

SUMMARY OF PRODUCT CHARACTERISTICS

1 TRADE NAME OF THE MEDICINAL PRODUCT

The 50:50 Ointment.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active ingredient</u>	<u>%w/w</u>
White Soft Paraffin	50
Liquid Paraffin	50

3 PHARMACEUTICAL FORM

Ointment for cutaneous use.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For general use as an emollient in the symptomatic relief of dry skin conditions.

4.2 Posology and method of administration

Adults, Children and the Elderly.

Apply a thin film of the ointment to the affected area of the skin, in the direction of hair growth, as required. Repeat as necessary. Ideally the product should be applied three or four times a day, or at least twice a day.

In adults, where a large area of the body is affected, up to 500g a week may be used.

For topical administration.

4.3 Contraindications

Hypersensitivity to either White Soft Paraffin or Liquid Paraffin.

4.4 Special warnings and special precautions for use

The ointment should be applied in the direction of hair growth to reduce the incidence of folliculitis.

4.5 Interactions with other medicaments and other forms of interaction

No clinically significant interactions known.

4.6 Pregnancy and lactation

The safety of White Soft Paraffin and Liquid Paraffin during pregnancy and lactation has not been established, but use during these periods is not considered to constitute a hazard.

4.7 Effects on ability to drive and to use machines

The ointment is greasy and if applied to the hands, appropriate care should be taken if driving or operating machinery.

4.8 Undesirable effects

Rarely hypersensitivity reactions. Prolonged use of large quantities may cause folliculitis, should this occur, use of the product should be discontinued.

4.9 Overdose

The 50:50 ointment is of low toxicity and if ingested treatment should be supportive and symptomatic. Gastric lavage should not be attempted following ingestion of paraffin-based products, due to the risk of inhalation or aspiration into the lungs.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

White Soft Paraffin and Liquid Paraffin are emollients with occlusive properties for topical application.

5.2 Pharmacokinetic properties

There is no significant systemic absorption of the active ingredients. Following topical application, not all the product remains on the skin surface and there is substantial penetration into the stratum corneum.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product of Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Not applicable.

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life
24 months.

6.4 Special precautions for storage
Do not store above 25°C. Store in the original container. Stir well if separation occurs.

6.5 Nature and contents of container
Polypropylene jar with unlined polyethylene cap
Pack size: 500g.

6.6 Instructions for use/handling
No special requirements.

7 MARKETING AUTHORISATION HOLDER

The Boots Company
1 Thane Road
Nottingham
NG2 3AA

8 MARKETING AUTHORISATION NUMBER

PL 00014/0622

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF (PARTIAL) REVISION OF THE TEXT

July 2000