

POLYTAR[®] Plus Liquid

PRODUCT INFORMATION

NAME OF THE MEDICINE

Polytar Plus Liquid medicated scalp cleanser, contains coal tar solution.

DESCRIPTION

Polytar Plus Liquid contains coal tar solution 4% w/w.

Polytar Plus Liquid also contains: sodium laureth sulfate, cocamidopropyl betaine, sodium phosphate dibasic, citric acid monohydrate, benzyl alcohol, PEG-150 distearate, hexylene glycol, oleyl alcohol, Polyquaternium 10, Timotei Fragrance AF17050 and water-purified.

PHARMACOLOGY

Polytar Plus Liquid is a medicated scalp cleanser (shampoo) that is applied topically to the scalp. It contains 4% coal tar solution as the active ingredient.

Coal tar preparations have been used extensively for over 50 years in the management of various skin disorders, especially psoriasis and eczema. The use of cytostatic agents e.g. coal tar is a direct approach to controlling dandruff which is both safe and effective. The precise mechanism of action of the tars is uncertain – all have some keratolytic, antipruritic, antiseptic action, the last probably due to the presence of phenols. Coal tar has been shown to depress DNA synthesis and thus cell reproduction. This is of significance in the management of skin disorders associated with increased cell replication such as dandruff, seborrhoeic dermatitis and psoriasis.

INDICATIONS

Polytar Plus Liquid is indicated for the treatment of scalp disorders such as psoriasis, dandruff, seborrhoeic dermatitis, eczema and the pruritus associated with these conditions.

The product is intended for daily use or as often as needed, in the treatment of the above conditions.

CONTRAINDICATIONS

Polytar Plus Liquid should not be used in patients with:

- Known hypersensitivity to coal tar, or to any of the excipients in the preparation
- Infected open skin lesions
- Sore or acute pustular psoriasis

PRECAUTIONS

For cutaneous use only.

Polytar Plus Liquid should not be used with other forms of psoriasis therapy such as UV radiation or prescription drugs unless directed to do so by a doctor.

Coal tar preparations may cause irritancy, therefore contact with sensitive areas, such as broken or very inflamed skin, should be avoided.

If irritation develops, treatment should be discontinued.

Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.

Coal tar products can stain skin and clothes. Contact with clothes should be avoided. Skin stains will wear off after treatment is stopped.

In rare instances, temporary hair colour changes may occur.

As Polytar Plus Liquid may cause increased sensitivity to sunlight, sunlamps should not be used and deliberate or prolonged exposure of the scalp to sunlight should be avoided or minimised.

Polytar Plus Liquid should be used with caution if the patient is also taking drugs known to be photosensitisers (e.g. thiazides, tetracyclines, fluoroquinolones, phenothiazines, sulphonamides) because of the increased possibility of augmented photosensitivity.

Effects on Fertility

There are no data on the effects of topical coal tar preparations on human fertility.

Use in Pregnancy

There are limited data from the use of coal tar preparations in pregnant women. Coal tar has been shown to be foetotoxic and teratogenic to the offspring of laboratory animals when administered topically, orally or by inhalation at high and maternally toxic doses.

Use of coal tar preparations during pregnancy should only be considered if the expected benefit to the mother outweighs the potential risk to the foetus.

The use of coal tar products should be avoided in the first trimester of pregnancy.

Use in Lactation

The safe use of topical coal tar preparations during lactation has not been established.

It is not known whether the topical application of coal tar preparations could result in sufficient systemic absorption to produce detectable amounts in breast milk.

Use of coal tar preparations during lactation should only be considered if the expected benefit to the mother outweighs the potential risk to the infant.

If used during lactation, patients should be advised to ensure that any residual product is fully washed off the breast prior to breast-feeding in order to avoid accidental ingestion by the infant.

Paediatric Use

The safety and efficacy of Polytar Plus Liquid in children under 12 years of age have not been established.

Coal tar preparations have been used in children for many years, but since there is very little documented clinical data in this patient population, Polytar Plus Liquid should be used with caution.

It is not recommended for use on children under 2 years of age except under the direction and supervision of a doctor

Effects on Ability to Drive and use Machines

There have been no studies to investigate the effect of Polytar Plus Liquid on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of Polytar Plus Liquid.

INTERACTIONS WITH OTHER MEDICINES

No data on drug interactions with topical coal tar formulations are available. Considering the low level of systemic absorption, systemic drug interactions are unlikely to occur. However, the risk of photosensitivity could in theory be increased if Polytar Plus Liquid is used in patients also taking drugs known to be photosensitizers (e.g. thiazides, tetracyclines, fluoroquinolones, phenathiazines, sulphonamides).

ADVERSE EFFECTS

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$ and $< 1/10$), uncommon ($\geq 1/1,000$ and $< 1/100$), rare ($\geq 1/10,000$ and $< 1/1,000$) and very rare ($< 1/10,000$), including isolated reports.

Post-marketing data

Immune system disorders

Rare: Hypersensitivity (including pruritus, angioedema, dyspnoea)

Eye disorders

Rare: Eye irritation

Skin and subcutaneous tissue disorders

Rare: Alopecia, dermatitis, hair colour changes, abnormal hair texture, photosensitivity reaction, skin irritation (including dry skin, erythema, and skin burning sensation).

General disorders and administration site conditions

Rare: Application site hypersensitivity, application site pain, application site rash, localised oedema.

DOSAGE AND ADMINISTRATION

Polytar Plus Liquid is for topical application to the scalp.

The hair should be wetted and sufficient Polytar Plus Liquid applied to produce abundant lather. The scalp and adjacent areas should be vigorously massaged with the fingertips. The hair should be thoroughly rinsed and the procedure repeated. Taking both these shampoo applications into consideration, the total leave on time for the shampoo should be 3-5 minutes.

Polytar Plus Liquid should be used daily or as often as necessary for the treatment of scalp disorders. The normal duration of use is 4 weeks, after which the condition should improve. Longer duration of therapy should be continued under the supervision of a physician.

Use in children (under 12 years of age)

Polytar Plus should be used with caution in children under 12 years of age. The safety and efficacy in this age group have not been established.

Not recommended for use on children under 2 years of age except under the direction and supervision of a doctor.

OVERDOSAGE

Topical coal tar overdose may increase the rate of skin irritation and photosensitivity (see ADVERSE EFFECTS).

Treatment

Management should be as clinically indicated or as recommended by the Poisons Information Centre 13 11 26 (Australia).

PRESENTATION AND STORAGE CONDITIONS

Polytar Plus Liquid contains 4% w/w coal tar solution in a shampoo base for topical application. The product is presented in a 150 mL plastic bottle fitted with cap.

Store below 25°C.

NAME AND ADDRESS OF THE SPONSOR

GlaxoSmithKline Australia Pty Ltd
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AUSTRALIA

POISON SCHEDULE OF THE MEDICINE

Polytar Plus Liquid is an unscheduled medicine.

Date of first inclusion in the Australian Register of Therapeutic Goods (the ARTG)

29 October 1998

Date of most recent amendment

21 November 2012

Polytar[®] is a registered trade mark of Stiefel Laboratories, Inc.

Version 3.0

