

melano™

Fluocinolone Acetonide USP 0.01%, Tretinoin
USP 0.05 % & Hydroquinone USP 4%

Composition: Each gram cream contains Fluocinolone Acetonide USP 0.1 mg, Tretinoin USP 0.5 mg and Hydroquinone USP 40 mg.

Pharmacology: Melano™ Cream contains three active ingredients - Fluocinolone Acetonide, Tretinoin and Hydroquinone. All of these are used to treat melasma. However, the mechanism of action of these active ingredients in the treatment of melasma is unknown. Fluocinolone Acetonide is a corticosteroid for topical dermatological use and is classified therapeutically as an anti-inflammatory agent. Hydroquinone is classified therapeutically as a depigmenting agent, which may interrupt one or more steps in the Tyrosine-Tyrosinase pathway of Melanin synthesis. Tretinoin is classified therapeutically as a keratolytic agent.

Indication: Melano™ Cream is indicated for the short-term treatment of moderate to severe melasma of the face (in the presence of measures for sun avoidance, including the use of sunscreens).

Dosage and Administration: Apply a thin film of Melano™ Cream to the affected area once daily, at least 30 minutes before bedtime. Gently wash the face and neck with a mild cleanser. Rinse and pat the skin dry.

Contraindication: This product is contraindicated in individuals with a history of hypersensitivity, allergy or intolerance to this product or any of its components.

Precaution: This product contains Hydroquinone and Tretinoin that may cause mild to moderate irritation. Local irritation, such as skin reddening, peeling, mild burning sensation, dryness and pruritus may be expected at the site of application. If a reaction suggests hypersensitivity or chemical irritation, the use of the medication

should be discontinued. It also contains the corticosteroid Fluocinolone Acetonide. Systemic absorption of topical corticosteroids can produce reversible Hypothalamic-Pituitary-Adrenal (HPA) axis suppression. If HPA axis suppression is noted, the use of this product should be discontinued.

Side Effect: A very few patients may get severe allergic reactions from this product. They may have trouble breathing or severe asthma attacks. While patients use this product, skin may develop mild to moderate redness, peeling, burning, dryness or itching.

Drug Interaction: Avoid use of medicated or abrasive soaps, cleansers, soaps, cosmetics with drying effects, products with high concentration of alcohol, astringent & other irritants or keratolytic drugs. Also avoid concomitant use of medications with photosensitizing effects.

Pregnancy and Lactation:

Pregnancy: Pregnancy Category C. Melano™ Cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Lactation:** Caution should be exercised when this product is administered to nursing women.

Pediatric Use: Safety and effectiveness of this Cream have not been established in pediatric patients.

Storage: Store below 25°C at a dry place, protected from light. Keep out of the reach of children.

How Supplied: Each pack has a laminated tube containing 30 gm Cream.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH