

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tar Pomade

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Coal tar solution	6.0% w/w
Salicylic Acid	2.0% w/w

3 PHARMACEUTICAL FORM

Light brown coloured ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

It is recommended for use in the treatment of eczema, psoriasis and related skin affections.

4.2 Posology and method of administration

Dosage

Apply to the affected area as directed by the pharmacist and/or the physician.

Administration

Cutaneous (topical) use.

4.3 Contraindications

Use in persons hypersensitive to any of the ingredients.

4.4 Special warnings and special precautions for use

If the condition does not improve, or is aggravated consult the doctor.

Exposure of the treated areas to direct sunlight should be avoided after application.

Avoid contact with eyes.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions known.

4.6 Pregnancy and lactation

Use in pregnancy and lactation has not been established for this product, however, due to the established nature of the ingredients, no adverse effects are anticipated.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

Tar pomade has antipruritic, keratolytic and antiseptic properties.

5.2 Pharmacokinetic properties

Not relevant.

5.3 Preclinical safety dataCoal Tar

Skin and eye irritation:

Skin (human):	15 µg/3D-1	Mild
Skin (rabbit):	5%/3H	Mild

Salicylic Acid

Skin and eye irritation:

Skin (rabbit)	500 mg/24H	Mild
Eye (rabbit)	100 mg	Severe

Skin (man): TDLo: 57 mg/kg Sense organs and special senses

(Registry of Toxic Effects of Chemical Substances 1985-86)

6 PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Emulsifying wax
 Yellow soft paraffin
 Liquid paraffin
 Polysorbate 80

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

Plastic jar.

100 g.

400 g.

6.6 Instructions for use and handling

None.

7 MARKETING AUTHORISATION HOLDER

Foran Chemical Limited,
2 Cherry Orchard Industrial Estate,
Dublin 10.

8 MARKETING AUTHORISATION NUMBER

PA 484/26/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th January 1991

Date of last renewal: 29th January 2001

10 DATE OF REVISION OF THE TEXT

December 2001