BRIGHTEN LIGHTENING- hydroquinone gel
CEN BEAUTY LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ACTIVE INGREDIENT

ZINC OXIDE 15%

OCTINOXATE 6%

PURPOSE

SUNSCREEN

USES

- Lightens discolored skin such as freckles, age and liver spots or pigment in the skin that may occur from pregnancy or from the use of oral contraceptives

WARNINGS

FOR EXTERNAL USE ONLY

DO NOT USE

- IF YOU HAVE VERY SENSITIVE SKIN

WHEN USING THIS PRODUCT

- Keep out of eyes. Rinse with water to remove.

STOP USE AND ASK A DOCTOR IF RASH OCCURS.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

ASK A DOCTOR BEFORE USE

- On children under 12 years of age
- If you are pregnant, breastfeeding or intend to become pregnant within 3 months of use.

DIRECTIONS

- Apply a thin layer on affected area twice daily or as directed by a doctor.
- If no improvement is seen after 3 months treatment, discontinue use.
- Lightening effect may not be noticeable when used on very dark skin.
- Limit sun exposure during and after use to prevent darkening from reoccurring.
- Use a sun blocking agent or protective clothing. This product is not for use in the prevention of sunburn.
- Consult your physician before use.

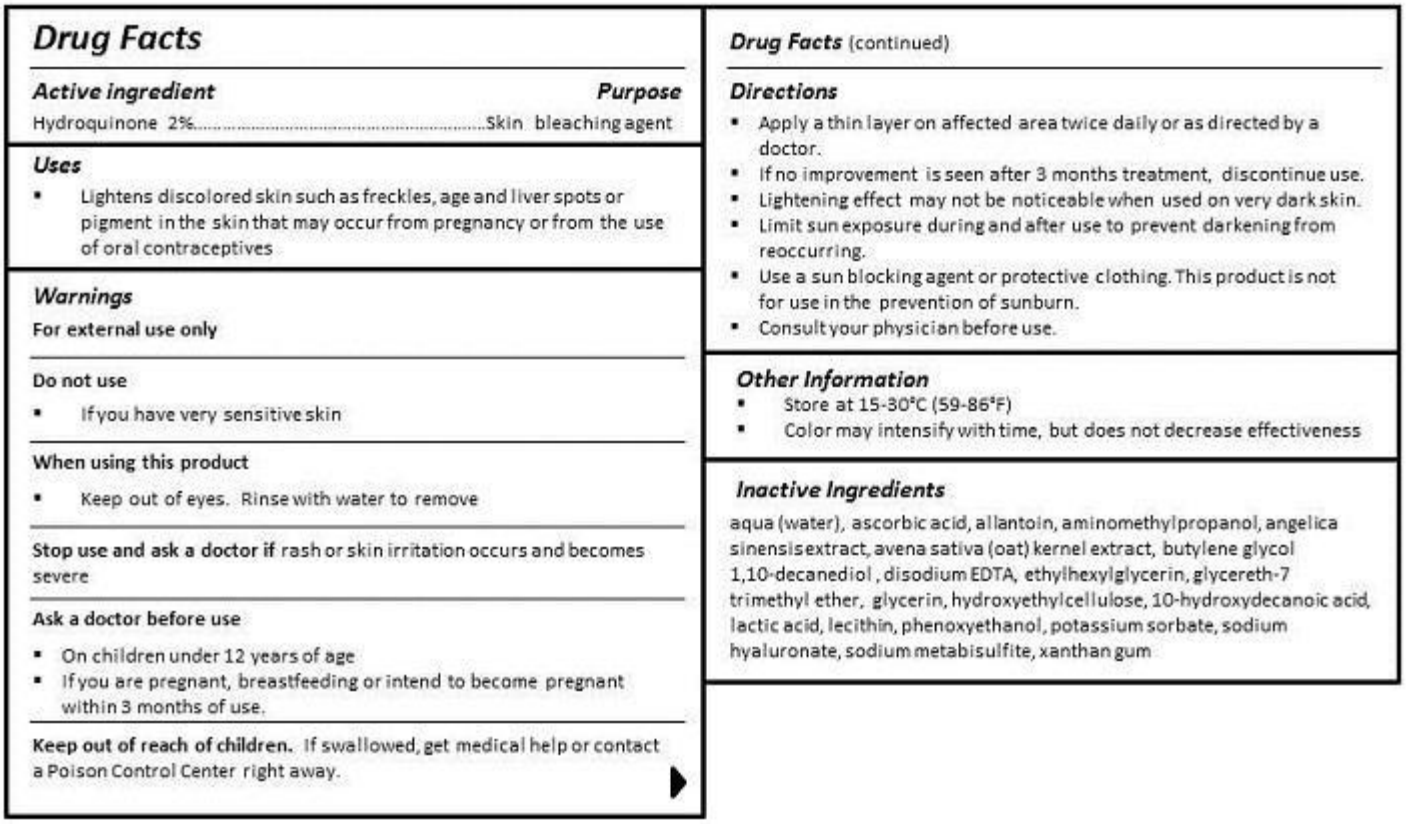
Other Information

- STORE AT 15-30°C (59-86°F)
- PROTECT THIS PRODUCT FROM EXCESSIVE HEAT AND DIRECT SUN.

INGREDIENTS

aqua (water), cyclopentasiloxane, PEG-10 dimethicone, dimethicone, butylene glycol, cyclohexasiloxane, glycerin, carollina officinalis extract, algae extract, avena sativa (oat) kernel extract, angelica sinensis extract, 10-hydroxydecanoic acid, sebacic acid, 1,10-decanediol acid, betaine,

dimethicone/vinyl dimethicone crosspolymer, lauryl PEG-9 polydimethylsiloxyethyl dimethicone, lecithin, dimethicone/PEG-10/15 crosspolymer, triethoxycaprylylsilane, decamethylcyclopentasiloxane, trifluoromethyl C1-C4 alkyl dimethicone, quaternium-90, bentonite, butylene glycol, sodium chloride, sodium citrate, ethylhexylglycerin, propylene carbonate, propylene glycol, potassium sorbate, methylisothiazolinone, iodopropynyl butylcarbamate, phenoxyethanol



Drug Facts

Active ingredient — **Purpose**

Hydroquinone 2% ..... Skin bleaching agent

Uses

- Lightens discolored skin such as freckles, age and liver spots or pigment in the skin that may occur from pregnancy or from the use of oral contraceptives

