BENCIN GEL

(Clindamycin 10 mg/g + Benzoyl Peroxide 50 mg/g)
TOPICAL ANTI-ACNE PREPARATION

COMPOSITION

Each gram of gel contains **clindamycin 10 mg (1%)**, as clindamycin phosphate, and **benzoyl peroxide 50 mg (5%)**. Excipients: according to approved product formula. For external use only.

DESCRIPTION AND PHARMACOLOGY

Bencin Gel combines a lincosamide antibacterial (clindamycin) with an oxidizing antimicrobial and keratolytic agent (benzoyl peroxide) for topical treatment of acne vulgaris.

Clindamycin suppresses protein synthesis in susceptible bacteria by binding to the 50S ribosomal subunit and reduces acne-associated inflammatory lesions. Benzoyl peroxide releases free radicals with bactericidal action against Cutibacterium acnes and helps reduce comedones. Combined treatment reduces acne-associated bacteria, including the likelihood of developing clindamycin resistance compared with topical antibiotic alone.

Following topical application, systemic clindamycin exposure is generally low but absorption can occur. Benzoyl peroxide is converted in the skin to benzoic acid, which is eliminated mainly in urine.

INDICATIONS

Topical treatment of **mild to moderate acne vulgaris**, particularly inflammatory papules and pustules, in adults and adolescents aged **12 years and above**. Use according to the locally approved indication.

DOSAGE AND ADMINISTRATION

Adults and adolescents 12 years and older: Apply a thin layer to the entire affected area **once daily, preferably in the evening**, or as directed by the physician. Clean the skin gently, rinse and dry before application. Wash hands after use.

Use only enough gel to lightly cover affected skin. Avoid eyes, eyelids, mouth, lips, inside the nose, mucous membranes, cuts, eczema and sunburned skin. If accidental contact occurs, rinse thoroughly with water.

Clinical improvement may take several weeks. Review response regularly; use beyond **12 weeks** should be reassessed by the prescriber. Applying more frequently or in larger amounts will not improve results and may increase irritation.

Children younger than 12 years: Safety and efficacy are not established. Do not use unless specifically instructed by a doctor.

CONTRAINDICATIONS

Hypersensitivity to clindamycin, lincomycin, benzoyl peroxide or any component of the gel. Contraindicated in patients with a history of **regional enteritis (Crohn's disease), ulcerative colitis or antibiotic-associated colitis**, including pseudomembranous colitis.

WARNINGS AND PRECAUTIONS

Antibiotic-associated colitis: Clindamycin absorbed through the skin can rarely cause severe diarrhea or colitis. Stop use and seek medical attention if persistent, severe or bloody diarrhea, abdominal cramps or colitis develops. Symptoms may occur during or after treatment. Do not self-treat such diarrhea with medicines that slow intestinal motility.

Skin irritation: Dryness, peeling, redness, stinging and burning can occur, especially in early treatment. If irritation is severe, discontinue and seek medical advice. Consider non-comedogenic moisturizer, gentle cleanser and reducing other irritating topical products.

Sun exposure: Minimize exposure to sunlight, sunlamps and tanning beds. Use suitable sun protection. Avoid application to sunburned skin until healed.

Bleaching: Benzoyl peroxide may bleach hair, fabrics, towels, clothes or bedding. Allow the gel to dry before contact.

Avoid abrasive cleansers, medicated soaps, alcohol-containing products, peeling agents or other topical acne medicines unless advised by the clinician. Use cautiously on sensitive areas, particularly neck and around eyes.

DRUG INTERACTIONS

Do not combine with topical or oral **erythromycin** unless directed, due to potential antagonism with clindamycin. Concurrent topical retinoids, salicylic acid, sulfur, resorcinol, alcohol-based products or abrasive preparations can increase irritation; the prescriber may separate administration times.

Clindamycin may enhance the action of neuromuscular blocking agents; inform the treating doctor if such medicines are being used. Concurrent topical sulfonamide products may cause temporary yellow-orange discoloration of the skin or facial hair.

PREGNANCY

Adequate controlled studies of this combination in pregnancy are lacking. Use during pregnancy only when the physician considers treatment necessary after evaluating potential benefits and risks.

LACTATION

It is not known whether topical use of this combination produces clinically relevant amounts in breast milk. Use only on medical advice. Do not apply to the breast or any area that could come into direct contact with the infant.

PEDIATRIC AND GERIATRIC USE

Safety and efficacy below 12 years are not established. Clinical data in older adults are limited; assess skin tolerance and concurrent medicines.

ADVERSE REACTIONS

Common local reactions: Dry skin, erythema, peeling, burning, stinging, pruritus and irritation at the application site. These usually occur early and may improve with continued appropriate use.

Less common: Contact dermatitis, worsening acne, photosensitivity, rash or local discomfort. Rare systemic adverse reactions may include diarrhea, abdominal pain and antibiotic-associated colitis.

Serious reactions: Hypersensitivity, facial swelling, severe dermatitis or persistent/bloody diarrhea require immediate discontinuation and medical assessment.

OVERDOSAGE

Excessive topical application can cause pronounced redness, dryness and peeling. Stop use and provide supportive skin care as advised. Accidental ingestion can cause gastrointestinal upset and may require urgent medical assessment. No specific antidote is known.

EFFECT ON DRIVING AND MACHINERY

The gel is not expected to affect the ability to drive or operate machinery.

STORAGE CONDITIONS

Storage requirements depend on the validated Bencin formulation and approved stability data. Some equivalent 1%/5% preparations require **refrigeration at 2-8°C before dispensing**, with storage **below 25°C after dispensing**; do not freeze. **Confirm Bencin-specific storage temperature and in-use shelf life before printing.** Keep out of reach of children.

PRESENTATION

Bencin Gel: 10 g tube for external use.

Manufactured by:

Vega Pharmaceuticals (Pvt.) Ltd.
30 Km, Multan Road, Lahore - Pakistan.

Prescription medicine. Draft for QA / regulatory approval before printing.