

**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

**MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007**

**(S.I. No.540 of 2007)**

**PA0144/030/001**

Case No: 2034129

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

**Stiefel Labs (U.K.) Ltd.**

**Holtspur Lane, Wooburn Green, High Wycombe, Bucks HP10 0AU, England**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

**Polytar Anti-fungal Shampoo**

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **22/04/2007**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Polytar Anti-Fungal Shampoo

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tar Blend 1% w/w

Zinc Pyrithione 1% w/w

For a full list of excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Shampoo

A beige to pale brown coloured viscous opaque liquid.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Polytar Anti-Fungal is indicated in the treatment of scaling scalp disorders such as psoriasis, dandruff, seborrhoeic dermatitis and eczema, and the pruritus associated with these conditions.

##### 4.2 Posology and method of administration

The following doses and schedules are applicable to adults, children and the elderly.

###### Directions for use

Shake the bottle before use. Wet the hair and massage Polytar Anti-Fungal into the hair, scalp and surrounding skin. Leave for 2-3 minutes, then rinse thoroughly.

###### Treatment

Use once or twice weekly for at least three weeks, or until the condition clears.

###### Prophylaxis for seborrhoeic dermatitis and dandruff:

Use Polytar Anti-Fungal weekly.

##### 4.3 Contraindications

Known hypersensitivity to any of the ingredients.

##### 4.4 Special warnings and precautions for use

Polytar Anti-Fungal is for external use only. As with all shampoo products, avoid contact with the eyes.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.6 Pregnancy and lactation**

The safety of Polytar Anti-Fungal in pregnant and lactating women has not been established.

#### **4.7 Effects on ability to drive and use machines**

None.

#### **4.8 Undesirable effects**

Tar products may occasionally cause skin irritation, rashes and rarely, skin photosensitivity. Zinc pyrithione may cause contact dermatitis. If irritation occurs and persists, treatment with Polytar Anti-Fungal should be discontinued.

Although carcinogenicity of coal tar has been demonstrated in animal studies, no studies demonstrating an increased risk of skin cancer with normal therapeutic use in humans have been reported. There is no unequivocal evidence to link the use of topically applied coal tar products with skin cancer (See also section 5.3).

#### **4.9 Overdose**

Not applicable.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Tar preparations are anti-pruritic, keratoplastic, and weakly antiseptic. Zinc pyrithione has bacteriostatic and fungicidal properties.

#### **5.2 Pharmacokinetic properties**

Little is known about the percutaneous absorption, fate and excretion of tars, although epidermal metabolism of polyaromatic hydrocarbons probably does occur. The urine of patients treated with large amounts of crude coal tar contains substances that are apparently derived from the applied crude tar.

In a human pharmacokinetic study using radio labelled zinc pyrithione 2% in a shampoo, 1-2% of the applied dose was found on the head after shampooing; systemic absorption was not detected.

The potential for absorption of tar blend and zinc pyrithione from Polytar Anti-Fungal, containing 1% of each of the active ingredients is extremely low.

#### **5.3 Preclinical safety data**

Tar preparations have been in wide use for many years. Although coal tar preparations containing polycyclic aromatic hydrocarbons (PAHs) have been demonstrated to be carcinogenic in the skin of experimental animals, present evidence based upon epidemiology studies in humans and follow-up trials, reveals no evidence of increased risk of skin or internal cancer, particularly when the product is used as directed.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Imidurea  
Triethanolamine Lauryl Sulphate  
Carbomer 940  
Coconut Diethanolamide  
Sodium Hydroxide  
Hypromellose  
Glycerol  
Octylphenoxy polyethoxyethanol  
Purified Water

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf Life**

#### **a) For the product as packaged for sale**

Three years.

#### **b) After first opening the container**

Comply with expiry date.

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and contents of container**

High density polyethylene bottles fitted with screw caps.  
Pack contents 150 ml.

### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Stiefel Laboratories (UK) Ltd  
Holtspur Lane  
Wooburn Green  
High Wycombe  
Buckinghamshire HP10 0AU  
England

## **8 MARKETING AUTHORISATION NUMBER**

PA 144/30/1

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

Date of first authorisation: 22<sup>nd</sup> April 1992

Date of last renewal: 22<sup>nd</sup> April 2007

**10 DATE OF REVISION OF THE TEXT**

January 2008