Summary of Product Characteristics

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tendease 50,000 IU/100 g gel for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 g gel contains:

Active substances:	
Heparin sodium	50,000 IU
Hydroxyethyl salicylate	5.0 g
Levomenthol	0.5 g
Excipient(s):	
Copper complexes of chlorophyllins (E 141ii)	6,89 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel.
A clear green 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. Tendease also promotes the early reabsorption of haematoma and oedematous swelling resulting from such conditions.

4.3 Contraindications

Do not use in known cases of hypersensitivity to the active substances or to any of the excipients.

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. Do not apply to mucous membranes, open wounds or skin lesions. Discontinue treatment if local reactions occur.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid contact with the eyes, mucous membranes or skin lesions.
In case of accidental contact with the eyes, mucous membranes or skin lesions, cleanse the affected areas with clean water, seek medical advice immediately if irritation or other clinical signs occur and show the package leaflet or the label to the physician.

People with known hypersensitivity to Tendease 50,000 IU/100 g gel for horses should avoid contact with the veterinary medicinal product. To avoid sensitisation, impervious gloves should be worn when applying the product.

4.6 Adverse reactions (frequency and seriousness)

Animals may, in rare cases, 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.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use in pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy.
Pregnancy and lactation:
Use of the product during pregnancy or lactation is not recommended.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For cutaneous administration. Using slight fingertip pressure, up to a total daily quantity of 50 g gel is massaged onto the skin of the affected area according to the veterinarian's instructions, until clinical signs have subsided.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

A threefold overdose resulted in mild skin reactions (wrinkling of the skin and hair loss). If this occurs, any remaining product should be thoroughly washed off and product use discontinued until full recovery of the patient.

4.11 Withdrawal period(s)

Meat and offal: 0 days.
Not authorised for use in animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Topical products for joint and muscular pain, preparations with salicylic acid derivatives, combinations
ATCvet Code: QM02AC99.

5.1 Pharmacodynamic properties

Heparin
Heparin inhibits blood coagulation. Due to its strong anionic charge, it forms a complex with cationic protein molecules. This applies particularly to antithrombin III (AT III), an α_2-globulin and endogenous inhibitor of the coagulation system, whose rate of inhibition is hereby significantly increased.
The main mechanism of action is the activation of AT III, which in turn inhibits the activity of 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.

Furthermore, heparin enhances lipolysis by activating the clearing factor and by catalising the release of lipoprotein lipase from endothelial cells, leading to breakdown of large-molecular chylomicrons in plasma.
Heparin is involved in allergic and anaphylactic reactions. Heparin and histamine are released following degranulation of mast cells. In shock-related stasis of blood flow, the anticoagulant effect of heparin will reduce blood clotting activity. 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.
Following absorption, salicylic acid is released, exerting an analgesic and anti-inflammatory effect. The mechanism of action consists in the inhibition of prostaglandin synthesis, and formation of the pain-inducing bradykinin from its precursors is reduced.
The released salicylic acid supports the antithrombotic action of heparin by preventing platelet aggregation.
The keratolytic properties of salicylic acid soften keratinized epidermal tissue, thereby facilitating 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. Simultaneously, it excites the thermal receptors sensitive to cold stimuli in the epidermis, thereby creating a cooling effect which is further 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
Parenterally administered heparin enters endothelial cells and the reticuloendothelial system. Most of it is inactivated by binding to proteins which are not involved in the coagulating process. Heparin-degrading enzymes such as heparinase, heparin sulfamidase and depolymerising enzymes are located in the liver, in lymphatic fluid and in plasma. The half-life is dose-dependent. Undegraded heparin and low-molecular degradation products are eliminated mainly via the kidneys.
Following cutaneous absorption, heparin exerts its complex actions in superficial subcutaneous tissues. Absorption through the intact skin is dose-dependent and is proven for concentrations of 300 IU/g and above. Administration to the skin does not lead to systemic effects.

Hydroxyethyl salicylate
Salicylate is quickly released from the hydrophilic gel base of Tendease and rapidly absorbed through the skin. In tissues, breakdown occurs to salicylic acid and ethylene glycol. The salicylate is partially oxidized and the remaining salicylate is bound to glucuronic acid and excreted in the urine. Ethylene glycol is oxidized 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

Copper complexes of chlorophyllins (E 141 ii)
Purified water
Isopropyl alcohol
Propylene glycol
Macrogolglycerol cocoates
Trolamine
Carbomer 980

6.2 Major Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 36 months.
Shelf life after first opening the immediate packaging: 6 months.

6.4. Special precautions for storage

Do not store above 30 °C.

6.5 Nature and composition of immediate packaging

300 g gel in a polyethylene bottle, with a polypropylene/HDPE-cap with a tilting lid.
Pack sizes:
1 bottle
6 x 1 bottle in a cardboard box
Not all pack sizes 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

Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION

Date of first authorisation:
Date of last renewal:

10 DATE OF REVISION OF THE TEXT