

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Polytar Emollient 25% w/w Bath Additive

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tar Blend 25.0 % w/w comprises:

Tar	7.5	% w/w
Cade Oil	7.5	% w/w
Coal Tar Solution	2.5	% w/w
Arachis Oil*(BP) extract of Coal Tar	7.5	% w/w

*also known as peanut oil

For a full list excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Bath additive

A black viscous oily liquid with an odour of tar.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Polytar Emollient is indicated in the treatment of psoriasis, eczema, atopic and pruritic dermatoses. The use of Polytar Emollient may be combined with ultra-violet radiation and other adjunctive therapy. Polytar Emollient is also of value in removing loose psoriatic scales and ointments and pastes used in the treatment of Psoriasis.

4.2 Posology and method of administration

Two to four capfuls of Polytar Emollient should be added to an 8 inch (20cm) bath of water and the patient instructed to soak for 20 minutes.

Polytar Emollient should be used once or twice weekly.

4.3 Contraindications

Known hypersensitivity to the ingredients.

4.4 Special warnings and precautions for use

Avoid contact with the eyes.

Patients should be instructed to guard against slipping when entering or leaving the bath.

Polytar Emollient 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 Emollient.

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 Emollient 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.

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

Pharmacotherapeutic group: Antipsoriatics for Topical Use; tars

ATC code: D05AA

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.

In Polytar Emollient, Tar Blend is presented in an emollient base for use as a bath additive. The use of emollient bath oils in the management of widespread dry and itching skin is well established. Liquid paraffin exerts its emollient effect through skin absorption.

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 bath additive used twice weekly.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light liquid paraffin
Octyl Phenoxy polyethoxy ethanol
Sorbitan mono-oleate
Isopropyl palmitate
Macrogol 400 dilaurate

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 and polyvinyl chloride bottles of 350ml 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
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8 MARKETING AUTHORISATION NUMBER

PA0678/116/002

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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