

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

Sulphur 10% w/w ointment USP

Galenicos CP-Sulfur ointment 10% w/w USP

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition

#### Active Ingredient

Sulphur 10% w/w

For a full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Topical ointment.

A yellow coloured ointment.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Sulphur ointment is used in the treatment of scabies, seborrheic dermatitis, and acne vulgaris. It is also used in the treatment of other chronic skin conditions like psoriasis, ringworm and lupus erythematosus.

#### 4.2 Posology and method of administration

##### Adults, children over 12 years and the elderly

##### *Mild dandruff*

To be used intermittently as an adjunctive treatment to be applied approximately once a week.

##### *Psoriasis, eczema, seborrhoeic dermatitis and severe dandruff*

To be used daily for three to seven days until improvement has been achieved. Intermittent repeated applications may be necessary to maintain improvement. In all cases, the affected area should be treated and shampooed off using warm water approximately one hour later.

#### Children 6 - 12 years

To be used under medical supervision only.

#### Children under 6 years

Not recommended.

### **4.3 Contraindications**

The product is contraindicated in patients known to be sensitive to sulphur, or in the presence of local infections.

### **4.4 Special warnings and precautions for use**

Do not use if the tube membrane is already perforated. Avoid contact with the eyes and wash hands immediately after use.

Discontinue use if irritation develops. If symptoms persist after four weeks, consult your doctor.

### **Important information on excipients**

None.

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

None.

### **4.6 Fertility, pregnancy, and breastfeeding**

If possible, it should not be used during pregnancy or lactation. However, inadvertent, accidental exposure is not cause for clinical intervention. There is no sufficient clinical experience to establish the safety of sulphur in general during pregnancy and lactation. It is unknown whether sulphur crosses the placenta or is excreted in breast milk.

### **4.7 Effects on ability to drive and use machines**

None known.

### **4.8 Undesirable effects**

Bronchospasm has been reported very rarely in patients with either pre-existing asthma or a family history of hypersensitivity to salicylates.

## Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the e-PV desktop applications

([https://drive.google.com/file/d/16hwTz0587ZWtSWadbBAMwQPOD\\_KSExZP/view](https://drive.google.com/file/d/16hwTz0587ZWtSWadbBAMwQPOD_KSExZP/view)) or search for e-PV Mobile applications on the Google Play or Apple App Store.

## **4.9 Overdose**

Not likely to occur with normal usage. Treat symptomatically, if necessary.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacological Classification: 14.1.5 Dermatological and topical preparations – Scabicides and pediculocides.

Sulphur is a keratolytic, with weak antiseptic and parasiticide properties.

### **5.2 Pharmacokinetic properties**

Sulphur is not adsorbed through the skin following topical administration.

### **5.3 Preclinical safety data**

Extemporaneously prepared formulations containing the same active constituents, in the same concentrations as are present in Galenicos CP-Sulfur ointment have been used extensively for several decades. The product has a well-documented safety and efficacy profile and therefore no toxicological data was presented.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Liquid paraffin heavy BP

Emulsifying wax BP

White Petroleum Jelly BP

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

24 months.

### **6.4 Special precautions for storage**

Store above 30°C in well closed containers. Avoid prolonged exposure to excessive heat. Protect from light. Keep container tightly closed.

### **6.5 Nature and contents of container**

Sulphur 10% w/w ointment is available in pack sizes of 50 g, and 100 g and is packaged in white polypropylene (PP) jars and with PP screw caps.

### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

## **7. APPLICANT**

Cospharm Pharmaceuticals  
Stand 12896, Madokero Industrial Area  
Harare, Zimbabwe

## **8. MANUFACTURER**

Cospharm Pharmaceuticals  
Stand 12896, Madokero Industrial Area  
Harare, Zimbabwe

## **9. REGISTRATION DETAILS**

Zimbabwe registration number: 2023/14.1.5/6368

Zimbabwe category for distribution: Pharmacy Medicines (P.)

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

May 2023