Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Polytar Liquid 1% w/w Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tar Blend 1.00 % w/w comprises:

Tar	0.3	% w/w
Cade Oil	0.3	% w/w
Coal Tar Solution	0.1	% w/w
Arachis Oil* extract of Coal Tar	0.3	% w/w

*also known as peanut oil

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Shampoo
Clear brownish liquid with an odour of tar.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Polytar Liquid is indicated in the treatment of scalp disorders including psoriasis, dandruff, seborrhoea, eczema and pruritis. Polytar Liquid is also of value in the removal of ointments and pastes used in the treatment of psoriasis.

4.2 Posology and method of administration

The hair should be wetted and sufficient Polytar Liquid applied to produce an abundant lather. The scalp and adjacent areas should be vigorously massaged with the fingertips. The hair should then be thoroughly rinsed and the procedure repeated.

Polytar liquid should be used once or twice weekly.

4.3 Contraindications

Known hypersensitivity to the ingredients.

4.4 Special warnings and precautions for use

Polytar Liquid contains Arachis oil (peanut oil) and should not be applied by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and Soya, patients with Soya allergy should also avoid Polytar Liquid.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, pregnancy and lactation

There are no restrictions on the use of Polytar Liquid in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Tar products may cause skin irritation, rashes and rarely photosensitivity. If irritation occurs and persists, treatment should be discontinued. Experience of many years of marketing has shown that the incidence of adverse reactions to Polytar Liquid is less than one percent. These reactions of erythema, dryness, contact dermatitis, irritation and acne-like eruptions are mild and of very low incidence.

An increased risk of skin cancer in patients with psoriasis treated with a combination of coal tar and UVB radiation has 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

Tars suppress DNA synthesis in hyperplastic skin, inhibiting mitotic activity and protein synthesis. They decrease epidermal proliferation and dermal infiltration and thus promote a return to normal keratinisation.

Tars also have vasoconstrictor, antipruritic and antiseptic properties.

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 (PAH’s) 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 a rinse off shampoo used twice weekly.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Coconut Diethanolamide
Hexylene Glycol
Oleyl Alcohol
Polysorbate 80
Triethanolamine Laurylsulphate (42% solution)
Sodium Chloride
Citric Acid Monohydrate
Octylphenoxy polyethoxy ethanol
Fragrance
Imidurea
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

High density polyethylene bottles of 65ml, 150ml, 250ml and 500ml.

Not all pack sizes may be marketed.

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

GlaxoSmithKline Consumer Healthcare (Ireland) Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
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8 MARKETING AUTHORISATION NUMBER

PA 0678/116/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 01 October 2009

10 DATE OF REVISION OF THE TEXT

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