Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benzoyl Peroxide Cream 5 %

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzoyl Peroxide 5 % w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cream
Creamy, white thixotropic cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Acne Vulgaris.

4.2 Posology and method of administration

For topical use only.

Adults, children and the elderly:
By gentle massage over all the affected area two or three times daily.

4.3 Contraindications

Acne Rosacea. Patients with known sensitivity to Benzoyl Peroxide.

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.

Individuals may notice dry skin.

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

4.5 Interaction with other medicinal products and other forms of interaction

Benzoyl Peroxide is an oxidising agent. Hence, Benzoyl Peroxide Cream 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

Benzoyl Peroxide Cream 5% is not contra-indicated in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None known.

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 pharmacist consulted for advice.

4.9 Overdose

If accidentally ingested symptomatic and supportive management is advised.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Benzoyl Peroxide is a mild keratolytic agent and also has antiseptic properties. It has a local effect only and is not absorbed by the skin.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin
Emulgade F (consisting of: Cetostearyl alcohol, Sodium cetostearyl sulphate and PEG – 40 Castor oil)
Edetic acid
Sodium dihydrogen phosphate dihydrate
Lactic acid
Maize starch
Purified water

6.2 Incompatibilities

Any topical agent that would react with an oxidising agent.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the container tightly closed.

6.5 Nature and contents of container

Heat-sealed, low-density polyethylene tubes with a flush-fitting polypropylene cap containing 50g of product. Each tube is cartoned and contains a package insert.

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

Gently massage over all the affected area two or three times daily.

7 MARKETING AUTHORISATION HOLDER

Ferndale Pharmaceuticals Ltd
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8 MARKETING AUTHORISATION NUMBER

PA 1155/7/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6 November 1987

Date of last renewal: 6 November 2002

10 DATE OF REVISION OF THE TEXT

June 2005