

VIVANT TRUE TONE FORTE- hydroquinone gel

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 Forte (Export Only)

Active Ingredient

Hydroquinone (2%)

Indication

Skin Lightening

Uses

Uses

- 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

Alcohol Denat, Ethoxydiglycol, Ethylhexyl Dimethyl PABA Hydroquinone USP, Kojic Acid USP, Citric Acid USP, Retinyl Propionate

Propylene Glycol, Hydroxypropylcellulose

When using this product

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

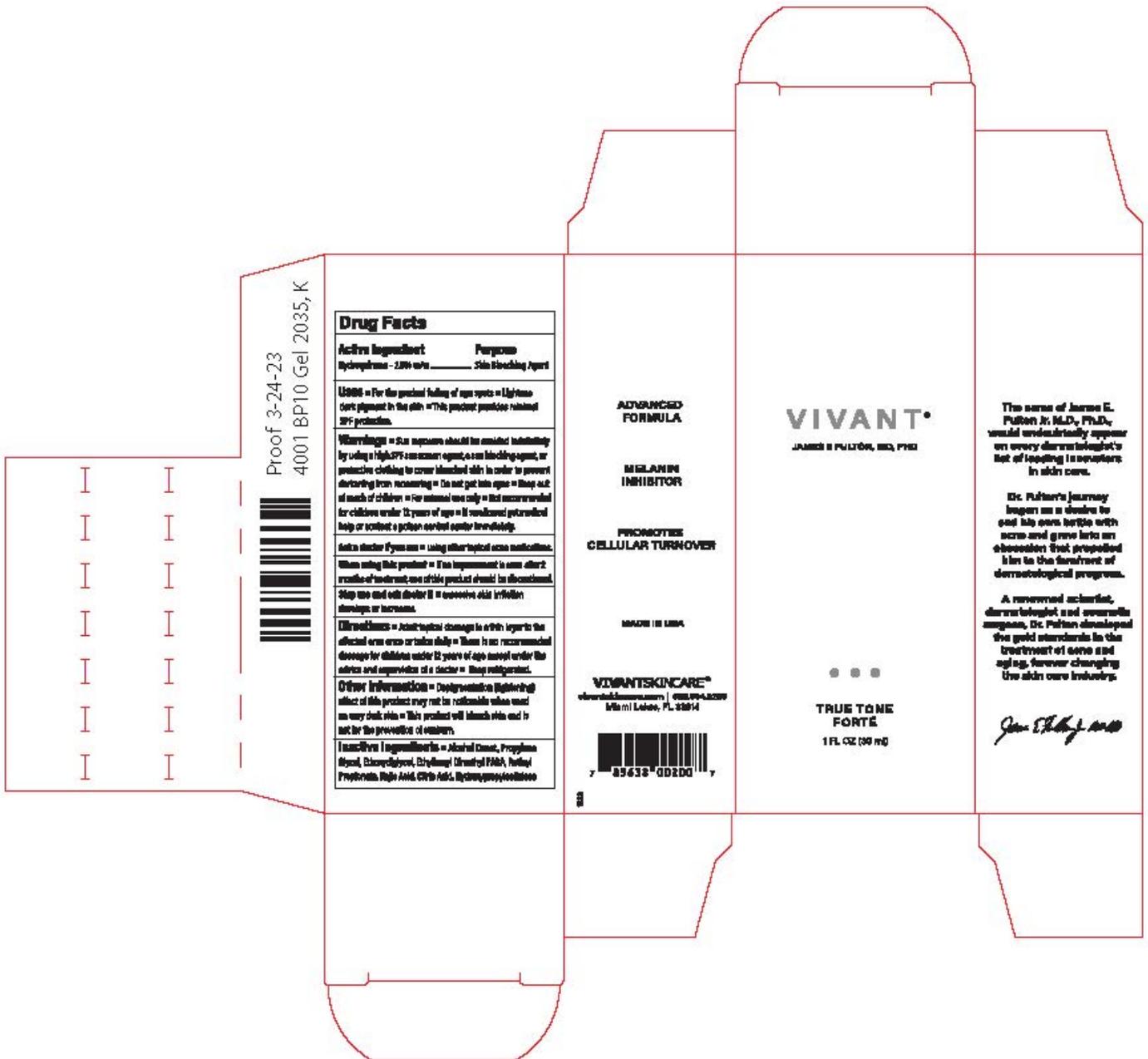
Stop use and ask the doctor if

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

Principal Display Panel



VIVANT TRUE TONE FORTE

hydroquinone gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63750-001
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
ALCOHOL (UNII: 3K9958V90M)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A18X02B)	
PADIMATE O (UNII: Z11006CMUZ)	
KOJIC ACID (UNII: 6K23F1TT52)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
RETINYL PROPIONATE (UNII: 32JK994WMC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE (11% HYDROXYPROPYL; 140000 MW) (UNII: 599BTP6K9F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63750-001-01	1 in 1 BOX	02/01/2024	
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	

Labeler - Vivant Pharmaceuticals, LLC (782696814)

Establishment

Name	Address	ID/FEI	Business Operations
Vivant Pharmaceuticals, LLC		782696814	manufacture(63750-001)

Revised: 2/2024

Vivant Pharmaceuticals, LLC