Warnings

For external use only

Do not use

- If you have very sensitive skin

When using this product

- Keep out of eyes. Rinse with water to remove

Stop use and ask a doctor if rash or skin irritation occurs and becomes severe

Ask a doctor before use

- On children under 12 years of age
- If you are pregnant, breastfeeding or intend to become pregnant within 3 months of use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions

- Apply a thin layer on affected area twice daily or as directed by a doctor.
- If no improvement is seen after 3 months treatment, discontinue use.
- Lightening effect may not be noticeable when used on very dark skin.
- Limit sun exposure during and after use to prevent darkening from reoccurring.
- Use a sun blocking agent or protective clothing. This product is not for use in the prevention of sunburn.
- Consult your physician before use.

Other Information

- Store at 15-30°C (59-86°F)
- Color may intensify with time, but does not decrease effectiveness

Inactive Ingredients

aqua (water), ascorbic acid, allantoin, aminomethylpropanol, angelica sinensis extract, avena sativa (oat) kernel extract, butylene glycol 1,10-decanediol , disodium EDTA, ethylhexylglycerin, glycereth-7 trimethyl ether, glycerin, hydroxyethylcellulose, 10-hydroxydecanoic acid, lactic acid, lecithin, phenoxyethanol, potassium sorbate, sodium hyaluronate, sodium metabisulfite, xanthan gum

BRIGHTEN LIGHTENING

hydroquinone gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54272-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	2 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ALLANTOIN (UNII: 344S277G0Z)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
OAT (UNII: Z6J799EAJK)	
ANGELICA SINENSIS WHOLE (UNII: 697D19QDBN)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
10-HYDROXYDECANOIC ACID (UNII: NP03XO416B)	
1,10-DECANEDIOL (UNII: 5I577UDK52)	

LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LACTIC ACID (UNII: 33X04XA5AT)	
GLYCERETH-7 TRIMETHYL ETHER (UNII: XMC7402M60)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54272-301-11	30 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	02/21/2013	

Labeler - CEN BEAUTY LLC (078664118)

Registrant - CEN BEAUTY LLC (078664118)

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