilisate**

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

OVISER 5000 IU lyophilisate for solution for injection

**2. STATEMENT OF ACTIVE SUBSTANCES****Composition per vial:**

Pregnant Mare Serum Gonadotrophin (PMSG) 5000 IU

**3. PACKAGE SIZE**

5000 IU

10 x 5000 IU

**4. TARGET SPECIES**

Sheep (ewe) and goat.

**5. INDICATIONS****6. ROUTES OF ADMINISTRATION**

Dissolve the lyophilisate with the solvent.

Administer 4 – 6 ml of the reconstituted veterinary medicinal product per animal by intramuscular or subcutaneous route.

Read the package leaflet before use.

**7. WITHDRAWAL PERIODS****Withdrawal period:**

Meat and offal: zero days.

Milk: zero days.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once reconstituted use immediately.

<b>9. SPECIAL STORAGE PRECAUTIONS</b>
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Store in a refrigerator (2 °C – 8 °C).

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

<b>10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”</b>
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Read the package leaflet before use.

<b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
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**FOR ANIMAL TREATMENT ONLY**

<b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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Keep out of the sight and reach of children.

<b>13. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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Laboratorios Hipra, S.A.  
Avda. la Selva, 135  
17170 Amer (Girona) SPAIN

<b>14. MARKETING AUTHORISATION NUMBERS</b>
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<b>15. BATCH NUMBER</b>
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Lot {number}

<b>MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS</b>
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<b>Vial of lyophilisate</b>
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<b>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</b>
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OVISER 5000 IU lyophilisate for solution for injection

<b>2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES</b>
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**Composition per vial:**

Pregnant Mare Serum Gonadotrophin (PMSG) 5000 IU

<b>3. BATCH NUMBER</b>
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Lot {number}

<b>4. EXPIRY DATE</b>
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Exp. {mm/yyyy}

Once reconstituted use immediately.

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Box with vial of solvent**

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

SOLVENT FOR OVISER 5000 IU

**2. STATEMENT OF ACTIVE SUBSTANCES****Composition per vial:**

Phosphate buffer solution (PBS) 50 ml

**3. PACKAGE SIZE**

50 ml

10 x 50 ml

**4. TARGET SPECIES**

Sheep (ewe) and goat.

**5. INDICATIONS****6. ROUTES OF ADMINISTRATION**

Dissolve the lyophilisate with the solvent.

Administer 4 – 6 ml of the reconstituted veterinary medicinal product per animal by intramuscular or subcutaneous route.

Read the package leaflet before use.

**7. WITHDRAWAL PERIODS****Withdrawal period:**

Meat and offal: zero days.

Milk: zero days.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once reconstituted use immediately.

<b>9. SPECIAL STORAGE PRECAUTIONS</b>
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Store below 25°C.

<b>10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”</b>
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Read the package leaflet before use.

<b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
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**FOR ANIMAL TREATMENT ONLY**

<b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
--

Keep out of the sight and reach of children.

<b>13. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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Laboratorios Hipra, S.A.  
Avda. la Selva, 135  
17170 Amer (Girona) SPAIN

<b>14. MARKETING AUTHORISATION NUMBERS</b>
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<b>15. BATCH NUMBER</b>
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Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Vial of solvent**

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

SOLVENT FOR OVISER 5000 IU

**2. STATEMENT OF ACTIVE SUBSTANCES****Composition per vial:**

Phosphate buffer solution (PBS) 50 ml

**3. TARGET SPECIES**

Sheep (ewe) and goat.

**4. ROUTES OF ADMINISTRATION**

Administer by intramuscular or subcutaneous route.

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS****Withdrawal period:**

Meat and offal: zero days.

Milk: zero days.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

Once reconstituted use immediately.

**7. SPECIAL STORAGE PRECAUTIONS**

Store below 25°C.

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Laboratorios Hipra, S.A.

Avda. la Selva, 135

17170 Amer (Girona) SPAIN

<b>9. BATCH NUMBER</b>
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Lot {number}