*[Version 9.1,11/2024]*

**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(NI) |
| 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 to 244.1 mg Diammonium copper EDTA) |
| Zinc | 40 mg | (corresponding to 238.4 mg Diammonium zinc EDTA) |

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Tartrazine (E102) | 2.2 mg |
| Carmellose sodium | |
| Sodium starch glycolate (type C) | |
| Isopropyl alcohol | |
| Glycerol | |
| Purified water | |

Green water-based viscous gel.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dairy cattle.

### 3.2 Indications for use for each target species

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

### 3.3 Contraindications

None.

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Dairy cattle:
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

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

### 3.8 Interaction with other medicinal products and other forms of interaction

None known.

### 3.9 Administration routes and dosage

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.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No information available.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Zero days.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code : QD03

### 4.2 Pharmacodynamics

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.

### 4.3 Pharmacokinetics

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.

### 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 pose an ecotoxicological risk.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

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

### 5.2 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.

### 5.3 Special precautions for storage

Do not refrigerate or freeze.

### 5.4 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.

Pack size:
Carton box with 6 containers of 430 g of gel and 6 brushes.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intracare B.V.

## 7. MARKETING AUTHORISATION NUMBER(S)

*To be completed nationally.*

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: *To be completed nationally.*

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

*To be completed nationally.*

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

**ANNEX II**

**LABELLING AND PACKAGE LEAFLET**

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

**POLYPROPYLENE CONTAINER AND CARTON BOX**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

## 2. COMPOSITION

**Active substances:**
Copper: 40 mg/g
Zinc: 40 mg/g

**Excipients:**
Tartrazine (E102): 2.2 mg/g

Green water-based viscous gel.

## 3. PACKAGE SIZE

6 x 430 gram
430 gram

## 4. TARGET SPECIES

Dairy cattle.

## 5. INDICATIONS FOR USE

**Indications for use**
For use as part of a treatment programme of digital dermatitis.

## 6. CONTRAINDICATIONS

**Contraindications**
None.

## 7. SPECIAL WARNINGS

**Special warnings**
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. Because systemic absorption of the active substances is low, it is unlikely that teratogenic, foetotoxic or maternotoxic effects will occur at the recommended dosage.
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Overdose:
No information available.

Major incompatibilities:
Do not mix with other veterinary medicinal products.

## 8. ADVERSE EVENTS

**Adverse events**
Dairy cattle:
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system: {national system details}

## 9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

**Dosage for each species, routes and method of administration**
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.

## 10. ADVICE ON CORRECT ADMINISTRATION

**Advice on correct 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.

## 11. WITHDRAWAL PERIODS

**Withdrawal periods**
Zero days.

## 12. SPECIAL STORAGE PRECAUTIONS

**Special storage precautions**
Keep out of the sight and reach of children.
Do not refrigerate or freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

## 13. SPECIAL PRECAUTIONS FOR DISPOSAL

**Special precautions for disposal**
Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

## 14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

**Classification of veterinary medicinal products**
Veterinary medicinal product not subject to prescription.

## 15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

*To be completed nationally.*

**Pack sizes**
Carton box with 6 containers of 430 gram of gel and 6 brushes.

## 16. DATE ON WHICH THE LABEL WAS LAST REVISED

**Date on which the label was last revised**
*To be completed nationally.*

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 17. CONTACT DETAILS

**Contact details**

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:
Intracare B.V.
Voltaweg 4
5466 AZ Veghel
The Netherlands
T. +31 413 354 105

## 18. OTHER INFORMATION

## 19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

## 20. EXPIRY DATE

Exp: {mm/yyyy}
Once opened use within 1 month.
Once opened use by…

## 21. BATCH NUMBER

Lot {number}