

## SUMMARY PRODUCT CHARACTERISTIC (SPC)

### COAL TAR 2% shampoo for external use

**NAME OF THE MEDICINAL PRODUCT**– COAL TAR  
**INTERNATIONAL NON-PROPERTY NAME** – COAL TAR

#### DOSAGE FORM

Shampoo for external use.

#### COMPOSITION

Each ml of shampoo for external use contents:

**Active ingredients:** COAL TAR - 20 mg;

**Excipients:** cocamidopropyl betaine, sodium laureth sulphate, cocamide DEA, sodium chloride, disodium EDTA, methylparaben, citric acid, purified water.

#### PHARMACOLOGICAL GROUP AND ATC CODE

Dermatological preparation, D11AC30

#### APPEARANCE

A yellowish brown viscous liquid with a strong, penetrating and characteristic odor.

#### PHARMACOLOGY

Crude COAL TAR preparation is for topical use in dermatology. Inhibits proliferation and infiltration of epidermis cells, has a weak antiseptic, antipruritic, astringent effects. Stimulates regeneration of the epidermis and keratinization processes. Has photosensitizing effect.

#### PHARMACOKINETICS

The drug is intended for topical use, systemic absorption data are not available.

#### USES

-Seborrheic dermatitis.

#### ADMINISTRATION

Shake well before use contents of the plastic bottle.

Apply the required amount of shampoo on wet hair and rub to form a foam, then rinse and apply again. The foam should be left on hair for about 5 minutes, then rinse the hair thoroughly. COAL TAR is recommended to use 2 times a week. Duration of usage set by your doctor.

#### ADVERSE EFFECTS

Because of irritant action of preparation dermatitis of pilar part of the scalp is possible (with prolonged use); chronic folliculitis; photosensitivity.

COAL TAR contains methylparaben, that may cause allergic reactions (possibly delayed).

#### CONTRAINDICATIONS

- Hypersensitivity to the ingredients of the preparation.
- Infected, damaged skin.
- Children under 12 years old.
- Pregnancy, breast-feeding.

- UV irradiation.

## **PRECAUTIONS**

During treatment is recommended to avoid sun exposure.

Avoid contact COAL TAR with eyes, mouth, nose, mucous membranes, on an open wound; in case of contact, immediately rinse with water.

## **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. 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.

## **EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

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

## **OVERDOSE**

### **Symptoms and signs**

Topical COAL TAR overdose may increase the rate of skin irritation and photosensitivity.

### **Treatment**

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

## **DRUG INTERACTIONS**

COAL TAR is not recommended to use in conjunction with preparations, having phototoxic and photoactive effects (eg, tetracyclines, psoralens, tretinoin).

## **PRESCRIPTION STATUS**

To be dispensed with prescription.

## **PRESENTATION**

Shampoo for external application of 2% in 90 ml plastic bottles with leaflet in cardboard box.

## **STORAGE CONDITIONS**

Store at temperature not higher than 25 °C, in a dry place, out of the reach of children.

## **EXPIRY DATE**

3 years. Do not use after the expiration date.

**MANUFACTURER**

**“ARPIMED” LLC**

Kotayk Marz, Abovyan, 2204, 2nd Micro-District, 19 Building, Republic of Armenia

Tel.: (374) 222 21703

Fax: (374) 222 21924

**MARKETING AUTHORIZATION HOLDER**

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