

Gel10/50 Clindasol (Clindamycin + Benzoyl peroxide)

COMPOSITION

Each gram contains:
Clindamycin (as phosphate) 10mg
Anhydrous benzoyl peroxide (as hydrous benzoyl peroxide) 50mg
(Innovator's specifications)

DESCRIPTION

Clindasol Gel 10/50 contains clindamycin phosphate and benzoyl peroxide. This fixed dose combination is used for the treatment of mild to moderate acne. Clindamycin is a semi-synthetic lincosamide antibiotic used in the treatment of a variety of serious infections due to susceptible microorganisms as well as topically for acne vulgaris.

MECHANISM OF ACTION

Clindamycin is a lincosamide antibiotic with bacteriostatic action against Gram-positive aerobes and a wide range of anaerobic bacteria. Lincosamides such as clindamycin bind to the 23S subunit of the bacterial ribosome and inhibit the early stages of protein synthesis. The action of clindamycin is predominantly bacteriostatic although high concentrations may be slowly bactericidal against sensitive strains. Benzoyl peroxide is mildly keratolytic acting against comedones at all stages of their development. It is an oxidising agent with bactericidal activity against Propionibacterium acnes, the organism implicated in acne vulgaris. Furthermore it is sebostatic, counteracting the excessive sebum production associated with acne. Clindamycin + Benzoyl Peroxide Gel has a combination of mild keratolytic and antibacterial properties providing activity particularly against inflamed lesions of mild to moderate acne vulgaris.

INDICATIONS

Clindamycin + Benzoyl Peroxide Gel is indicated for the topical treatment of mild to moderate acne vulgaris, particularly inflammatory lesions, in adults and adolescents aged 12 years and above.

DOSAGE & ADMINISTRATION

Adults and Adolescents (aged 12 years and above)

Clindamycin + Benzoyl Peroxide Gel should be applied once daily in the evening, to the entire affected area. Patients should be advised that excessive application will not improve efficacy, but may increase the risk of skin irritation. If excessive dryness or peeling occurs, frequency of application should be reduced or application temporarily interrupted. An effect on inflammatory and non-inflammatory lesions may be

seen as early as week 2-5 of treatment. The safety and efficacy of Clindamycin + Benzoyl Peroxide Gel has not been studied beyond 12 weeks in acne vulgaris clinical trials. Treatment with this medicine should not exceed more than 12 weeks of continuous use.

Paediatric population

The safety and efficacy of Clindamycin + Benzoyl Peroxide Gel has not been established in children under 12 years of age, therefore this medicine is not recommended for use in this population.

Elderly patients

No specific recommendations.

Method of administration

Clindamycin + Benzoyl Peroxide Gel should be applied in a thin film after washing gently with a mild cleanser and fully drying. If the gel does not rub into the skin easily, too much is being applied. Hands should be washed after application.

Information for Patients

Patients using Clindamycin + Benzoyl Peroxide Gel should receive the following information and instructions:

1. It is to be used as directed by the physician. It is for external use only. Avoid contact with eyes, and inside the nose, mouth, and all mucous membranes, as this product may be irritating.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. Patients should not use any other topical acne preparation unless otherwise directed by their physician.
4. Patients should report any signs of local adverse reactions to their physician. Patients who develop allergic symptoms such as severe swelling or shortness of breath should discontinue use and contact their physician immediately.
5. This medication may bleach hair or colored fabric.
6. Store the gel between 2-8°C in a refrigerator. Do not freeze. Keep tube tightly closed. Keep out of the reach of small children. Discard any unused product after 2 months.
7. Before applying gel to affected areas, wash the skin gently, rinse with warm water, and pat dry.
8. Excessive or prolonged exposure to sunlight should be limited.
9. To minimize exposure to sunlight, a hat or other clothing should be worn.

کلنڈاسول جیل ۱۰/۵۰

(کلینڈامائسین + بیٹیزول پراوکسائیڈ)

In a maximised percutaneous absorption study the mean plasma clindamycin levels during a four-week dosing period for Clindamycin + Benzoyl Peroxide Gel were negligible (0.043% of applied dose). The presence of benzoyl peroxide in the formulation did not have an effect on the percutaneous absorption of clindamycin. Radio-label studies have shown that 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.

