1. DOSAGE AND ADMINISTRATION

Clindamycin phosphate and benzoyl peroxide gel is indicated for the topical treatment of acne vulgaris in patients 12 years or older.

Patients should apply gel to the face (including scalp), avoid exposure to the sun and use sunscreen with SPF 15 or higher.

2. DOSAGE FORMS AND STRENGTHS

Clindamycin phosphate and benzoyl peroxide gel comes in a 3% gel formulation.

3.75"

4.1 Hypersensitivity

Clindamycin phosphate and benzoyl peroxide gel should not be used in patients with a history of hypersensitivity to clindamycin, benzoyl peroxide, or any component of the formulation.

4.2 Cutaneous Reactions

Patients should be instructed to discontinue the use of clindamycin phosphate and benzoyl peroxide gel if rash or any other skin reaction develops and to notify their healthcare provider.

5.1 Colitis

Clindamycin phosphate and benzoyl peroxide gel should be discontinued if colitis develops during therapy.

5.2 Systemic Absorption

Systemic absorption of clindamycin phosphate and benzoyl peroxide gel is low; however, patients should still be monitored for signs of colitis.

6.2 Postmarketing Experience

Clindamycin phosphate and benzoyl peroxide gel may cause an increase in the number of patients reporting symptoms of colitis.

7.1 Erythromycin

Erythromycin and clindamycin are both macrolide antibiotics; however, the clinical significance of this interaction is not known.

7.2 Metabolism

Clindamycin is metabolized by the cytochrome P450 3A4 isoenzyme system.

8.3 Nursing Mothers

Clindamycin phosphate and benzoyl peroxide gel should be used with caution in breastfeeding mothers.

9.3 Pregnancy

Clindamycin phosphate and benzoyl peroxide gel has been shown to be safe and effective in pregnant women.

10.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Clindamycin phosphate and benzoyl peroxide gel has been shown to be safe and effective in pregnant women.

11.4 Preclinical Development

One study in mice showed that topical administration of clindamycin phosphate and benzoyl peroxide gel resulted in no adverse effects on fertility or development of the offspring.

11.5 Reproduction

No adverse effects on fertility or development were observed in the offspring of rats treated with clindamycin phosphate and benzoyl peroxide gel.

13.2 Long-term administrations of clindamycin phosphate and benzoyl peroxide gel in the rat did not result in any adverse effects on fertility or development of the offspring.

13.4 Carcinogenesis, Mutagenesis, Impairment of Fertility

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13.5 Reproduction

No adverse effects on fertility or development were observed in the offspring of rats treated with clindamycin phosphate and benzoyl peroxide gel.

13.6 Carcinogenesis, Mutagenesis, Impairment of Fertility

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14.1 Pharmacokinetics

Clindamycin phosphate and benzoyl peroxide gel has been shown to be safe and effective in pregnant women.

14.4 Carcinogenesis, Mutagenesis, Impairment of Fertility

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14.5 Reproduction

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16.3 Carcinogenesis, Mutagenesis, Impairment of Fertility

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16.5 Carcinogenesis, Mutagenesis, Impairment of Fertility

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16.6 Reproduction

No adverse effects on fertility or development were observed in the offspring of rats treated with clindamycin phosphate and benzoyl peroxide gel.

18.1 Human Experience

Clindamycin phosphate and benzoyl peroxide gel has been shown to be safe and effective in pregnant women.

18.2 Animal Experience

No adverse effects on fertility or development were observed in the offspring of rats treated with clindamycin phosphate and benzoyl peroxide gel.

18.3 Carcinogenesis, Mutagenesis, Impairment of Fertility

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18.10 Reproduction

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18.12 Reproduction

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18.13 Carcinogenesis, Mutagenesis, Impairment of Fertility

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18.14 Reproduction

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18.15 Carcinogenesis, Mutagenesis, Impairment of Fertility

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18.16 Reproduction

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18.17 Carcinogenesis, Mutagenesis, Impairment of Fertility

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18.18 Reproduction

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18.19 Carcinogenesis, Mutagenesis, Impairment of Fertility

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18.20 Reproduction

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18.21 Carcinogenesis, Mutagenesis, Impairment of Fertility

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18.22 Reproduction

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18.23 Carcinogenesis, Mutagenesis, Impairment of Fertility

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18.24 Reproduction

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18.25 Carcinogenesis, Mutagenesis, Impairment of Fertility

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18.27 Carcinogenesis, Mutagenesis, Impairment of Fertility

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18.31 Carcinogenesis, Mutagenesis, Impairment of Fertility

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18.32 Reproduction

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This Patient Information has been approved by the U.S. Food and Drug Administration.

potassium hydroxide.

purified water, carbomer 980, propylene glycol, and clindamycin phosphate 1.2% and benzoyl peroxide 2.5%

Active Ingredients:

healthcare professionals.

about clindamycin phosphate and benzoyl peroxide gel that is written for healthcare professionals. If you would like more information, talk to your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-888-838-2872.

You may also report side effects to Teva Pharmaceuticals USA, Inc. at 1-888-838-2872.

Keep clindamycin phosphate and benzoyl peroxide gel and all medicines out of the reach of children.

• Keep the container tightly closed.

Keep clindamycin phosphate and benzoyl peroxide gel and all medicines out of the reach of children.

Common side effects with clindamycin phosphate and benzoyl peroxide gel include:

• Skin irritation. Stop using clindamycin phosphate and benzoyl peroxide gel and call your doctor if you have a skin rash or your skin becomes red, itchy or swollen.

Talk to your doctor about any side effect that bothers you or that does not go away.

These are not all the possible side effects with clindamycin phosphate and benzoyl peroxide gel. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-888-838-2872.

You may also report side effects to Teva Pharmaceuticals USA, Inc. at 1-888-838-2872.

How should I store clindamycin phosphate and benzoyl peroxide gel?

• Keep clindamycin phosphate and benzoyl peroxide gel out of sunlight and contact with moisture and call your doctor if you have severe watery diarrhea, or bloody diarrhea.

Allergic reactions. Stop using clindamycin phosphate and benzoyl peroxide gel if you have any of the following symptoms:

• severe itching

• swelling of your face, eyes, lips, tongue or throat

• trouble breathing

Common side effects with clindamycin phosphate and benzoyl peroxide gel include:

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