

# Adapalene INN

#### COMPOSITION

Fona ° 0.1% cream: Each gm cream contains Adapalene INN 1 mg. Fona ° 0.3% gel: Each gm gel contains Adapalene INN 3 mg.

#### **PHARMACOLOGY**

Adapalene acts on retinoid receptors that are commonly found in the skin of face, back and chest. Biochemical and pharmacological studies have demonstrated that Adapalene is a modulator of cellular differentiation, keratinization, and inflammatory processes, all of that represent important features in the pathology of acne vulgaris. Adapalene binds with specific retinoic acid nuclear receptors that normalize the differentiation of follicular epithelial cells resulting in decreased microcomedone formation. Absorption of Adapalene through human skin is low.

#### INDICATION

**Fona** 0.1% cream and 0.3% gel are indicated for topical treatment of acne vulgaris.

## DOSAGE AND ADMINISTRATION

- Fona® 0.1% cream: Fona® 0.1% cream should be applied to the affected areas of skin, once daily at night-time
- Fona® 0.3% gel: Fona® 0.3% gel should be applied to the entire face and any other affected areas of the skin, once daily in the evening
- A thin film of gel or cream should be applied to the skin areas where lesions present, using enough to cover the entire affected areas lightly
- For detail information, please see the enclosed leaflet

#### CONTRAINDICATION

Adapalene should not be administered to individuals who are hypersensitive to Adapalene or any of its components.

#### PRECAUTION

Adapalene should not be applied to cuts, abrasions, eczematous or sunburned skin.

#### SIDE EFFECT

Erythema, scaling, dryness, pruritus, burning sensation, skin irritation, stinging unburn, acne flares, etc. are commonly seen during the first month of therapy but usually lessen with continued use of the medication.

# DRUG INTERACTION

- Concomitant use of other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect, products with high concentrations of alcohol, astringents, spices or lime) should be approached with caution
- Exercise particular caution in using preparations containing sulfur, resorcinol or salicylic acid in combination with Adapalene
- If any of these preparations have been used, it is advisable not to start therapy with Adapalene until the effects of such preparations in skin have subsided. If combined use of both medications is important, it is better to use in two different times

# **USE IN PREGNANCY AND LACTATION**

Use Adapalene during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether this drug is excreted in breast milk. Exercise caution when administering Adapalene to a nursing mother.

#### **USE IN CHILDREN**

Safety and effectiveness in children below 12 years of age have not been established.

# STORAGE

Store in a cool and dry place (below 25°C). Do not freeze.

## **HOW SUPPLIED**

**Fona**  $^{\circ}$  0.1% cream: Each pack has a laminated tube containing 10 gm cream. **Fona**  $^{\circ}$  0.3% gel: Each pack has a laminated tube containing 10 gm gel.

Manufactured by :

