Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Acetoxyl 5 Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrous Benzoyl Peroxide equivalent to Benzoyl peroxide 5%w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Gel
A white gel, free from gritty particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Acetoxyl 5 Gel is indicated for the treatment of mild to moderate acne vulgaris.

4.2 Posology and method of adminstration

Adults
Apply to the whole of the affected area once or twice daily. Wash with soap and water prior to application.

Paediatric use
The safety and efficacy of Acetoxyl 5 Gel has not been established in children since acne vulgaris rarely presents in this age group.

Elderly patients
There are no specific recommendations. Acne vulgaris does not present in the elderly.

4.3 Contraindications

Patients with known hypersensitivity to any of the ingredients should not use the product.

4.4 Special warnings and precautions for use

Avoid contact with the eyes, mouth and other mucous membranes. Care should be taken when applying the product to the neck and other sensitive areas.

The product may bleach coloured or dyed fabrics.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

The safety of benzoyl peroxide in human pregnancy is established. There are no restrictions on the use of Acetoxyl 5 Gel during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

In normal use, a mild burning sensation will probably be felt on first application and a moderate reddening and peeling of the skin will occur within a few days. During the first few weeks of treatment, a sudden increase in peeling will occur in most patients, this is not harmful and will normally subside in a day or two if treatment is temporarily discontinued.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Benzoyl peroxide has antibacterial activity against *Propionibacterium acnes,* the organism implicated in acne vulgaris. It has keratolytic activity and is sebostatic, counteracting the hyperkeratinisation and excessive sebum production associated with acne.

5.2 Pharmacokinetic properties

After topical application, benzoyl peroxide is absorbed in varying quantities through the skin of man and animals.

Radio-labelled studies have shown that the absorption of benzoyl peroxide through the skin can only occur following its conversion to benzoic acid. Benzoic acid is mostly conjugated to form hippuric acid which is excreted via the kidneys.

5.3 Preclinical safety data

Animal toxicity studies of benzoyl peroxide have shown that the compound is non-toxic when applied topically.

Benzoic acid, to which benzoyl peroxide is converted prior to absorption, has a wide margin of safety. Benzoic acid is an approved food additive.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trolamine
Propylene glycol (E1520)
Carbomer 940
Sodium laurilsulfate solution
Acetone
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Lacquered aluminium tubes with white polypropylene screw caps containing 40g.

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 144/10/2

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