

Dapgel

Dapsone USP 7.5% w/w Gel

Composition

Each gram gel contains Dapsone USP 75 mg.

Pharmacology

Dapsone has both anti-inflammatory and antimicrobial properties. A combination of these activities may account for its efficacy in acne. Anti-inflammatory effects include inhibition of neutrophil myeloperoxidase and eosinophil peroxidase activity, suppression of hypochlorous acid production, scavenging of reactive oxygen species, suppression of neutrophil activity, and inhibition of chemoattractant-induced signal transduction. Antimicrobial activity, similar to that of sulfones and sulfonamides, is by inhibition of bacterial dihydropteroate synthase in the folic acid metabolic pathway. This mechanism is effective against microorganisms synthesizing their own folic acid. In vitro susceptibility testing has demonstrated some activity for Dapsone against *Propionibacterium* species, including *Propionibacterium acnes* (*P. acnes*).

Indication

Dapgel is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

Dosage & Administration

After the skin is gently washed and patted dry, apply approximately a pea-sized amount of **Dapgel** in a thin layer to the entire face once daily. In addition, a thin layer may be applied to other affected areas once daily. Rub in **Dapgel**, gently and completely. If there is no improvement after 12 weeks, treatment with **Dapgel** should be reassessed. Not for oral, ophthalmic or intravaginal use.

Contraindication

Those who are hypersensitive to Dapsone.

Side effects

Most common (incidence $\geq 0.9\%$) effects are application site dryness and pruritus.

Precaution & Warning

- Methemoglobinemia: Cases of methemoglobinemia have been reported. Discontinue Dapsone if signs of methemoglobinemia occur.
- Hemolysis: Some patients with Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency using topical Dapsone developed laboratory changes suggestive of hemolysis.

Drug Interactions

- Trimethoprim/ sulfamethoxazole (TMP/ SMX) increases the systemic level of Dapsone and its metabolites.
- Topical benzoyl peroxide used at the same time as Dapsone may result in temporary local yellow or orange skin discoloration.

Use in Special Population

Pregnancy

Pregnancy Category C. There are no adequate and well controlled studies in pregnant women. Dapsone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Although systemic absorption of Dapsone following topical application of Dapsone is minimal relative to oral Dapsone administration, it is known that Dapsone is excreted in human milk. Because of the potential for oral Dapsone to cause adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue Dapsone, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness of Dapsone have not been established in pediatric patients below the age of 12 years.

Geriatric Use

Clinical trials of Dapsone did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects.

Storage

Store in a cool & dry place. Keep out of reach of children. Do not freeze.

Packaging

Each carton contains a tube of 30 g gel, an insert and a usage guideline leaflet.

Manufactured by



Ziska Pharmaceuticals Ltd.

Kaliakoir, Gazipur, Bangladesh