

PIONA- hydroquinone lotion
Grand Stream Enterprise, Inc

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

HYDROQUINONE 1.95%.....Skin Bleaching

INACTIVE INGREDIENT

ALLANTOIN, ANGELICA GIGAS ROOT, ASIAN GINSENG, BETAINE, BLACK COHOSH, BUTYLENE GLYCOL, CETOSTEARYL ALCOHOL, COPTIS CHINENSIS ROOT, DIMETHICONE, EDETATE DISODIUM ANHYDROUS, FALLOPIA MULTIFLORA ROOT, GARLIC, GLYCERIN, GLYCERYL MONOSTEARATE, GLYCOLIC ACID, GLYCYRRHIZA GLABRA, GREEN TEA LEAF, INDIGOFERA TINCTORIA LEAF, METHYLPARABEN, MINERAL OIL, MORUS ALBA BARK, NIACINAMIDE, OLIVE OIL, PAEONIA LACTIFLORA ROOT, PEG-100 STEARATE, PHELLINUS LINTEUS MYCELIUM, POLYSORBATE 60, PROPYLPARABEN, PUNICA GRANATUM ROOT BARK, RICE GERM, SAFFLOWER, SCUTELLARIA BAICALENSIS ROOT, SESAME SEED, SODIUM ASCORBYL PHOSPHATE, SODIUM BISULFATE, SODIUM LAURYL SULFATE, SODIUM METABISULFITE, SOPHORA FLAVESCENS ROOT, STEARIC ACID, WATER, XANTHAN GUM

KEEP OUT OF REACH OF CHILDREN

INDICATIONS & USAGE

Gracually fades skin discolorations such as age spots, freckles and scars.

WARNINGS

Sun exposure should be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin after treatments completed in order to prevent darkening from reoccurring.

Avoid contact with eyes.

Some users of this product may experience a mild ski, irritation. If ski, irritation becomes severe, stop use and consult a doctor.

If pregnant or breast-feeding, ask a health professional before use.

If swallowed, get medical help or contact a Poison Control center right away.

DOSAGE & ADMINISTRATION

Adults: apply a small amount as a thin layer on the affected area twice daily, or use as drected by a doctor. If no improvement is seen after 3 months of treatment use of this product should be discontinued.

PURPOSE

Skin Bleaching

PIONA Skin Lightening Body Lotion

Questions or Comments? 954-731-0165 or piona@grandstream.com

Formulated in France

Made in Korea

Distributed by: Grand Stream Enterprise, Inc. 2219 NW 29 St., Oakland Park, FL 33311



PIONA

hydroquinone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52927-200
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	1.95 in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BETAINE (UNII: 3SCV180C9W)	
NIACINAMIDE (UNII: 25X51I8RD4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

OLIVE OIL (UNII: 6UYK2W1W1E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALLANTOIN (UNII: 344S277G0Z)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM BISULFATE (UNII: BU8V88OWIQ)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
BLACK COHOSH (UNII: K73E24S6X9)	
FALLOPIA MULTIFLORA ROOT (UNII: AUZ3VD75MC)	
SESAME SEED (UNII: 7Y1255HVXR)	
PELLINUS LINTEUS MYCELIUM (UNII: 40K19XJV3C)	
ANGELICA GIGAS ROOT (UNII: 32766B2FHX)	
MORUS ALBA BARK (UNII: 7O71A48NDP)	
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24BT1D)	
INDIGOFERA TINCTORIA LEAF (UNII: 2K7DF8HZDM)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
COPTIS CHINENSIS ROOT (UNII: CXS4LJR7EL)	
GARLIC (UNII: V1V998DC17)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
RICE GERM (UNII: 7N2B70SFEZ)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52927-200-01	296 mL in 1 TUBE; Type 0: Not a Combination Product	11/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	11/01/2016	

Labeler - Grand Stream Enterprise, Inc (805697948)

Establishment

Name	Address	ID/FEI	Business Operations
JIC SKIN KOREA CO.,LTD.		557837776	MANUFACTURE(52927-200)

Revised: 12/2016

Grand Stream Enterprise, Inc