Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pragmatar Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetyl alcohol - coal tar distillate	4	% w/w
Sulphur for external use	3	% w/w
Salicylic Acid	3	% w/w

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cream
A smooth textured, cream or pale buff coloured cream, free from grittiness with a characteristic viscosity and perfume.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of dandruff, other seborrhoeic conditions, and common scaly skin disorders.

4.2 Posology and method of administration

For topical application to the skin.

Adults and children:
For mild dandruff, apply the cream once a week when the hair is washed. For more severe cases, treat the entire scalp daily at bedtime, applying lightly but thoroughly with the fingertips. The cream can be washed out the next morning or left as a pleasant hair dressing. For other indicated subacute or chronic skin disorders, apply daily in small quantities to affected areas only.

Infants:
The cream may be diluted by mixing with a few drops of water in the palm of the hand.

4.3 Contraindications

Do not use in the presence of acute local infection or on broken skin. Do not use in patients who are sensitive to sulphur, coal tar, salicylic acid or any of the other ingredients.

4.4 Special warnings and precautions for use

Use with care near the eyes, mucous membranes or on acutely inflamed areas if any cream should accidentally enter the eye, flush with normal saline solution. Avoid using the cream on genital or rectal areas.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Safety in pregnancy and lactation has not been established. Pragmatar should only be used in these circumstances when considered essential by the physician.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

No side-effects are to be expected if the cream is used according to directions. Excessive use, however, may cause erythema and irritation. Very rarely, coal tar preparations may cause photosensitivity. Coal tar preparations may cause staining of skin, hair and fabric.

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 Section 5.3, “Preclinical Safety Data”).

4.9 Overdose

If ingestion occurs, gastro-intestinal disturbances may follow. Treatment consists of rinsing out the mouth together with symptomatic measures if necessary. Even with massive ingestion, salicylate poisoning seems unlikely.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pragmatar has mild antipruritic, antiseptic and keratolytic properties.

5.2 Pharmacokinetic properties

Coal tar is a complex intricate compound with a variable composition. As a result, it is not possible to perform normal pharmacokinetic analysis as for other medications. Consequently, there are no reliable data on the rate of absorption, blood levels or excretion of coal tar. However, the conspicuous absence of systemic toxicity over many years of use has led most clinicians to conclude that there is little or no systemic absorption of coal tar.

Salicylic acid is absorbed through skin when applied in ointments, and systemic poisoning has occurred from excessive application to large areas of skin. After absorption, salicylic acid is distributed throughout most body tissues and transcellular fluids, primarily by a pH-dependent passive process. It is mainly metabolised by the liver and excreted via the kidneys, and has a half-life of 2 to 3 hours in low doses.

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

Sodium carboxymethylcellulose 7MF
Glycerol (E422)
Sodium laurilsulfate
Cetyl alcohol
Light liquid paraffin
Perfume bouquet 3522
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Store below 30°C. Replace cap tightly after use.

6.5 Nature and contents of container

Printed aluminium internally lacquered tubes of 25g or 100g with screw-on cap of urea formaldehyde high density polythene or polypropylene.

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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