LABELLING AND PACKAGE LEAFLET

A. LABELLING

Note: As the package leaflet is printed onto the tube, not all points given in this section. Labelling of the QRD template are taken into consideration, as they are already considered in the package leaflet.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Tube

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Compagel gel for horses

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

2. STATEMENT OF ACTIVE SUBSTANCES

Information given in the package leaflet which is printed onto the tube

3. PHARMACEUTICAL FORM

Gel

4. PACKAGE SIZE

250 g

5. TARGET SPECIES

Horses

6. INDICATION(S)

Information given in the package leaflet which is printed onto the tube

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Information given in the package leaflet which is printed onto the tube

8. WITHDRAWAL PERIOD(S)

Information given in the package leaflet which is printed onto the tube

9. SPECIAL WARNING(S), IF NECESSARY

Information given in the package leaflet which is printed onto the tube

10. EXPIRY DATE

EXP {month/year}
Once broached/opened, use by…

11. SPECIAL STORAGE CONDITIONS

Information given in the package leaflet which is printed onto the tube

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Information given in the package leaflet which is printed onto the tube

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 SIGHT AND REACH OF CHILDREN"

Information given in the package leaflet which is printed onto the tube

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 273
55216 Ingelheim Am Rhein
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04491/3009

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

Note: The package leaflet is printed onto the tube

PACKAGE LEAFLET

Compagel gel for horses

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

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

Marketing authorization holder:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 273
55216 Ingelheim Am Rhein
Germany

Manufacturer responsible for batch release:
C.P.M. ContractPharma GmbH
Frühlingsstrasse 7
83618 Feldkirchen-Westerham

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Compagel gel for horses

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

100 g gel contains:

Active substances:

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

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.

Compagel 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 substance or any of the excipients.
Do not apply to broken skin.
Do not apply to open wounds or fresh or encrusted skin lesions.

6. ADVERSE REACTIONS

If side effects occur, treatment should be discontinued.

If you notice an adverse reaction in your horse/horses which is not listed in the package leaflet, report it to your veterinary surgeon or pharmacist.

7. TARGET SPECIES

Horses

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

See section "Dosage and method of administration".

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 C.
After first opening, use within 3 months.
The discard date should be determined at time of first opening and written in the space provided below.
Do not use this veterinary medicinal product after the expiry date (EXP) which is stated on the tube.

12. SPECIAL WARNING(S)

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.

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

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

Any unused product or waste materials should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

250 g

Compagel is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, used under licence.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 25 November 2024
Gavin Hall