

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1 NAME OF THE MEDICINAL PRODUCT

Cocois (Coconut Oil Compound Ointment).

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| Active ingredients          | % w/w |
|-----------------------------|-------|
|                             |       |
| Coal Tar Solution BP        | 12.0  |
| Precipitated Sulphur Ph.Eur | 4.0   |
| Salicylic Acid Ph.Eur       | 2.0   |

### 3 PHARMACEUTICAL FORM

Ointment for topical application.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Cocois has mild, antipruritic, antiseptic and keratolytic properties. It is indicated in the treatment of scaly skin disorders of the scalp such as psoriasis, eczema, seborrhoeic dermatitis and dandruff.

#### 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 any of the ingredients including sulphur and salicylates, in the presence of acute local infections, or acute pustular psoriasis.

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

Do not use if the tube membrane is already perforated. Do not use on inflamed or broken skin. Avoid contact with mouth, mucous membranes and eyes and wash hands immediately after use. Discontinue use if irritation develops.

If symptoms persist after four weeks, a doctor should be consulted.

Cocois may stain fabrics and jewellery.

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

None

### **4.6 Pregnancy and lactation**

If possible Cocois should not be used during pregnancy or lactation. However, inadvertent, accidental exposure is not cause for clinical intervention. Minimal systemic absorption of salicylic acid may occur after topical application. There are no data on the use of coal tar in pregnant or lactation women. It is unknown whether coal tar crosses the placenta or is excreted in breast milk. 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

#### **4.8 Undesirable effects**

Coal tar may cause skin irritation, folliculitis and rarely photosensitivity.

Cocois may cause skin irritations, acne like eruptions, dermatitis, folliculitis, alopecia and rarely photosensitivity and hypersensitivity. Discolouration of skin and hair may also occur.

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

Although carcinogenicity of coal tar has been demonstrated in animal studies, no studies demonstrating an increased risk of skin cancer with normal therapeutic use in humans have been reported. There is no unequivocal evidence to link the use of topically applied coal tar products with skin cancer.

##### 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 Yellow Card Scheme on the MHRA website ([www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)).

#### **4.9 Overdose**

Overdose is extremely unlikely. Treat symptomatically, if necessary.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Coal Tar is antipuritic, keratoplastic and a weak antiseptic.

Salicylic acid has keratolytic properties.

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

Combinations of coal tar, salicylic acid and sulphur are widely used in the treatment of hyperkeratotic and scaling skin conditions.

### **5.2 Pharmacokinetic properties**

No data is available for the proposed formulation.

### **5.3 Preclinical safety data**

None stated.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Coconut Oil

White Soft Paraffin

Cetostearyl Alcohol

Glycerol

Liquid Paraffin

Polyoxyethylene Glycerol Monostearate

Hard Paraffin

### **6.2 Incompatibilities**

None known

### **6.3 Shelf life**

2 years.

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

Store between 10°C and 25°C.

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

Cocois is packed into internally lacquered, membrane sealed, aluminium tubes (5g, 15g, 40g and 100g) fitted with a polyurethane cap.

#### **6.6 Special precautions for disposal**

None stated.

### **7 MARKETING AUTHORISATION HOLDER**

RPH Pharmaceuticals AB,  
Lagervägen 7,  
136 50 Haninge,  
Sweden

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

PL 36301/0022

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

Date of first authorisation: 9<sup>th</sup> June 1997  
Date of renewal: 6<sup>th</sup> November 1998

**10 DATE OF REVISION OF THE TEXT**

28/05/2015