

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gelcotar Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Strong Coal Tar Solution	1.25	% w / w
Cade Oil	0.50	% w / w

For excipients see 6.1.

3 PHARMACEUTICAL FORM

Shampoo

Gelcotar Shampoo is a clear, viscous shampoo, deep red to brown in colour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Psoriasis of the scalp, seborrhoeic dermatitis and dandruff.

4.2 Posology and method of administration

Route of administration

For topical use only.

Adults, children and the elderly

Wet the scalp and hair with warm water. Sufficient Gelcotar Shampoo should be applied to produce a generous lather. Massage the scalp and surrounding area with the fingertips. Rinse and repeat. Finally rinse the hair and scalp thoroughly.

Use twice weekly or as directed by the Medical Practitioner.

4.3 Contraindications

Patients with known sensitivity or intolerance to strong coal tar or cade oil should not use Gelcotar Shampoo.

4.4 Special warnings and precautions for use

Contact with eyes and other mucosal surfaces should be avoided. All medicines should be kept out of the reach of children. Gelcotar Shampoo can be easily removed by warm water.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Gelcotar Shampoo is not contra-indicated in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

Not applicable.

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).

4.9 Overdose

Not applicable. Gelcotar Shampoo is for topical use only.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The combination of strong coal tar solution and cade oil provides a preparation with antiseptic and keratolytic properties to be used as a medicated scalp cleanser.

5.2 Pharmacokinetic properties

Not applicable.

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

Polyethylene-glycol-200 hydrogenated glyceryl palmate
 Disodium fatty acid monoethanolamide sulphosuccinate
 Ricinoleic propyl amido trimethyl ammonium methosulphate
 Coconut diethanolamide
 Triethanolamine lauryl sulphate
 Chlorocresol
 Lecithin
 Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Two years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Gelcotar Shampoo is packed in printed polythene bottles of 150 ml and 350 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

Quinoderm Limited
Manchester Road
Hollinwood
Oldham
OL8 4PB
Lancashire
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 308/12/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18 April 1988

Date of last renewal: 18 April 2003

10 DATE OF REVISION OF THE TEXT

April 2003