

## **SUMMARY OF PRODUCTS CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Golden Udder Gel

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

<u>Qualitative composition</u>	<u>Quantitative composition</u>
Active Substances	% w/w
Sulphur for external use	10.0
Salicylic Acid	1.5

For full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Gel;  
Yellow aqueous gel

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Cattle

#### **4.2 Indications for use, specifying the target species**

- a) An aid in the control of bovine mastitis
- b) A soothing antiseptic gel for cattle the treatment of minor skin conditions

#### **4.3 Contraindications**

None known.

#### **4.4 Special warnings for each target species**

Topical application only.

## **4.5 Special precautions for use**

### **i. Special precautions for use in animals**

Wash and dry udders and teats before milking  
If symptoms of mastitis persist after 6 days consult your  
veterinary surgeon  
For external use only

### **ii. Special precautions for the person administering the veterinary medicinal product to animals**

Avoid contact with eyes. In the event of accidental eye contact,  
rinse with plenty of clean water and seek medical advice. In the  
event of accidental ingestion wash out mouth thoroughly with  
water, then drink plenty of water and seek medical advice. Wash  
hands after use. The use of a barrier cream is recommended  
should dryness of the hands occur.

## **4.6 Adverse reactions (frequency and seriousness)**

None known

## **4.7 Use during pregnancy, lactation or lay**

The product may be used in pregnant and lactating cows.

## **4.8 Interaction with other medicinal products and other forms of interaction**

- a) With other medicinal products: None known
- b) Other interactions: None known

## **4.9 Amount(s) to be administered and administration route**

### **1. Clinical Mastitis:**

At each milking rub in sufficient product to cover the infected quarter  
(approximately 20 - 30 g - up to 1 level tablespoon). Continue  
treatment for a minimum of three days. If symptoms persist after 6  
days consult your veterinary surgeon.

### **2. At calving down:**

Use as for clinical mastitis:

### **3. Treatment of minor skin conditions:**

Apply twice daily to the affected area until the condition clears.

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

The possibility of overdose due to topical application or of accidental poisoning by Golden Udder is very remote. The signs or symptoms of overdose or accidental poisoning are:

a) Due to salicylic acid. (As for aspirin overdose)

In Animals: Depression, vomiting, loss of appetite, increased respiratory rate and elevated temperature.

Treatment: Stop applications of Golden Udder. Intravenous forced alkaline diuresis or sodium bicarbonate by stomach tube, intraperitoneal lactate Ringers solution and frusemide (frusemide) intramuscularly.

b) Due to sulphur. (Oral ingestion of extreme doses only)

Animals - Symptoms of hydrogen sulphide poisoning.

Purgation, depression, anorexia, weak and rapid pulse, paralysis.

Treatment:- Cease application of Golden Udder.

#### **4.11 Withdrawal period(s)**

Meat: Zero days

Milk: Zero hours

### **5. PHARMACOLOGICAL PROPERTIES**

#### **Pharmacotherapeutic group:**

Salicylic acid is an aromatic carboxylic acid possessing anti-inflammatory, analgesic, antimicrobial and keratolytic properties. Anti-inflammatory and analgesic action appears to be mediated by the inhibition of prostaglandin synthesis via the inhibition of the cyclo-oxygenase enzyme.

Sulphur is a non-metallic element used for topical dermatologic therapy, possessing antiseptic, antifungal, antiparasitic, anti-acne, anti-pruritic, antiseborrhoeic and keratolytic properties.

Pharmacological action is mediated through the formation of disulphides and polythionic acids formed by the interaction of sulphur with organic substances or micro-organisms present on the skin.

**ATC Vet Code:** QD11 AC08

## **5.1 Pharmacodynamic properties**

### Salicylic acid:

Exhibits antimycotic and antimicrobial actions and is considered a safe broad spectrum antiseptic. In addition salicylic acid has anti-inflammatory and analgesic properties. Salicylic acid also has keratolytic properties with keratin dispersing and keratostatic activities. Salicylic acid displays superficial astringent and anti-pruritic properties.

Salicylic acid appears to exert its anti-inflammatory action and analgesic properties by the inhibition of prostaglandin synthesis via the inhibition of the cylo-oxygenase enzyme.

Salicylic acid belongs to the group of aromatic carboxylic acids and is also considered a member of the group of non-steroidal anti-inflammatory substances (NSAIDS).

### Sulphur for External Use

Sulphur exhibits antiseptic, antifungal, and antiparasitic properties. Additionally anti-acne, anti-pruritic and antiseborrhoeic properties are reported for sulphur. Sulphur is a keratolytic agent. The pharmacological activity of topically applied sulphur is mediated through the formation of disulphides and polythionic acids formed by the interaction of sulphur with organic substances or micro-organisms present on the skin.

Sulphur belongs to the group of non-metallic elements.

## **5.2 Pharmacokinetic properties**

Various figures are cited in the literature for absorption of salicylic acid through the skin. Plasma binding of salicylic acid is 50% with a half-life in cattle of 30 minutes. 1% of topically applied sulphur has been shown to be absorbed.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Tragacanth, gum  
Zinc oxide  
Water Potable

### **6.2 Incompatibilities**

None known

**6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale 3 years

**6.4 Special precautions for storage**

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

**6.5 Nature and composition of immediate packaging**

600g high density polyethylene bottle with integral hook and polypropylene cap with integral valve/spout.

180g polypropylene screw jar with polypropylene cap (screw fit or push fit) tamper evident.

Not all pack types may be marketed.

**6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate**

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**

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**8. MARKETING AUTHORISATION NUMBER(S)**

VM 00292/4007

**9. DATE OF FIRST AUTHORISATION**

**Date:** 06 April 2002

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

**Date:** January 2009