

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Polytar Plus Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tar Blend	1.0	% w / w
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Tar Blend 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

For excipients see 6.1

3 PHARMACEUTICAL FORM

Shampoo

Crystal clear brownish shampoo with a characteristic odour of tar.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Polytar Plus Shampoo is indicated in the treatment of scalp disorders including psoriasis, dandruff, seborrhoea, eczema, and pruritus. Polytar Plus Shampoo 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 Plus Shampoo 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 Plus Shampoo should be used once or twice weekly.

4.3 Contraindications

Known hypersensitivity to any of the ingredients.

4.4 Special warnings and special precautions for use

None

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

There are no restrictions on the use of Polytar Plus Shampoo in pregnancy and 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 Plus Shampoo 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 hyperplasic 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.

Hydrolysed animal protein and oleyl alcohol are added to the formulation as hair conditioning agents.

5.2 Pharmacokinetic properties

Little is known about the percutaneous absorption, fate and excretion of tars, although epidermal metabolism of polyaromatic hydrocarbons probably does occur. The urine of patients treated with large amounts of crude coal tar contains substances that are apparently derived from the applied crude tar.

5.3 Preclinical safety data

Tar preparations have been in wide use for many years. Although coal tar preparations containing 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

Hydrolysed Collagen (Polypeptide SF)
Oleyl Alcohol
Coconut Diethanolamide
Hexylene Glycol
Polyoxyethylene 10 Oleyl Ether
Polysorbate 80
TriethanolamineLauryl Sulphate (42% aqueous solution)
Citric Acid Monohydrate
Octoxinol
Imidurea
Fragrance 5412
Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

Three years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

High density polyethylene bottles of 25 ml, 65 ml, 150 ml, 250 ml, 350 ml, 500 ml, fitted with screw caps.

6.6 Instructions for use and handling

No special requirements

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 144/4/1

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