

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Tarmed shampoo

Polytar Scalp Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100g shampoo contain 4g coal tar solution (4% w/w)

Excipients with known effect:

Benzyl alcohol 1g (1.0% w/w) and Fragrance Oil (0.5% w/w)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Shampoo.

Viscous brown homogeneous liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The medicine is indicated for the treatment of scalp disorders including:

psoriasis,

seborrhoeic dermatitis,

eczema,
pruritus and scaling associated with psoriasis, seborrhoeic
dermatitis and eczema
itchy, oily scalp,
dandruff.

4.2 Posology and method of administration

Adults and Adolescents

This medicine is for topical application to the scalp. The hair should be wetted and sufficient amount applied to produce abundant lather. The scalp and adjacent areas should be vigorously massaged with the fingertips. The hair should be then thoroughly rinsed and the procedure repeated. Taking both of these shampoo applications into consideration, the total leave on time for the shampoo should be 3-5 minutes. This medicine should be used once or twice weekly for the treatment of scalp disorders. 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 the Elderly

The dosage instructions given above are suitable for the elderly.

Use in Children

Not established for use in children under the age of 12 years.

Coal tar preparations have been used, for many years, when recommended by a doctor to treat children however, there is very little documented clinical data in this patient population.

Use in Renal/Hepatic Impairment

No dosage adjustment is necessary

4.3 Contraindications

- Known hypersensitivity to the active substance or to any of the excipients.
- Infected open skin lesions.
Sore or acute pustular psoriasis

4.4 Special warnings and precautions for use

This medicine is for cutaneous use only.

- 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.

Contact with the eyes should be avoided. If contact occurs rinse eyes thoroughly with water.

- This medicine 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.

- This medicine 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.

Special warnings about excipients

This medicine contains 1g benzyl alcohol per 100g of shampoo. Benzyl alcohol may cause allergic reactions and mild local irritation.

This medicine contains fragrance with the following allergens: Linalool, Alpha-Isomethyl ionone (3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one), Citronellol, Hexyl cinnamal (Hexyl cinnamaldehyde), Benzyl salicylate, Benzyl benzoate, Coumarin, Eugenol, Geraniol, Hydroxycitronellal, Isoeugenol, d-Limonene, Benzyl alcohol, Amyl cinnamal, Amylcinnamyl alcohol, Anisyl alcohol (Anise alcohol), Benzyl cinnamate, Cinnamal, Cinnamyl alcohol, Citral, Farnesol. These may cause allergic reactions. In addition to allergic reactions in sensitised patients, nonsensitised patients may become sensitised.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

Fertility

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

This medicine should be used in pregnancy only when clearly necessary.

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 (see section 5.3).

Use of this medicine during pregnancy should only be considered if the expected benefit to the mother outweighs the potential risk to the foetus.

The use of this medicine 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.

4.7 Effects on ability to drive and use machines

No effect on the ability to drive and use machines have been observed.

4.8 Undesirable 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 $< 1/1,000$), very rare ($< 1/10,000$), including isolated reports and Not known (cannot be estimated from the available data).

Post-marketing data

Immune system disorders

Not known Hypersensitivity (including pruritus, angioedema, dyspnoea)

Eye disorders

Not known Eye irritation

Skin and subcutaneous tissue disorders

Not known

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

Not known

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via www.mhra.gov.uk/yellowcard.

4.9 Overdose

Symptoms and signs

Topical coal tar overdose may increase the rate of skin irritation and photosensitivity. (*see section 4.8*).

Treatment

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D05AA

Tar preparations have been used extensively for over 50 years in the management of various skin conditions such as psoriasis, eczema and other dermatoses. The precise mechanism of action is uncertain. Coal tars are known to 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. Coal tar has anti-inflammatory, antibacterial, antipruritic, keratolytic, keratoplastic and vasoconstrictive effects.

This is of significance in the management of psoriasis and other dermatoses associated with increased cell replication, such as dandruff. The use of coal tar preparations in products for scalp disorders is well established and such treatments have generally been shown to be safe and effective.

5.2 Pharmacokinetic properties

In a study using a variety of coal tar preparations total urinary poly aromatic hydrocarbons were significantly elevated in patients treated dermally for different forms of dermatoses. The treatment period was for an average of 7 days using 1.5% - 40% coal tar preparations over a body surface area that ranged from 9 to 90%. Therefore some of the hydrocarbons present in coal tar may be absorbed through the skin. The highest levels absorbed depend largely on the body surface area treated and on the duration of exposure.

Many of the hydrocarbons will be subject to extensive metabolic transformation by both oxidation and conjugation. Drug-metabolizing enzymes (both in the skin and systemically) may be induced by coal tar application.

The potential for systemic absorption of coal tar from this medicine, containing 4% Coal Tar Solution BP, when used as wash-off shampoo is extremely low.

5.3 Preclinical safety data

Carcinogenesis and Mutagenesis

No long term studies have been conducted with the product formulations. Coal tar contains certain chemicals that are mutagenic to microorganisms and mammalian cells *in vitro*. Topical and oral administration of high doses of coal tar to laboratory animals induces DNA adduct formation.

High dose administration of coal tar to laboratory animals is carcinogenic. However, epidemiological evidence that includes prospective and retrospective studies in thousands of patients receiving coal tar therapy followed for more than 40 years do not suggest a potential increased risk of skin or systemic cancer.

Reproductive Toxicology

Coal tar is foetotoxic and teratogenic at maternally toxic doses following dermal application, oral administration, or inhalation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Lauryl Ether Sulphate
Cocamidopropyl Betaine
Disodium Phosphate Dihydrate
Citric Acid Monohydrate
Benzyl Alcohol
Macrogol 150 Distearate
Hexylene Glycol
Oleyl Alcohol
Polyquaternium-10
Fragrance Oil
Purified Water

6.2 Incompatibilities

None

6.3 Shelf life

4 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

High density polyethylene bottles fitted with polypropylene caps.
Licensed pack size: 150ml.

6.6 Special precautions for disposal

There are no special instructions for use or handling of Tarmed.

7 MARKETING AUTHORISATION HOLDER

Universal Medicines Limited
83-85 Baker Street,
London, W1U 6AG,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 60688/0001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

14th November 1995/14th November 2005

10 DATE OF REVISION OF THE TEXT

19/05/2026