[Version 8.1, 01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intra Hoof-fit Gel 40 mg/g + 40 mg/g gel for dairy cattle	FR, EE, LT, LU, LV, NL, UK
Intra Hoof-fit 40 mg/g + 40 mg/g gel for dairy cattle	DK
Pecopro vet 40 mg/g + 40 mg/g gel for dairy cattle	SE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per gram:

Active substances:
Copper 40 mg
(Corresponding with 244.1 mg copper diammonium EDTA)

Zinc 40 mg
(Corresponding with 238.4 mg zinc diammonium EDTA)

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

3. PHARMACEUTICAL FORM

Gel.
Green water-based viscous gel.

4. CLINICAL PARTICULARS

4.1 Target species

Dairy cattle.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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.

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

No information is available.

4.11 Withdrawal period(s)

Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dermatologicals, preparations for treatment of wounds & ulcers.

ATCvet code: QD03

5.1 Pharmacodynamic properties

Copper has antimicrobial properties and a positive effect on wound healing.

Zinc stimulates wound healing and has a mild antimicrobial effect against gram positive bacteria.

5.2 Pharmacokinetic particulars

The product is administered dermally, directly on the lesion.

Possible absorbed amounts of copper are bound by weak bonds to albumin in blood plasma and stored in the liver. Excess of copper is excreted via bile, a small percentage via urine and partly via milk.

Possible absorbed amounts of zinc are mainly excreted via bile (80%), partly via urine and partly via milk.

5.3 Environmental properties

After treatment with the gel, the majority will disappear into the manure on the barn floors and will be removed with the slurry to the pasture of the farmer. The amounts of copper and zinc exposed to the environment are negligible and will not form an ecotoxicological risk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tartrazine (E102).
Carmellose sodium.
Sodium Starch Glycolate type C.
Isopropyl Alcohol.
Glycerol.
Purified Water.

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 1 month.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Polypropylene (PP) container with a high density polyethylene (HDPE) screw lock cap.
Polypropylene (PP) brush with stainless steel spacer and polyester bristle.
Carton box with 6 containers of 430 g of gel and 6 brushes.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intracare B.V.
Voltaweg 4
5466 AZ Veghel
+31 (0) 413 354 105
+31 (0) 413 362 324
info@intracare.nl

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: To be completed nationally
Date of last renewal: To be completed nationally

10 DATE OF REVISION OF THE TEXT

To be completed nationally

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be completed nationally

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
5466 AZ Veghel

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Intra Hoof-fit Gel 40 mg/g + 40 mg/g gel for dairy cattle	FR, EE, LT, LU, LV, NL, UK
Intra Hoof-fit 40 mg/g + 40 mg/g gel for dairy cattle	DK
Pecopro vet 40 mg/g + 40 mg/g gel for dairy cattle	SE

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

To be completed nationally

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(S)

To be completed nationally

22. MANUFACTURER'S BATCH NUMBER

Lot.:

B. PACKAGE LEAFLET

(All information is provided on the label / packaging)