Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Quinoderm Lotio-Gel 5%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzoyl Peroxide B.P.	5.00 %
Potassium Hydroxyquinoline Sulphate B.P.	0.50 %

3 PHARMACEUTICAL FORM

Gel.
Gel formulated to give the colour and consistency of a creamy white lotion.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Acne.

4.2 Posology and method of administration

Route of administration
For topical use only.

Adults, Children and the Elderly.

Initial use should be preceded by a patch test with the product left on the skin behind the ear for 12 hours. If no undue reaction occurs application should be once to thrice daily to the affected areas.

The Lotio-Gel should be applied sparingly by gentle massage over all the affected area. A single course of treatment should not extend beyond three months unless there is clear evidence of response.

4.3 Contraindications

Acne Rosacea. Patients with known sensitivity to either of the active ingredients should not use Quinoderm Lotio-Gel 5%

4.4 Special warnings and precautions for use

Contact with mouth and eyes should be avoided. Care should be taken to avoid contact with dyed fabrics as this product may adversely affect dye fastness.

In a few isolated cases, overreaction to Quinoderm Lotio-Gel 5% may occur. To minimise this possibility, select a small area of skin behind the ear, apply the Lotio-Gel and leave for twelve hours. If severe irritation or pronounced redness occurs, do not proceed with treatment.

The product should only be used with caution in areas of thin or sensitive skin. Fair skinned individuals are likely to be particularly sensitive to irritation.

Benzoyl Peroxide should not be used in patients with fair or sensitive skin if there is extensive exposure to sunlight or ultraviolet light.

4.5 Interaction with other medicinal products and other forms of interaction

Benzoyl Peroxide is an oxidising agent. Hence, Quinoderm Lotio-Gel 5% should not be used at the same time as other topical agents which would react with an oxidising agent.

4.6 Pregnancy and lactation

Quinoderm Lotio-Gel 5% is not contra-indicated in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

If symptoms persist or if the condition worsens or if irritation, itch or rash occurs, treatment should be discontinued and the Physician or the Pharmacist consulted for advise.

4.9 Overdose

If accidentally ingested symptomatic and supportive management is advised.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The main pharmacological action of benzoyl peroxide is considered to be keratolytic and comedolytic. Potassium hydroxyquinoline sulphate has broad spectrum antibacterial activity. This combination is formulated in a specifically researched and developed base and is designed to aid the resolution of the polymorphic lesions of acne.

The base has been developed with the objective of providing a stable pharmaceutical form which maximises the advantages of a gel and lotion in a system which does not employ organic solvents and therefore has a correspondingly lower irritancy, toxicity and abuse potential.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light liquid paraffin
Edetic acid
Sodium acid phosphate
Maize starch

Lactic Acid
Ceto macrogol 1000
Cetyl stearyl alcohol
Sodium cetyl stearyl sulphate
P.E.G. 40 castor oil
Purified water

6.2 Incompatibilities

Any topical agent that would react with an oxidising agent.

6.3 Shelf Life

Two years.

6.4 Special precautions for storage

Quinoderm Lotio-Gel 5 % should be stored in a cool, dry place at room temperature (below 25ºC).

6.5 Nature and contents of container

Quinoderm Lotio-Gel 5 % is available in polyethylene bottles with a flip-top cap containing 30 ml of product. Each bottle is cartoned and contains a patient information leaflet.

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 instructions.

7 MARKETING AUTHORISATION HOLDER

Ferndale Pharmaceuticals Ltd.
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8 MARKETING AUTHORISATION NUMBER

PA 1155/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 May 1986

Date of last renewal: 19 May 2001