



Description

Melasin cream contains Flucinolone Acetonide USP, Hydroquinone USP and Tretinoin USP in a hydrophilic cream base for topical application. Flucinolone Acetonide is a synthetic fluorinated corticosteroid for topical dermatological use and is classified therapeutically as an anti-inflammatory agent. Hydroquinone is classified therapeutically as a depigmenting agent. Tretinoin is all-trans-retinoic acid formed from the oxidation of the aldehyde group of retinene to a carboxyl group.

Composition

Each gram cream contains Flucinolone Acetonide USP 0.1 mg (0.01%), Hydroquinone USP 40 mg (4%) and Tretinoin USP 0.5 mg (0.05%).

Indications

Melasin 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.

Dosages & Administration

Melasin cream should be applied once daily at night. It should be applied at least 30 minutes before bedtime.

Gently wash the face and neck with a mild cleanser. Rinse and pat the skin dry. Apply a thin film of the cream to the hyperpigmented areas of melasma including about 1/2 inch of normal appearing skin surrounding each lesion. Rub lightly and uniformly into the skin. Do not use occlusive dressings. During the day time, avoid sunlight exposure. Patients may use moisturizers and/or cosmetics during the day.

Drug Interactions

Patients should avoid medicated or abrasive soaps, cleansers and cosmetics with drying effects, products with high concentration of alcohol and astringent while on Melasin cream treatment. Patients are cautioned on concomitant use of medications that are known to be photosensitizing.

Side Effects

The most frequently reported adverse events that were observed from the controlled clinical trials and the long term safety were erythema, desquamation, and burning, at the site of application. The number and percentages of these events were markedly lower in the long-term study than in the controlled clinical studies. The great majority of these events were mild to moderate in severity.

Contraindications

Melasin cream is contraindicated in individuals with a history of hypersensitivity or intolerance to Melasin cream or any of its components.

Warnings

Melasin cream contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life threatening asthmatic episodes in susceptible people.

Melasin cream contains Hydroquinone, which may produce exogenous ochronosis, a gradual blue-black darkening of the skin, whose occurrence should prompt discontinuation of therapy.

Precautions

Melasin cream 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. Transient skin reddening or mild burning sensation does not preclude treatment. If a reaction suggests hypersensitivity or chemical irritation, the use of the medication should be discontinued.

Exposure to sunlight, sunlamp, or ultraviolet light should be avoided. Patients who are consistently exposed to sunlight or skin irritants either through their working environment or habits should exercise particular caution. Sunscreen use is an essential aspect of melasma therapy, as even minimal sunlight sustains melanocytic activity.

Use in Pregnancy

Teratogenic Effects: Pregnancy Category C.

There are no adequate and well-controlled studies in pregnant women. Melasin cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in Nursing Mothers

Corticosteroids, when systemically administered, appeared in human milk. It is not known whether topical application of Melasin cream could result in sufficient systemic absorption to produce detectable quantities of Flucinolone Acetonide, Hydroquinone or Tretinoin in human milk. Because many drugs are secreted in human milk, caution should be exercised when Melasin cream is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Melasin cream in pediatric patients have not been established.

Storage Condition

Keep tightly closed. Store in a cool and dry place, protected from light and moisture. Keep out of reach of children.

How Supplied

Melasin cream : Tube containing 15 or 30 gm cream



Manufactured by
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