

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Denorex Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Coal Tar Solution	7.5	% w/w
Levomenthol	1.5	% w/w

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Shampoo

An amber/brown liquid shampoo with the characteristic odour of coal tar.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of the symptoms of and in the management of dandruff, seborrhoeic dermatitis and psoriasis of the scalp.

4.2 Posology and method of administration

Use topically as shampoo.

Shampoo every other day for the first ten days, then 2 - 3 times weekly thereafter.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

1. Discontinue use if irritation occurs.
2. Do not use on highly inflamed or broken skin.
3. If no improvement is seen consult a doctor.
4. Keep out of eyes.
5. Keep out of reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Not contraindicated.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Occasional irritation.

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. (See also Section 5.3).

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Coal Tar acts locally to slow down production and shedding of skin cells.

Menthol helps to relieve the inflammation of itching.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

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 directed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trolamine laurilsulfate
Hypromellose
Lauryl diethanolamide
Stearic acid
Chloroxylonol
Perfume compound 64.404 NY/D
Purified water
Ethanol (96%)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

No special precautions necessary.

6.5 Nature and contents of container

The product is supplied in screw capped polypropylene bottles, fitted with ureaformaldehyde wadded caps filled with 125ml of shampoo.

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

Avoid contact with the eyes.

7 MARKETING AUTHORISATION HOLDER

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