SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Compagel vet., gel til hest (DK)
Compagel gel pour chevaux (FR)
Compagel gel voor paarden (NL)
Compagel vet., gel, för häst (SE)
Compagel gel for horses (UK)

[The name "Compagel" will be used in the SmPC, label and leaflet.]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 g gel contains:

Active substances:

Heparin sodium	50 000 IU
Levomenthol:	0.5 g
Hydroxyethyl salicylate:	5.0 g

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel, clear green

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.

Compagel 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.
Do not apply to broken skin.
Do not apply to open wounds or fresh or encrusted skin lesions.

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.

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.

4.6 Adverse reactions (frequency and seriousness)

If side effects occur, treatment should be discontinued.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
No clinical data are available on the topical use of Compagel during pregnancy.
The use is not recommended 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

Up to a total daily quantity of 50 g gel per day is applied using finger tip 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

No overdose is known when the product is used topically as intended.

4.11 Withdrawal period(s)

Meat and offal: 0 days
Do not use in pregnant or lactating animals which are intended to produce milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Musculo-skeletal system: Preparations with salicylic acid derivatives in combinations for topical application for joint and muscular pain.

ATCvet Code: QM02AC99

5.1 Pharmacodynamic properties

Heparin
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 Compagel 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

Purified water
2-propanol
propylene glycol
carbomer 980
macrogol glycerol cocoate
chlorophylline copper complex trisodium salt (E141)
trolamine

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the container: 3 months
Discard any product remaining in the container at this time.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

LDPE tube with ethylene vinyl alcohol copolymer middle layer, HDPE top and polypropylene cap, containing 250 g of gel.

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

<To be completed nationally>

8. MARKETING AUTHORISATION NUMBER

<To be completed nationally>

9. DATE OF FIRST AUTHORISATION

<To be completed nationally>

10. DATE OF REVISION OF THE TEXT

<To be completed nationally>

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.