

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sebco

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

3 PHARMACEUTICAL FORM

Ointment for topical application.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Sebco™ has mild, antipruritic, antiseptic and keratolytic properties. It is indicated in the treatment of common 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

Apply to the affected areas of the scalp and remove after one hour using warm water and shampoo. Repeat the process daily for three to seven days until control has been obtained. With mild scaliness use intermittently as necessary.

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 sulfur, salicylates, coal tar 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.

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

4.6 Fertility, pregnancy and lactation

To be used at the discretion of the physician.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Coal Tar may occasionally cause irritation of the skin, inflammation of the hair follicles and rarely photosensitivity of the skin.

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 national reporting system in the United Kingdom: Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

Overdose is extremely unlikely. If necessary, remove medication by washing with warm water and treat symptomatically where necessary.

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 such as psoriasis, eczema and seborrhoeic dermatitis.

ii) Salicylic Acid

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

iii) Sulfur

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

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 SEBCO.

iii) Sulfur

Sulfur 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 Sebco 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.

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 up to 25°C. Do not refrigerate. 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

Sebco is packed into internally lacquered, membrane sealed, aluminium tubes fitted with a polyurethane cap. The product is available in pack sizes of 5g, 15g, 40g and 100g.

The tubes are subsequently packed in unit, printed, boxboard cartons.

6.6 Special precautions for disposal

Pierce the tube membrane by inverting the cap. Do not use if membrane is already perforated. Refer to the patient information leaflet.

Replace cap and wash hands immediately after use.

Keep the tube out of the reach of children.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 19876/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22/11/2002 / 25/06/2008

10 DATE OF REVISION OF THE TEXT

04/09/2017