

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cocois Ointment, coal tar 12.0% sulphur for external use 4.0%, salicylic acid 2.0%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	% w/w
Coal Tar Solution	12.0
Sulphur for External Use	4.0
Salicylic Acid	2.0

Excipient: Contains cetostearyl alcohol 11% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment
Khaki coloured unctuous solid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Cocois had 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

Because of the theoretical risk of skin damage if used for long periods, patients should be advised to consult their doctor if, after the first week, the condition has not improved or if symptoms persist after four weeks.

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.

For all cases the affected area should be treated and shampooed off 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, 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. Coal tar may stain fabrics and jewellery. If symptoms persist after four weeks, a doctor should be consulted.

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

4.6 Pregnancy and lactation

The safety of Cociois in pregnant women has not been established, therefore Cociois is not indicated for use during pregnancy.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Coal tar may cause skin irritation, acne like eruptions, dermatitis folliculitis, alopecia and rarely alopecia areata, 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.

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 not unequivocal evidence to link the use of topically applied coal tar products with skin cancer (See also section 5.3).

4.9 Overdose

Overdose is extremely unlikely.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

i) Coal Tar

The precise mode of action of coal tar in the treatment of skin diseases such as psoriasis, eczema and seborrhoeic dermatitis is unknown. It has, however, been shown that coal tar exhibits a cytostatic effect in inhibiting DNA synthesis in the hairless mouse. In human studies, it has been shown that the application of topical coal tar induces hyperplasia initially, followed by atrophic changes to the epidermis. This provides some explanation of its efficacy in hyperproliferative diseases of the skin.

ii) Salicylic Acid

In topical use salicylic acid has a keratolytic action, producing desquamation by solubilising the intercellular cement which binds in the stratum corneum.

iii) Sulphur

Sulphur possesses keratolytic, fungicidal, parasiticidal and germicidal properties (after oxidative conversion to pentathionic acid by epidermal cells). Prolonged topical use may result in dermatitis venerea.

5.2 Pharmacokinetic properties

i) Coal Tar

There is no reliable data available concerning the rate of adsorption, blood levels or excretion of coal tar, which itself is a complex mixture of hydrocarbons formed during the destructive distillation of bituminous coal.

ii) Salicylic Acid

Salicylic acid is adsorbed through the skin following topical application and is distributed throughout most body tissues and transcellular fluids primarily by the liver and excreted by the kidneys. There is no data available regarding salicylic acid adsorption following the topical application of Cocus.

iii) Sulphur

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 Cocus have been used extensively for several decades. The product has a well documented safety and efficacy profile and therefore no toxicological data is presented in this instance.

Tar preparations have been in wide use for many years. Although coal tar preparations containing polycyclic aromatic hydrocarbons (PAHs) have been demonstrated to be carcinogenic in the skin of experimental animals, present evidence based upon epidemiology studies in humans and follow-up trials, reveals no evidence of increased risk of skin or internal cancer, particularly when the product is used as directly.

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

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25 °C. Do not refrigerate or freeze. Always replace cap after use and return tube to carton. Discard tube no later than 4 weeks after opening.

6.5 Nature and contents of container

Cocois is packed into internally lacquered, membrane sealed, aluminium tubes fitted with a polyurethane cap. The tubes are subsequently packed in unit, printed, boxboard cartons in pack sizes of 40g and 100g.

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 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 365/77/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 May 1996

Date of last renewal: 01 May 2006

10 DATE OF REVISION OF THE TEXT

August 2006