

VIVANT TRUE TONE- hydroquinone cream
Vivant Pharmaceuticals, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Vivant True Tone (Export Only)

Active Ingredient

Hydroquinone (2%)

Indication

Skin Bleaching Agent

Uses

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- For the gradual fading of age spots
- Lightens dark pigment in the skin
- This product provides minimal SPF protection.

Warnings

Warnings ■ Sun exposure should be avoided indefinitely by using a high SPF sunscreen agent, a sunblocking agent, or protective clothing to cover bleached skin in order to prevent darkening from reoccurring ■ Do not get into eyes ■ Keep out of reach of children ■ For external use only ■ Not recommended for children under 12 years of age ■ If swallowed get medical help or contact a poison control center immediately.

Ask a doctor if you are:

using other topical acne medications

Directions

Directions ■ Adult topical dosage is a thin layer to the affected area once or twicedaily ■ There is no recommended dosage for children under 12 years of age except under the advice and supervision of a doctor ■ Keep refrigerated

Inactive Ingredients

Inactive Ingredients • Water, Mineral Oil, Propylene Glycol, Glyceryl Stearate, PEG-100 Stearate, Vitis Vinifera (Grape Seed) Seed Oil, Cetyl Alcohol, Emulsifying Wax, Caprylic/Capric Triglyceride, Retinyl Propionate, Kojic Acid, EthylhexylDimethyl PABA, Dimethicone, HydrolyzedOat Protein, Aloe Barbadensis Leaf Juice, Polyacrylamide, C13-14 isoparaffin, Laureth-7, Xanthan Gum, Sodium Hydroxide, Sodium Metabisulfite, Sodium Bisulfite, Phenoxyethanol, Ethylhexylglycerin

When using this product

if not improvement is seen after 2 months of treatment, use of this products should be discontinued

Stop use and ask the doctor if

excessive skin irritation develops or increases

Warnings

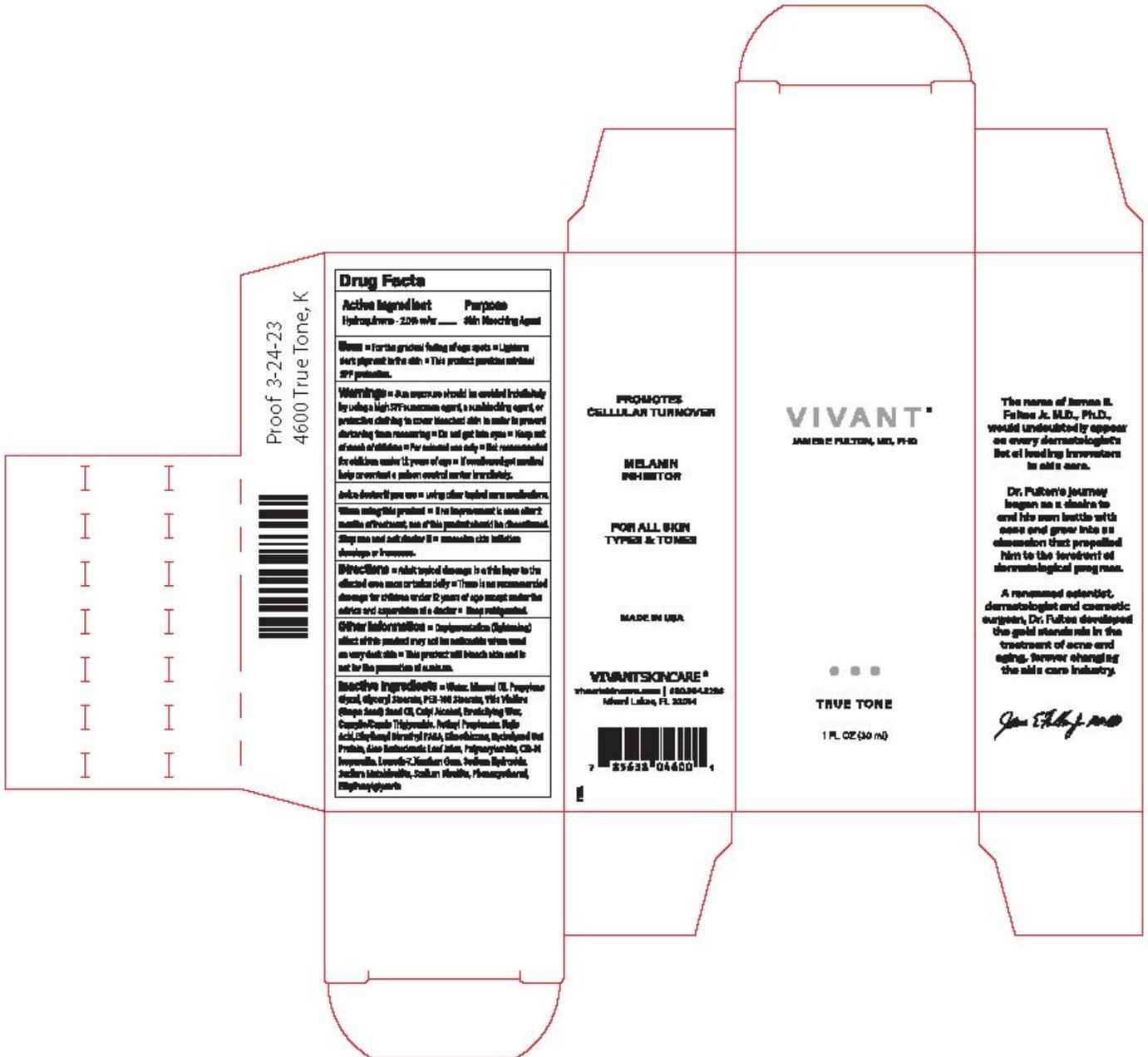
Keep out of reach of children ■ For external only ■ Not recommended for children under 12 years of age

Other Information

Other Information • Depigmentation (lightening) effect of this product may not be noticeable when used on very dark skin

This product will bleach skin and is not for the prevention of sunburn.

Principal Display Panel



VIVANT TRUE TONE

hydroquinone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63750-002
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
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PADIMATE O (UNII: Z11006CMUZ)	
VITIS VINIFERA LEAF OIL (UNII: 76K69S9H5Z)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
KOJIC ACID (UNII: 6K23F1TT52)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
RETINYL PROPIONATE (UNII: 32JK994WMC)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
AVENA SATIVA LEAF (UNII: 206PI19V7R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SODIUM BISULFITE (UNII: TZX5469Z6I)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
PEG-60 STEARATE (UNII: 7TB32G765E)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
MINERAL OIL (UNII: T5L8T28FGP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63750-002-01	1 in 1 BOX	02/01/2024	03/31/2026
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/01/2024	03/31/2026

Labeler - Vivant Pharmaceuticals, LLC (782696814)

Establishment

Name	Address	ID/FEI	Business Operations
Vivant Pharmaceuticals, LLC		782696814	manufacture(63750-002)