PRECAUTIONS

Contact with the mouth, eyes, lips, other mucous membranes or areas of irritated or broken skin should be avoided. Application to sensitive areas of skin should be made with caution. In case of accidental contact, rinse well with water.

Clindamycin + Benzoyl Peroxide Gel should be used with caution in patients with a history of regional enteritis or ulcerative colitis, or a history of antibiotic-associated colitis.

This medicine should be used with caution in atopic patients, in whom further skin drying may occur.

During the first weeks of treatment, an increase in peeling and reddening will occur in most patients. Depending upon the severity of these side effects, patients can use a non-comedogenic moisturiser, temporarily reduce the frequency of application of Clindamycin + Benzoyl Peroxide Gel or temporarily discontinue use; however, efficacy has not been established for less than once daily dosing frequencies.

Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy may occur, which sometimes may be severe, especially with the use of peeling, desquamating, or abrasive agents.

If severe local irritancy (e.g. severe erythema, severe dryness and itching, severe stinging/burning) occurs, Clindamycin + Benzoyl Peroxide Gel should be discontinued.

As benzoyl peroxide may cause increased sensitivity to sunlight, sunlamps should not be used and deliberate or prolonged exposure to sun should be avoided or minimized. When exposure to strong sunlight cannot be avoided, patients should be advised to use a sunscreen product and wear protective clothing.

If a patient has sunburn, this should be resolved before using this medicine.

If prolonged or significant diarrhoea occurs or the patient suffers from abdominal cramps, treatment with Clindamycin + Benzoyl Peroxide Gel should be discontinued immediately, as the symptoms may indicate antibiotic-associated colitis. Suitable diagnostic methods, such as the determination of Clostridium difficile and toxin and, if necessary, colonoscopy should be employed and treatment options for colitis considered.

The product may bleach hair or colored fabrics. Avoid contact with hair, fabrics, furniture or carpeting.

Pregnancy

There are no adequate data from the use of this medicine in pregnant women. The safety of Clindamycin + Benzoyl Peroxide Gel in human pregnancy is not established. Therefore, this medicine should only be prescribed to pregnant women after careful risk/benefit assessment by the physician in charge.

Breastfeeding

Use of Clindamycin + Benzoyl Peroxide Gel has not been studied during breastfeeding. Percutaneous absorption of clindamycin and benzoyl peroxide is low however; it is not known whether clindamycin or benzoyl peroxide is excreted in human milk following the use of this medicine. Oral and parenteral administration of clindamycin has been reported to result in the appearance of clindamycin in breast milk. For this reason, Clindamycin + Benzoyl Peroxide Gel should be used during lactation only if the expected benefit justifies the potential risk to the infant.

SIDE EFFECTS

Allergic reactions including hypersensitivity and anaphylaxis, colitis (including pseudomembranous colitis), hemorrhagic diarrhoea, diarrhoea, abdominal pain, erythema, peeling, dryness (generally reported as 'mild' in severity), burning sensation, dermatitis, pruritus, erythematous rash, worsening of acne, urticaria, application site reactions including skin discoloration.

CONTRAINDICATIONS

Clindamycin + Benzoyl Peroxide Gel is contraindicated in those individuals who have shown hypersensitivity to any of its components or to lincosamides. It is also contraindicated in those having a history of regional enteritis, ulcerative colitis, pseudomembranous colitis, or antibiotic-associated colitis.

STORAGE & INSTRUCTIONS

Store between 2-8°C in a refrigerator. Do not freeze.

Protect from heat, sunlight and moisture.

Keep away from the reach of the children.

To be sold on the prescription of a registered medical practitioner only.

FOR EXTERNAL USE ONLY.

HOW SUPPLIED

10g tube.

خوراک و طریقہ استعمال:

دن میں ایک دفعہ شام کے وقت متاثرہ حصے پر پینل لگائیں یا ڈاکٹرن کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۲-۸ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان ریفریجریٹر میں رکھیں۔ دھوپ، گرمی، نمی اور نمندہو سنے سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔ صرف مستعمل ڈاکٹرن کے نسخے پر فروخت کریں۔ صرف بیرونی استعمال کے لئے ہے۔

Manufactured by:

PHARMASOL

PRIVATE LIMITED

Plot # 549, Sundar Industrial Estate,
Lahore, Pakistan.