Fona™ Plus

Adapalene and Benzoyl peroxide.

COMPOSITION
Each gram of Fona™ Plus Gel contains 1 mg adapalene BP and 25 mg benzoyl peroxide.

PHARMACOLOGY
Fona™ Plus Gel is a combination of adapalene, a retinoid, and benzoyl peroxide, and is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older. Adapalene binds to specific retinoic acid nuclear receptors but does not bind to cytosolic receptor protein. Biochemical and pharmacological profile studies have demonstrated that adapalene is a modulator of cellular differentiation, keratinization and inflammatory processes. Adapalene binds with specific retinoic acid nuclear receptors that normalize the differentiation of follicular epithelial cells resulting in decreased microcomedone formation. Benzoyl peroxide is an oxidizing agent with bacteriocidal and keratolytic effects.

INDICATION
Fona™ Plus Gel is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

DOSAGE AND ADMINISTRATION
Apply a thin film of FonaTM Plus Gel to affected areas of the face and/or trunk once daily after washing. Use a pea-sized amount for each area of the face (e.g., forehead, chin, each cheek). Avoid the eyes, lips and mucous membranes.
Fona™ Plus Gel is not for oral, ophthalmic, or intravaginal use.

CONTRAINDICATION
Should not be administered to individuals who are hypersensitive to any of its component.

PREACAUTION
Ultraviolet Light and Environmental Exposure. Avoid exposure to sunlight and sunlamps. Wear sunscreen when sun exposure cannot be avoided.

SIDE EFFECT
Erythema, scaling, dryness, and stinging/ burning may occur with use of Fona™ Plus Gel. Most commonly reported adverse events are dry skin, contact dermatitis, application site burning, application site irritation, and skin irritation.

DRUG INTERACTIONS
Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating, or abrasive agents.
No formal drug-drug interaction studies were conducted with Fona™ Plus Gel.

USE IN PREGNANCY AND LACTATION
There are no well-controlled trials in pregnant women treated with Fona™ Plus Gel. Animal reproduction studies have not been conducted with the combination gel or benzoyl peroxide. Furthermore, such studies are not always predictive of human response; therefore, Fona™ Plus Gel should be used during pregnancy only if the potential benefit justifies the risk to the fetus.
It is not known whether adapalene or benzoyl peroxide is excreted in human milk following use of Fona™ Plus Gel. Because many drugs are excreted in human milk, caution should be exercised when Fona™ Plus Gel is administered to a nursing woman.

PEDIATRIC USE
Safety and effectiveness of Fona™ Plus Gel in pediatric patients under the age of 12 years have not been established.

STORAGE
Store below 25° C. Protect from light and keep away from heat. Keep out of the reach of children.

HOW SUPPLIED
Fona™ Plus Gel: Each pack has a laminated tube containing 10 gm gel.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH