

# Spotclen® Cream

Hydroquinone 4%

## Presentation

Spotclen® Cream: Each gram cream contains Hydroquinone BP 40 mg.

## Description

Hydroquinone is a skin bleaching agent. Topical application of hydroquinone produces reversible depigmentation of skin by inhibition of the enzymatic oxidation of tyrosine to 3,4-dihydroxyphenylalanine (DOPA) and suppression of other melanocyte metabolic process.

## Indications and Uses

Hydroquinone is indicated -

- for the gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentiginos and other unwanted areas of melanin hyperpigmentation.
- to reduce hyperpigmentation caused by photosensitization associated with inflammation or with the use of certain cosmetics.

## Dosage and Administration

Hydroquinone should be applied to the affected area and rubbed in well twice daily or as directed by a physician. Most discolorations begin to lighten after 4 weeks of treatment but it may take longer. After desired bleaching, use only as needed to maintain results of treatment. Hydroquinone bleaching is faster, more dependable and easier if the treated area is protected from ultraviolet light. Therefore, exposure to sunlight should be minimized at the period of treatment. During day, an effective broad-spectrum sunscreen should be used, unnecessary solar exposure should be avoided and protective clothing should be used to prevent repigmentation of treated areas. After reduction of hyperpigmentation, use of sunscreen agents and/or protective clothing should continue.

## Side Effects

No systemic adverse reactions have been reported. Occasional hypersensitivity (localized contact dermatitis) may occur in which case the medication should be discontinued.

## Contraindications

Hydroquinone is contraindicated to patients with prior history of hypersensitivity or allergic reaction to hydroquinone or other ingredients in the preparation.

## Precautions

Hydroquinone is a skin bleaching agent which may produce unwanted cosmetic effects if not used as directed. The physician should be familiar with the contents of this insert before prescribing or dispensing this medication.

Test for skin sensitivity before using by applying a small amount to an unbroken patch of skin to check in 24 hours. Minor redness is not a contraindication, but where there is itching or vesicle formation or excessive inflammatory response, further treatment is not advised. If no bleaching or lightening effect is noted after 2 months of treatment, the medication should be discontinued.

Contact with the eyes and lips should be avoided. Hydroquinone should not be applied to cut or abraded skin.

## Use in pregnancy and lactation

*Pregnancy:* It is not known whether hydroquinone can cause fetal harm when used topically on a pregnant woman or affect reproductive capacity. It is not known to what degree, if any, topical hydroquinone is absorbed systemically. Topical hydroquinone should be used in pregnant woman only when clearly indicated.

*Lactation:* It is not known whether topical hydroquinone is absorbed or excreted in human milk. Caution is advised when topical hydroquinone is used by a nursing mother.

## Use in children

Safety and efficacy in paediatric patients below the age of 12 years have not been established.

## Drug interactions

*Peroxide:* Concurrent use of peroxide may result in transient dark staining of skin areas due to oxidation of hydroquinone.

## Overdosage

There have been no systemic reactions from the use of topical hydroquinone. Some patients may experience a transient reddening of skin and mild burning sensation which does not preclude treatment.

## Commercial Pack

Spotclen® Cream: Each tube contains 10 gm cream.

Manufactured by  
 **Incepta Pharmaceuticals Ltd**  
Dhamrai Unit, Dhaka, Bangladesh  
® Registered Trademark

V.N. 02

SPC