

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Benzoyl Peroxide 5% Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzoyl Peroxide 5%.

3 PHARMACEUTICAL FORM

Gel

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

All stages of acne vulgaris.

4.2 Posology and method of administration

Adults

Treatment should be initiated with Benzoyl Peroxide 5% Gel once daily. The affected areas should be washed with soap and water and then dried before Benzoyl Peroxide 5% Gel is applied. For stubborn cases treatment may be continued with Benzoyl Peroxide 10% Gel provided that Benzoyl Peroxide 5% Gel has been well tolerated. For particularly sensitive skin, Benzoyl Peroxide 5% Gel should be applied on alternate days.

Children

Not applicable.

The Elderly

Not applicable.

4.3 Contraindications

Known hypersensitivity to benzoyl peroxide.

4.4 Special warnings and precautions for use

Avoid contact with eyes and mucosae. If the skin is exposed to strong or prolonged sunlight, this medicine should be applied at longer intervals and a highly protective sun-screening agent should be used. This medicine should only be applied to dry skin to avoid unnecessary irritation.

For external use only. Care should be taken to avoid contact with dyed fabrics as this product may adversely affect dye fastness.

4.5 Interaction with other medicinal products and other forms of interaction

This is an oxidising agent, therefore it should not be used at the same time as other topical agents, which would react with an oxidising agent.

4.6 Fertility, Pregnancy and lactation

The normal use of this medicine is not contraindicated during pregnancy.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

As with all keratolytic substances itching reddening burning and a feeling of skin tension may occur. This may be relieved by the use of a moisturising cream

or by temporary interruption of the use.

In rare cases a contact dermatitis occur in which event treatment should be stopped immediately.

Face Oedema.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Benzoyl peroxide has a strong antibacterial action against propioni-bacterium acnes. It is has keratolytic and sebostatic, which cause some dryness and desquamation.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer 980, Polyoxyethylene 23 Lauryl Ether, Propylene Glycol, Sodium Hydroxide and Purified water

6.2 Incompatibilities

This is an oxydising agent, therefore it should not be used at the same time as other topical agents, which would react with an oxidising agent.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

Low density polyethylene tubes 30g

Low density polyethylene tubes 40g

6.6 Special precautions for disposal

No Data Held

7 MARKETING AUTHORISATION HOLDER

Diomed Developments Limited (trading as Dermal Laboratories)

Tatmore Place, Gosmore

Hitchin, Herts

SG4 7QR

8 MARKETING AUTHORISATION NUMBER(S)

PL 00173/0411

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

27/08/2022