

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Tarmed 4% Shampoo.

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Coal Tar Solution 4% w/w

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Shampoo

A viscous, brown homogenous liquid with a characteristic odour intended as a shampoo

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Tarmed is indicated for the treatment of scalp disorders such as psoriasis, dandruff, seborrhoeic dermatitis, eczema and the pruritus associated with these conditions.

##### 4.2 Posology and method of administration

Adults:

Tarmed is for topical application to the scalp. The hair should be wetted and sufficient Tarmed applied to produce an abundant lather. The scalp and adjacent areas should be vigorously massaged with the fingertips. The hair should then be thoroughly rinsed and the procedure repeated. Tarmed should be used daily or as often as necessary for the treatment of scalp disorders.

Use in the Elderly:

The dosage instructions given above are suitable for the elderly.

Use in Children:

The dosage instructions given above are suitable for children.

##### 4.3 Contraindications

Patients with known hypersensitivity to any of the ingredients

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

None.

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

None known.

## 4.6 Pregnancy and lactation

Tar shampoos have been in wide use for many years without apparent adverse consequences. There are no restrictions on the use of Tarmed in pregnancy or lactation.

## 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. If irritation occurs and persists, treatment should be discontinued.

## 4.9 Overdose

Not applicable.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

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. 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, tars also have keratolytic, vasoconstrictive, antipruritic and antiseptic activity. This is of significance in the management of psoriasis and other dermatoses associated with increased cell replication, such as dandruff. The use of tar preparations in products for scalp disorders is well established and such treatment have generally been shown to be safe and effective

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

## 5.3 Preclinical safety data

Not applicable. Tar preparations have been in wide use for many years and their safety in humans has been established

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Sodium Lauryl Ether Sulphate  
Cocamidopropyl Betaine  
Disodium Hydrogen Phosphate  
Citric Acid Monohydrate  
Benzyl Alcohol  
PEG – 150 Distearate  
Hexylene Glycol  
Oleyl Alcohol  
Polyquaternium – 10

Fragrance AF17050  
Purified Water

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf Life**

3 years

## **6.4 Special precautions for storage**

Store below 25°C.

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

High density polyethylene bottles fitted with polypropylene caps, containing 25ml, 150ml and 250ml shampoo.

Not all pack sizes are marketed.

## **6.6 Instructions for use and handling**

No special requirements

## **7 MARKETING AUTHORISATION HOLDER**

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

## **8 MARKETING AUTHORISATION NUMBER**

PA 144/34/1

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

Date of first authorisation: 9<sup>th</sup> January 1998

Date of last renewal: 9<sup>th</sup> January 2003

## **10 DATE OF REVISION OF THE TEXT**

August 2004