

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 |

Excipient with known effect

Cetostearyl alcohol 11.0 % w/w

For the full list of excipients, see section 6.1

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

Posology

Adults, children over 12 years and the elderly

Mild Dandruff

To be used as an adjunctive treatment to be applied intermittently, 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 apply to the affected areas of the scalp and remove after approximately one hour using warm water and shampoo.

Children 6 - 12 years

To be used under medical supervision only.

Children under 6 years

Not recommended.

Method of administration

For topical application.

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients listed in section 6.1 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. Do not use on broken skin. Avoid contact with the 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.

Sebco may stain fabrics and jewellery.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

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.

Minimal systemic absorption of salicylic acid may occur after topical application. There are no data on the use of coal tar in pregnant or lactating women. It is unknown whether coal tar crosses the placenta or is excreted in breast milk. There is insufficient clinical experience to establish the safety of sulfur in general during pregnancy and lactation. It is unknown whether sulfur 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 occasionally cause irritation of the skin, inflammation of the hair follicles and rarely photosensitivity of the skin.

Sebco 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.

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 Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

Coal Tar is antipuritic, keratoplastic and a weak antiseptic.

Salicylic acid has keratolytic properties.

Sulphur is a keratolytic, with weak antiseptic and parasitocidal 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

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

High dose administration of coal tar to laboratory animals is carcinogenic. However, epidemiological evidence that includes prospective and retrospective studies in thousands of patients receiving coal tar therapy followed for more than 40 years do not suggest a potential increased risk of skin or systemic cancer.

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 and other handling

Wash hands immediately after use.

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

11/05/2023