ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGEAND 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 ggel 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

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

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.