Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Brasivol No. 1 Fine

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Aluminium oxide 38.0% w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Paste
A light beige finely gritty cutaneous paste with a slight perfume.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Brasivol is indicated in the treatment of acne vulgaris. Brasivol No. 1 Fine effectively cleanses and removes debris from blocked pores and removes excess sebum from the skin, thus maintaining patency of the pore duct openings.

4.2 Posology and method of administration

Two grades of Brasivol are available: Brasivol No. 1 Fine and Brasivol No. 2 Medium.

Treatment should normally commence with Brasivol No. 1 Fine. The abrasive cleansing paste should be applied to wetted skin and rubbed gently but firmly over the affected area with a circular motion for 15-20 seconds, then rinsed off thoroughly with water. This routine may be repeated two or three times daily, replacing ordinary soap and water.

In more severe conditions, after the use of Brasivol No. 1 Fine for several weeks, the skin may require the slightly more abrasive action of Brasivol No. 2 Medium.

4.3 Contraindications

Brasivol No. 1 Fine is contra-indicated in the presence of superficial venules and telangiectasia (actinic sequelae).

4.4 Special warnings and precautions for use

Care should be taken to avoid using Brasivol No.1 Fine close to the eyes or mouth.
Male patients using an electric razor should shave before applying Brasivol No.1 Fine.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

There are no restrictions on the use of Brasivol No.1 Fine in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

A degree of dryness and redness will be seen during the first few days of treatment.
Over-enthusiastic use, however, can cause irritation and, if this occurs, treatment should be interrupted for a day or two and then resumed.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Brasivol No. 1 Fine aids in the treatment of acne by exerting a debrading effect on the skin surface, unblocking the follicle, thus allowing the removal of retained sebum and permitting the sebaceous glands to return to normal size and activity. Various degrees of abrasion are made possible by the provision of two grades of Brasivol.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Macrogol
Stearic acid
Lauric acid
Myristic acid
1-(3-chloroallyl)-3, 5, 7 triaza 1-azoniadamantane chloride (Dowicil 200)
Bentonite
Sodium hydroxide
Sodium laurilsulphate solution (30%)
Perfume BV-2
Iron oxide yellow (E172)
Purified water

6.2 Incompatibilities

None.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

The product is packaged in white opaque low density polyethylene tubes of 75g.

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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8 MARKETING AUTHORISATION NUMBER

PA 144/25/1

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Date of last renewal: 01 October 2004

10 DATE OF REVISION OF THE TEXT

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