



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

DESCRIPTION

Nospot[®] is a combined preparation of Fluocinolone Acetonide, Hydroquinone & Tretinoin. Fluocinolone Acetonide is a synthetic fluorinated corticosteroid for topical dermatological use and is classified therapeutically as an anti-inflammatory. Hydroquinone is classified therapeutically as a depigmenting agent. It is prepared from the reduction of p-benzoquinone with sodium bisulfate. Hydroquinone, is a depigmenting agent, and may interrupt one or more steps in the tyrosine-tyrosinase pathway of melanin synthesis. Tretinoin is all-trans-retinoic acid formed from the oxidation of the aldehyde group of retinene to a carboxyl group. Tretinoin is classified therapeutically as a keratolytic. However, the mechanism of action of the active ingredients in **Nospot**[®] cream is unknown.

INDICATIONS

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.

DOSEAGE AND ADMINISTRATION

- **Nospot**[®] 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 dressing.
- During the day, use a sunscreen of SPF 30, and wear protective clothing. Avoid sunlight exposure. Patients may use moisturizers and/or cosmetics during the day.

SIDE EFFECTS

- Erythema • Desquamation • Burning • Dryness • Pruritus

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. This combination cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether topical application of this combination cream could result in sufficient systemic absorption to produce detectable quantities of Fluocinolone Acetonide, Hydroquinone, or Tretinoin in human milk. Because many drugs are secreted in

human milk, caution should be exercised when this combination cream is administered to a nursing woman. Care should be taken to avoid contact between the infant being nursed.

CONTRAINDICATIONS

History of hypersensitivity, allergy, or intolerance to this product or any of its components.

PRECAUTIONS AND WARNINGS

Fluocinolone Acetonide, Hydroquinone & Tretinoin 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.

This cream contains Sodium Metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening asthmatic episodes in susceptible people. It contains Hydroquinone, which may produce exogenous ochronosis, a gradual blue-black darkening of the skin, whose occurrence should prompt discontinuation of therapy. The majority of patients developing this condition are Black, but it may also occur in Caucasians and Hispanics.

PHARMACEUTICAL PRECAUTIONS

Do not store above 25 °C. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Nospot[®] Cream:

Tube containing 30 gm cream. Each gram contains Fluocinolone Acetonide USP 0.1 mg, Hydroquinone USP 40 mg and Tretinoin BP 0.5 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

MIRPUR, DHAKA, BANGLADESH

© REGD. TRADEMARK

M/PM01065 V02