

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Capasal Therapeutic Shampoo

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid 0.5% w/w

Coconut Oil 1.0% w/w

Distilled Coal Tar 1.0% w/w

Excipients with known effect:

Sodium benzoate (E 211)

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Shampoo

Golden brown foaming shampoo.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For use as a shampoo in the treatment of dry, scaly scalp conditions such as seborrhoeic eczema, seborrhoeic dermatitis, pityriasis capitis, psoriasis and cradle cap in children. It may also be used to remove previous scalp applications.

### 4.2 Posology and method of administration

For adults, children and the elderly.

Use as a shampoo, once or twice weekly until the condition improves. Thereafter, occasional use may be necessary. After thoroughly wetting the hair, massage a small amount of shampoo into the scalp (approximately a quantity the size of a two Euro piece for short hair, adjusting up depending on length/thickness of hair), and leave for a few minutes before washing out. If necessary, repeat, giving a thick lather.

Rinse the hair well and dry.

### 4.3 Contraindications

Not to be used in cases of hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

### 4.4 Special warnings and precautions for use

Protect the eyes from the shampoo.

Keep out of the sight and reach of children.

This medicine contains 0.15mg of sodium benzoate (E 211) per gram of shampoo. Sodium benzoate (E 211) may cause local irritation. May cause non-immunologic immediate contact reactions by a possible cholinergic mechanism. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old). Absorption of sodium benzoate through the immature skin of neonates is significant.

If there is no improvement after 4 weeks, or the condition is aggravated, discontinue treatment and consult your doctor, pharmacist or nurse.

For external use only.

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

None known.

#### **4.6 Fertility, pregnancy and lactation**

There is inadequate evidence of safety in pregnant and lactating women but coal tar preparations have been in use for many years without apparent ill-consequence and no harmful effects on the health of the child is anticipated with the proper use of this product. However, it is recommended that the use of coal tar in pregnancy and lactation be restricted to intermittent use, in a low concentration on a relatively small percentage of a body surface and that use during the first trimester be avoided.

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

None known.

#### **4.8 Undesirable effects**

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).

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 HPRAs Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie).

#### **4.9 Overdose**

There are no known toxic effects resulting from excessive use of Capasal.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Antipsoriatics for topical use, Tars. ATC Code D05AA.

The preparation has been designed as an aid in the treatment of dry, scaly scalp conditions by incorporating into a convenient shampoo formulation three well known ingredients which have been established as safe and effective, for example in, Coconut Oil Compound Ointment (Ung Cocos Co) for use in these indications.

They are as follows:

0.5% salicylic acid - mild keratolytic

1.0% coconut oil - emollient, softening agent and lubricant

1.0% distilled coal tar - anti-pruritic, keratoplastic

The preparation may also be used conveniently to remove any previous topical application.

#### **5.2 Pharmacokinetic properties**

The active ingredients of the formulation are readily available for intimate contact with the skin, as the shampoo is massaged into the scalp and left for a few minutes before washing out. This is then repeated in order to produce a rich lather.

The detergent effect of the shampoo will also remove any previous application to the scalp.

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

Tar preparations have been in wide use for many years. Although coal tar preparations containing polycyclic aromatic hydrocarbons 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**

Lauric acid diethanolamide

Coco amido propyl dimethyl betaine solution (contains sodium benzoate as a preservative)

Triethanolamine lauryl sulfate solution (contains methylchloroisothiazolinone /methylisothiazolinone (3:1) as a preservative)

Ammonium sulfate

Phenoxyethanol

Purified Water

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years

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

Do not store above 25°C.

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

30 ml high density polyethylene bottles with polypropylene screw caps.

50, 100, 125, 150, 200, 250, 300, 350 and 500 ml high density polyethylene bottles with polypropylene dispensing screw caps.

10 ml aluminium foil/polyester/polyethylene laminate sachets.

Not all pack sizes may be marketed.

### **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**

Dermal Laboratories (Ireland) Limited

38 Main Street

Swords

Co Dublin

K67 E0A2

Ireland

## **8 MARKETING AUTHORISATION NUMBER**

PA23128/008/001

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

Date of first authorisation: 10 January 1991

Date of last renewal: 10 January 2006

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

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