SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Equiparin 5.000 IU/100 g gel for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
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

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Gel
Clear green cutaneous gel.

4. CLINICAL PARTICULARS

4.1 Target species
Horses

4.2 Indications for use, specifying the target species
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.

4.3 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.

4.4 Special warnings for each target species
None.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)
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.

4.7 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.

4.8 Interaction with other medicinal products and other forms of interaction
None known.

4.9 Amounts to be administered and administration route
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
None known.

4.11 Withdrawal period(s)
Meat and offal: 0 days
Not permitted for use in mares producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group:
Preparations with salicylic acid derivatives in combinations for topical application.

ATCvet Code: QM02AC99

5.1 Pharmacodynamic properties

The product has been shown to increase the blood flow through the underlying skin.

<u>Heparin</u>
Heparin inhibits blood coagulation. Owing to its strong anionic charge, it forms a complex with cationic protein bodies. This applies particularly to antithrombin III (AT III), a α_2-globulin and endogenous inhibitor of the coagulation system, leading to a significant increase in its inhibitor reaction speed.
The essential action mechanism is the activation of AT III, which for its part inhibits thrombin and other serine proteases. Thus, not only thrombin (IIa), but also the

activated factors XIIa, IXa, Xa and kallikrein are inactivated. This inactivation is dose-dependent.

Heparin also possesses a lipolysis-promoting action by activating the clearing factor and catalysing the release of lipoprotein lipase from endothelial cells, whereby large-molecular chylomicrons are solubilised in the plasma.

Heparin is involved in allergic and anaphylactic reactions. Heparin and histamine are released in the degranulation of mast cells. In haemostasis caused by shock, the presence of heparin reduces the coagulability of the blood. In addition, heparin acts as a mediator in the release of the histamine-degrading enzyme diamine oxidase.

Hydroxyethyl salicylate
Hydroxyethyl salicylate, an ester of salicylic acid, is very readily absorbed.
The salicylic acid released after absorption has an analgesic and anti-inflammatory effect. The action mechanism lies in the inhibition of prostaglandin synthesis and reduced formation of the pain-producing bradykinin from its precursors.
The released salicylic acid supports the antithrombotic effect of heparin by means of inhibition of platelet aggregation.
The keratolytic properties of salicylic acid further loosen the epidermis and facilitate absorption of the other active substances.

Levomenthol
Levomenthol dissolved in alcohol has an antipruritic effect when applied to the skin and a mild local anaesthetic effect on the sensitive nerve endings of the skin.
At the same time it stimulates the cold receptors in the epidermis, whereby a cooling effect is felt, which is increased by the evaporation of the alcohol on the skin surface.

Heparin:	Antithrombotic
Hydroxyethyl salicylate:	Anti-inflammatory, analgesic; keratolytic
Levomenthol:	Local anaesthetic, antipruritic

5.2 Pharmacokinetic particulars

Heparin
After absorption through the skin, heparin develops its complex effects in the superficial subcutaneous tissue. Penetration through healthy skin is dose-dependent and is proven for concentrations of 300 IU/g and above. After application to the skin, no systemically therapeutic concentrations are reached.

Hydroxyethyl salicylate
The salicylate is readily released from the hydrophilic gel base of Equiparin Gel and rapidly absorbed through the skin. In the tissue it is metabolised into salicylic acid and ethylene glycol. Part of the salicylate is degraded by oxidation and the rest is bound to glucuronic acid and excreted renally. Ethylene glycol is oxidised and excreted as oxalate.

Levomenthol
Levomenthol is absorbed through the skin. It is metabolised in the liver by hydroxylation and subsequent glucuronidation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorophylline copper (E141),
Carbomer 980,
Isopropyl alcohol,
Macrogol glycerol cocoate,
Propylene glycol,

Trometamol (for pH adjustment),
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months
Shelf-life after first opening the container: 6 months

6.4. Special precautions for storage

Do not store above 25 °C.
Do not freeze.

6.5 Nature and composition of immediate packaging

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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 24745/4003

9. DATE OF FIRST AUTHORISATION

26 January 2010

10 DATE OF REVISION OF THE TEXT

December 2014

Approved:  **03/12/2014**