

Equiparin 5.000 IU/100 g gel for horses,

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

**A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE**

{bottle, box}

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

Equiparin 5.000 IU/100 g gel for horses  
Heparin sodium, Hydroxyethyl salicylate, Levomenthol

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

100 g gel contains:

**Active substances:**

Heparin sodium	5000 I.U.
Hydroxyethyl salicylate	5.0 g
Levomenthol	0.5 g

**Excipients:**

Chlorophyllin copper (E 141)	0.001 g
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**3. PHARMACEUTICAL FORM**

Gel

**4. PACKAGE SIZE**

285 g  
6 x 285 g

**5. TARGET SPECIES**

Horses

**6. INDICATION(S)**

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

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Withdrawal period:

Meat and offal: 0 days

Not permitted for use in mares producing milk for human consumption.

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

**10. EXPIRY DATE**

EXP {month/year}

Shelf-life after first opening the container:

6 months

Once opened, use by...

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25 °C.

Do not freeze.

**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 REACH AND SIGHT OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

aniMedica GmbH  
Im Südfeld 9  
48308 Senden-Bösensell  
Germany

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

**17. MANUFACTURER’S BATCH NUMBER**

Batch {number}

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET FOR:**  
Equiparin 5.000 IU/100 g gel for horses

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder and manufacturer responsible for batch release:

aniMedica GmbH  
Im Südfeld 9  
48308 Senden-Bösensell  
Germany

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

Equiparin 5.000 IU/100 g gel for horses  
Heparin sodium, Hydroxyethyl salicylate, Levomenthol

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

100 g gel contain:

**Active substances:**

Heparin sodium	5000 I.U.
Hydroxyethyl salicylate	5.0 g
Levomenthol	0.5 g

**Excipients:**

Chlorophyllin copper (E 141)	0.001 g
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Clear green cutaneous gel.

**4. INDICATION(S)**

For the treatment of local inflammatory swellings and bruising, including tendonitis, tenosynovitis, bursitis and other acute inflammatory conditions of the musculo-skeletal system in the horse.

Equiparin also promotes the early reabsorption of haematoma and oedematous swelling resulting from such conditions.

**5. CONTRAINDICATIONS**

Do not use in case of hypersensitivity to the active substances or to any of the excipients.  
Not permitted for use in mares producing milk for human consumption.

**6. ADVERSE REACTIONS**

Animals may, infrequently, experience a mild skin reaction (which includes hair loss and blisters) following use of this product. If this occurs any remaining product should be thoroughly washed off, product use discontinued, and veterinary attention sought.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

**7. TARGET SPECIES**

Horses

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

Gel for Cutaneous Use.

Prior to application ensure that the area to be treated is clean and dry. Apply up to a total daily quantity of 50 g Equiparin per day to the intact skin using fingertip pressure onto the affected area according to the veterinary surgeon's instructions until signs and symptoms resolve.

## **9. ADVICE ON CORRECT ADMINISTRATION**

None.

## **10. WITHDRAWAL PERIOD**

Meat and offal: 0 days

Not permitted for use in mares producing milk for human consumption.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not store above 25 °C

Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle.

Shelf-life after first opening the container:

6 months

## **12. SPECIAL WARNING(S)**

### **Special precautions for use in animals:**

Avoid contact with the eyes or mucous membranes.

Do not apply to open wounds or skin lesions.

Discontinue if side effects such as signs of discomfort or swelling occur.

### **Special precautions to be taken by the person administering the veterinary medicinal product to animals:**

Avoid contact with open wounds or with the eyes.

Impervious gloves should be worn when applying the product.

In case of accidental contact with the eye or skin, the affected eye(s) or skin should be washed with copious quantities of water and medical advice sought as necessary.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to any of the active ingredients or excipients should avoid contact with the veterinary medicinal product.

### **Use during pregnancy, lactation or lay:**

No clinical data are available on the topical use of the product during pregnancy. The safety of the product has not been established during pregnancy and lactation.

### **Overdose (symptoms, emergency procedures, antidotes):**

None known.

## **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION>**

285 g (300 ml) gel filled in an opaque polyethylene bottle. The closure system consists of a cap with a screw.

Pack size: 1 bottle, 6 x 1 bottle in a cardboard box.

Not all pack size may be marketed.