



## PRESCRIBING INFORMATION

### **DOAK<sup>®</sup> Oil**

coal tar (doak tar distillate 2%) liquid

### **DOAK<sup>®</sup> Oil Forte**

coal tar (doak tar distillate 10%) liquid

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Date of Revision:  
June 28, 2013

Submission Control No: 160326

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coal tar (doak tar distillate 2%) liquid

## **DOAK<sup>®</sup> Oil Forte**

coal tar (doak tar distillate 10%) liquid

### **INDICATIONS AND CLINICAL USE**

DOAK<sup>®</sup> Oil and DOAK<sup>®</sup> Oil Forte are indicated for adjuvant therapy in the management of dermatoses involving dry, itchy, or scaly skin, psoriasis, eczema.

### **CONTRAINDICATIONS**

DOAK<sup>®</sup> Oil and DOAK<sup>®</sup> Oil Forte are contraindicated in individuals with known hypersensitivity to coal tar or to any of the excipients in the preparation.

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

### **WARNINGS AND PRECAUTIONS**

DOAK<sup>®</sup> Oil and DOAK<sup>®</sup> Oil Forte are for external use only. DOAK<sup>®</sup> Oil and DOAK<sup>®</sup> Oil Forte are for cutaneous use only. Avoid contact with the eyes. If contact occurs rinse eyes thoroughly with water. Coal tar preparations, such as DOAK<sup>®</sup> Oil and DOAK<sup>®</sup> Oil Forte 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.

DOAK<sup>®</sup> Oil and DOAK<sup>®</sup> Oil Forte 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 DOAK<sup>®</sup> Oil and DOAK<sup>®</sup> Oil Forte may cause increased sensitivity to sunlight, exposure to artificial sources of UV light, such as sunlamps should be avoided unless the UV is being used as part of a treatment regimen.

When exposure to strong sunlight cannot be avoided, patients should be advised to use a sunscreen product and wear protective clothing. Due to the potential for photosensitivity, resulting in greater risk for sunburn, DOAK<sup>®</sup> Oil and DOAK<sup>®</sup> Oil Forte should be used with caution in patients with a personal or family history of skin cancer.

If a patient has sunburn, this should be resolved before using DOAK<sup>®</sup> Oil and DOAK<sup>®</sup> Oil Forte.

DOAK<sup>®</sup> Oil and DOAK<sup>®</sup> Oil Forte 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.

DOAK<sup>®</sup> Oil and DOAK<sup>®</sup> Oil Forte may make the bath slippery therefore the patient should be advised to use care, to avoid slipping in the bath.

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 fetus.

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**

Add 2 to 4 capfuls to bathtub of water. Soak 10 to 20 minutes. Use once daily or as directed by physician.

### **Children**

The safety and efficacy of DOAK<sup>®</sup> Oil and DOAK<sup>®</sup> Oil Forte in children under 12 years of age have not been established. DOAK<sup>®</sup> Oil and DOAK<sup>®</sup> Oil Forte 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.

## **DESCRIPTION AND COMPOSITION**

### **Description:**

DOAK<sup>®</sup> Oil is a light amber clear oily liquid.

DOAK<sup>®</sup> Oil Forte is a dark amber clear liquid.

### **Composition:**

Each gram of DOAK<sup>®</sup> Oil Liquid (coal tar as doak tar distillate 2%) contains 20 mg of doak tar distillate. DOAK<sup>®</sup> Oil Liquid also contains cetyl acetate/acetylated lanolin alcohol, mineral oil/lanolin alcohol, fragrance A-933, isopropyl palmitate, light mineral oil and nonoxynol-4.

Each gram of DOAK<sup>®</sup> Oil Forte Liquid (coal tar as doak tar distillate 10%) contains 100.0 mg of doak tar distillate. DOAK<sup>®</sup> Oil Forte Liquid also contains cetyl acetate/acetylated lanolin alcohol, mineral oil/lanolin alcohol, fragrance A-933, isopropyl palmitate, light mineral oil and nonoxynol-4.

## **AVAILABILITY**

DOAK<sup>®</sup> Oil (coal tar as doak tar distillate 2%) Liquid and DOAK<sup>®</sup> Oil Forte (coal tar as doak tar distillate 10%) Liquid are available in 250 mL bottles.

## **STORAGE**

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