

ANNEX II
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Polypropylene container and carton box.

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:

Intracare BV

Voltaweg 4

Veghel

5466 AZ

The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intra Hoof-fit Gel 40 mg/g + 40 mg/g gel for dairy cattle

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

Active substances:

Copper: 40 mg/g.

Zinc: 40 mg/g.

Excipient:

Tartrazine (E102).

Glycerol.

Carmellose Sodium.

Sodium Starch Glycolate type C.

Isopropyl Alcohol.

Purified Water.

4. PHARMACEUTICAL FORM

Gel. Green water-based viscous gel.

5. PACKAGE SIZE

Immediate packaging: Content of 430 gram.

Outer packaging: Content of 6 x 430 gram.

6. INDICATION(S)

For use as part of a treatment programme of digital dermatitis.

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

9. TARGET SPECIES

Dairy cattle.

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

In case the lesion is dirty, clean it with a disposable cloth to enable direct contact with the gel.

Administer the product to the lesion with a clean brush. The lesion is completely covered with the gel

during treatment containing steps:

Day 0: Administer the gel to the lesion and cover with bandage.

Day 3: Remove the bandage and administer the gel again, without bandage.

Day 7: In case of insufficient recovery, again administer the gel without bandage.

Contact a veterinary surgeon in case of no recovery on day 10.

For every container with gel a brush is supplied. The bandage is not supplied with the product.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD(S)

Zero days.

13. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze. Do not store above 25 °C.
Do not use after the expiry date stated on the label after EXP. The expiry date refers to the last day of that month.

14. SPECIAL WARNING(S)

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The product may cause eye irritation.

Avoid contact with eyes.

In case of contact with eyes, rinse immediately with plenty of water.

The product may be harmful after swallowing.

Avoid hand-to-mouth contact.

Do not eat, drink or smoke during treatment.

Wash hands after treatment.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Systemic absorption of actives being low, it is unlikely for teratogenic, foetotoxic or maternotoxic effects to occur at the recommended dosage. Use only accordingly to the risk-benefit assessment by the responsible veterinarian.

Incompatibilities:

Do not mix with other veterinary medicinal products.

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

17. OTHER INFORMATION

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

19. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

20. EXPIRY DATE

EXP.

Shelf life after first opening the container: 1 month.

Once opened, use by

21. MARKETING AUTHORISATION NUMBER

Vm 41870/4000

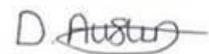
17. MANUFACTURER'S BATCH NUMBER

Lot.:

B. PACKAGE LEAFLET

(All information is provided on the label / packaging)

Approved: 24 October 2017

A handwritten signature in black ink, appearing to read "D. Austin", with a horizontal line extending to the right.