

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Capasal Therapeutic Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Distilled coal tar	1.0% w/w
Salicylic acid	0.5% w/w
Coconut oil	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

Viscous, golden brown 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, daily if necessary, reducing the frequency of use to once or twice a week as the condition improves. Thereafter, occasional use may be necessary. Wet the hair thoroughly. Massage a small amount of the shampoo into the scalp (approximately a quantity the size of a fifty pence piece for short hair, adjusting up depending on length/thickness of hair), leaving on for a few minutes before washing out. If necessary, repeat, producing a rich lather. Rinse 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

Keep away from the eyes.

Keep out of the sight and reach of children.

For external use only.

This medicine contains 0.15mg of sodium benzoate (E 211) per gram of shampoo. Sodium benzoate (E 211) may cause local irritation. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

In case of irritation, or if there is no improvement after 4 weeks, or the scalp condition seems to look or feel worse, discontinue treatment and tell your doctor, pharmacist or nurse.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

No known side effects.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None known.

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 the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 shampoo formulation three well known ingredients which have been established as safe and effective for use in this indication. They are as follows:

1.0% distilled coal tar - anti-pruritic, keratoplastic

0.5% salicylic acid - mild keratolytic

1.0% coconut oil - emollient, softening agent and lubricant

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 on 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

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lauric acid diethanolamide
Coco amido propyl dimethyl betaine (contains sodium benzoate as a preservative)
Triethanolamine lauryl sulfate (trolamine lauril sulfate) (contains methylchloroisothiazolinone /methylisothiazolinone (3:1) as a preservative)
Phenoxyethanol
Ammonium sulfate
Water, purified

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months in unopened container.

6.4 Special precautions for storage

Do not store above 25°C. Keep away from direct sunlight.

6.5 Nature and contents of container

30 ml high density polyethylene bottles with polypropylene screwcaps.

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

10 ml aluminium foil/polyester/polyethylene laminate sachets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Diomed Developments Limited

T/A Dermal Laboratories

Tatmore Place, Gosmore

Hitchin, Herts, SG4 7QR, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00173/0048

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

29 January 1996 / 29 January 2006

10 DATE OF REVISION OF THE TEXT

07/05/2024