Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tarmed AF Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Coal tar solution	4 % w/w.
Ciclopirox olamine	1 % w/w.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Shampoo
A viscous, yellowish brown liquid shampoo.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of adminstration

Adults:
Tarmed AF is for topical application to the scalp. The hair should be wetted and sufficient Tarmed AF 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 AF should be used two to three times weekly 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 safety and effectiveness in children have not been established.

4.3 Contraindications

Patients with known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Tarmed AF 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

Tar shampoos and Ciclopirox olamine have been in wide use for many years without apparent adverse consequences. However, the safety of Tarmed AF in pregnant or 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. If irritation occurs and persists, treatment with Tarmed AF should be discontinued.

An increased risk of skin cancer in patients with psoriasis treated with a combination of coal tar and UVB radiation has 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 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 treatments have generally been shown to be safe and effective.

Ciclopirox olamine is a broad spectrum antifungal agent which inhibits the growth of pathogenic dermatophytes, yeast and *Mallassezia furfur.* It has been shown in vitro to inhibit both *Pityrosporum ovale* and *Pityrosporum orbiculare,* the yeast forms of *Mallassezia furfur* which have been implicated as the causative organisms in conditions such as dandruff.

5.2 Pharmacokinetic properties

Little is known about the percutaneous absorption, fate and excretion of tar, although epidermal metabolism of polyaromatic hydrocarbons (PAH's) 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.

Following topical application of Ciclopirox olamine as a 1% cream to human skin, about 1.3% of the dose is absorbed systemically. Ciclopirox olamine is excreted in the urine with approximately 80% of an oral dose excreted as the glucuronide metabolite. The biological half-life is approximately 1.7 hours. Following oral administration in humans, 96% is excreted within 12 hours.

The potential for systemic absorption of coal tar and Ciclopirox olamine from Tarmed AF, containing 4% Coal Tar Solution and 1% Ciclopirox olamine, 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. Ciclopirox olamine has been in use for twenty years. It is used in leave-on topical anti-fungal preparations and vaginal creams. Studies have not demonstrated any prohibitive findings in reproduction toxicology, mutagenicity, carcinogenicity or phototoxicity.

Tar preparations have been in wide use for many years. Although coal tar preparations containing PAH's 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 a rinse-off shampoo used twice weekly.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium lauryl ether sulphate
Cocamidopropyl betaine
Disodium phosphate dodecahydrate
Citric acid monohydrate
PEG-150 distearate
Hexylene glycol
Oleyl alcohol
Polysorbate 80
Polyquaternium-10
Fruitier timotei AF17050
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

High density polyethylene bottles (150 ml) fitted with polypropylene screw caps.

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

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8 MARKETING AUTHORISATION NUMBER

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