

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benzamycin 3% / 5% w/w Gel.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of reconstituted gel contains 75 mg benzoyl peroxide, hydrous equivalent to 5% w/w benzoyl peroxide, anhydrous and 30 mg erythromycin equivalent to 3% w/w erythromycin.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

The product is a three component system:

- White, viscous gel.
- White to off-white erythromycin powder.
- Clear, colourless diluent.

After reconstitution, the final product is a white, viscous gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of acne vulgaris.

4.2 Posology and method of administration

Benzamycin Gel should be applied twice daily, morning and evening, to areas usually affected by acne or as directed by the physician. These areas should first be gently washed, rinsed with lukewarm water, and gently patted dry. Benzamycin should be applied in a thin layer with the fingertips until dry and the hands washed after application.

It is not recommended for children under 12 years of age.

4.3 Contraindications

Benzamycin is contraindicated in persons who have shown hypersensitivity to benzoyl peroxide hydrous, erythromycin or any of the other ingredients.

4.4 Special warnings and precautions for use

For external use only. Keep away from the eyes, nose, mouth and other mucous membranes.

Very fair skinned individuals should begin with a single application at bedtime allowing overnight medication.

May bleach hair or dyed fabrics.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant topical acne therapy should be used with caution to avoid a possible cumulative irritancy effect. Antagonism has been demonstrated between clindamycin and erythromycin.

4.6 Pregnancy and lactation

The safe use of Benzamycin Gel during pregnancy or lactation has not been established and should only be used if considered essential by the physician.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Reported adverse reactions have been dryness of the skin, urticaria and face oedema.

4.9 Overdose

Due to the topical administration of this product overdose is unlikely to occur.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Benzamycin Gel provides an anti-microbial agent with mild keratolytic properties plus antibiotic effects.

Erythromycin inhibits lipase production whilst benzoyl peroxide, hydrous reduces the comedone count and has anti-bacterial action.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no pre-clinical safety data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Sodium hydroxide
Ethanol
Lemon fragrance oil
Methyl salicylate
Docusate sodium 75% solution
Purified water
Ethanol 70%*

*Added by the pharmacist during reconstitution.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unreconstituted: 2 years.

Reconstituted: 3 months.

6.4 Special precautions for storage

Unreconstituted: Do not store above 25°C.

Reconstituted: Store in a refrigerator (2°C to 8°C). Do not freeze.

6.5 Nature and contents of container

Benzamycin Gel Base: 40 g in a white polypropylene jar.

Erythro-pak: 1.6 g in a white polypropylene vial.

Ethanol 70%: 6 ml in a glass, plastic-capped bottle.

Benzamycin Gel is dispensed in a plastic jar containing 46.6 g of gel.

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

Instructions for the Pharmacist:

Prior to dispensing, tap the erythromycin vial to loosen the powder. Add 6ml of the ethanol 70% provided to the powder. Shake to fully dissolve the erythromycin. Disperse the solution into the benzoyl peroxide gel by stirring for 60 to 90 seconds. Cold storage of the gel prior to reconstitution may cause the gel to thicken and hinder mixing.

Place a 3 month expiry date on the jar.

7 MARKETING AUTHORISATION HOLDER

SCHWARZ PHARMA Limited
5 Hercules Way
Leavesden Park
Watford
WD25 7GS
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8 MARKETING AUTHORISATION NUMBER

PA 0271/012/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 23rd September 2006

10 DATE OF REVISION OF THE TEXT

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