

## **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

### **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 BV

Voltaweg 4  
Veghel  
5466 AZ  
The Netherlands

**8. MARKETING AUTHORISATION NUMBER**

Vm 41870/4000

**9. DATE OF FIRST AUTHORISATION**

10 May 2013

**10. DATE OF REVISION OF THE TEXT**

October 2017

Approved: 24 October 2017

