**IRISH MEDICINES BOARD ACT 1995**

**EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007**

**(S.I. No. 786 of 2007)**

VPA: **10914/001/001**
Case No: 7004549

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

**Collective Chemical Company Ltd.**

**43 Bibury Avenue**, **Stoke Lodge**, **BS12 6DF**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

**Golden Udder Gel**

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **11/03/2008**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

# Part II

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Golden Udder Gel

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

| | |
|---|---|
| Sulphur for External Use | 10.0 % w/w |
| Salicylic Acid | 1.5 % w/w |

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Gel. A yellow aqueous gel.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Bovine

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

An aid in the control of bovine mastitis.
For the treatment of minor skin conditions.

### 4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

### 4.4 Special warnings for each target species

Topical application only.

### 4.5 Special precautions for use

**Special precautions for use in animals**
Wash udders and teats before milking.
If symptoms of mastitis persist, consult your veterinary surgeon.

**Special Precautions to be taken by the Person Administering the Medicinal Product to Animals**
Avoid contact with eyes. In the case of contact with eyes flush them thoroughly with water. 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

With other medicaments: None known.
Other interactions: None known.

## 4.9 Amounts to be administered and administration route

For topical administration only.

Recommended Dosage Schedules

*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 to a maximum of 6 days. If symptoms persist 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.

In humans: Signs of salicylism - Confusion, dizziness, headaches, rapid breathing, ringing or buzzing in ears.

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

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

Humans and 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 and offal: 0 days.
Milk: 0 days.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dermatologicals, Sulphur compounds
ATCvet Code: QD11AC08

## 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 cyclo-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

Powdered tragacanth
Zinc oxide
Purified water

## 6.2 Incompatibilities

None known.

## 6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

## 6.4 Special precautions for storage

Do not store above 25ºC.
Do not freeze.

## 6.5 Nature and composition of immediate packaging

Polyethylene squeeze-dispensing bottles with suspending hook and fitted with 28 mm disc top closures. 620 ml capacity.
Nett Contents: 600 grams

Polyethylene squeeze-dispensing bottles with suspending hook and fitted with 28 mm disc top closures. 250 ml capacity.
Nett Contents: 200 grams.

## 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste materials should be disposed of in accordance with national requirements.

# 7 MARKETING AUTHORISATION HOLDER

Collective Chemical Company Limited
43 Bibury Avenue
Stoke Lodge
Bristol
BS12 6DF
United Kingdom

# 8 MARKETING AUTHORISATION NUMBER(S)

VPA 10914/001/001

# 9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11th March 2008

# 10 DATE OF REVISION OF THE TEXT