



## PRESCRIBING INFORMATION

### **POLYTAR<sup>®</sup> Shampoo**

(juniper tar 0.16%, pine tar 0.16% and coal tar 0.09%)

### **POLYTAR<sup>®</sup> Mild Shampoo**

(juniper tar 0.09%, pine tar 0.09% and coal tar 0.04%)

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## **POLYTAR<sup>®</sup> Shampoo**

(juniper tar 0.16%, pine tar 0.16% and coal tar 0.09%)

## **POLYTAR<sup>®</sup> Mild Shampoo**

(juniper tar 0.09%, pine tar 0.09% and coal tar 0.04%)

### **INDICATIONS AND CLINICAL USE**

POLYTAR<sup>®</sup> Shampoo is indicated for the relief of dandruff and/or the symptoms (itching, irritation, redness, flaking and/or scaling) associated with dandruff.

### **CONTRAINDICATIONS**

POLYTAR<sup>®</sup> is contraindicated in individuals with known hypersensitivity to coal tar or to any of the excipients in the preparation.

POLYTAR<sup>®</sup> should not be used to treat infected open skin lesions or sore or acute pustular psoriasis.

### **WARNINGS AND PRECAUTIONS**

POLYTAR<sup>®</sup> is for external use only. POLYTAR<sup>®</sup> is for cutaneous use only.

Avoid contact with the eyes. If contact occurs rinse eyes thoroughly with water. Coal tar preparations, such as POLYTAR<sup>®</sup> 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.

POLYTAR<sup>®</sup> 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® 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 minimized.

POLYTAR® contains the excipient imidurea which releases traces of formaldehyde as a breakdown product. Formaldehyde may cause allergic sensitization or irritation upon contact with the skin.

POLYTAR® 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.

Consult a health care practitioner if condition worsens or does not improve after regular use of this product.

Consult a health care practitioner prior to use in children under 2 years of age.

## **Pregnancy and Lactation**

### **Fertility**

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

### **Pregnancy**

There are limited data from the use of coal tar preparations in pregnant women. Coal tar has been shown to be fetotoxic 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.

### **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.

## **ADVERSE REACTIONS**

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

### **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 edema.

## **DOSAGE AND ADMINISTRATION**

### **Adults and Children aged 12 years and older**

POLYTAR<sup>®</sup> is for topical application to the scalp.

Apply to wet hair, massage into scalp. Rinse and repeat. Use daily or as directed by physician or pharmacist.

### **Children**

The safety and efficacy of POLYTAR<sup>®</sup> in children under 12 years of age have not been established. POLYTAR<sup>®</sup> should be used with caution in children and only on the recommendation of a doctor or pharmacist.

## **SYMPTOMS AND TREATMENT OF OVERDOSE**

### **Symptoms**

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

### **Treatment**

Management should be as clinically indicated or as recommended by the national poisons centre, where available.

For management of a suspected overdose, contact your regional Poison Control Centre.
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## **DESCRIPTION AND COMPOSITION**

### **Description:**

POLYTAR<sup>®</sup> is a brown transparent liquid.

### **Composition:**

POLYTAR<sup>®</sup> Shampoo contains a tar blend comprised of juniper tar 0.16%, pine tar 0.16% and coal tar 0.09%. POLYTAR<sup>®</sup> Shampoo also contains citric acid, hexylene glycol, imidurea, lauramide DEA, oleyl alcohol, polyscent, polysorbate 80, Polytar B, purified water, sodium chloride and triethanolamine lauryl sulphate.

POLYTAR<sup>®</sup> Mild Shampoo contains a tar blend comprised of juniper tar 0.09%, pine tar 0.09% and coal tar 0.04%. POLYTAR<sup>®</sup> Shampoo also contains citric acid, ethoxylated oleyl alcohol, hexylene glycol, hydrolysed collagen, imidurea, lauramide DEA, oleyl alcohol, polyscent, polysorbate 80, purified water and triethanolamine lauryl sulphate.

## **AVAILABILITY**

POLYTAR<sup>®</sup> Shampoo (tar blend 1% w/w) and POLYTAR<sup>®</sup> Mild Shampoo (tar blend 0.5% w/w) is available in 150 mL and 350 mL bottles.

## **STORAGE**

Store at a controlled room temperature 15 - 30°C.