

FEDORA CONCENTRATING HYDRO MOISTURIZER - glycerin liquid
Fedora International Co., Ltd.

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.

Drug Facts

glycerin

water, butylene glycol, etc.

anti wrinklewhiteningskin protectant

keep out of reach of the children

apply proper amount to the skin

1. Do not use in the following cases(Eczema and scalp wounds)

2.Side Effects

1)Due to the use of this druf if rash, irritation, itching and symptopms of hypersnesitivity occur
dicontinue use and consult your phamacisr or doctor

3.General Precautions

1)If in contact with the eyes, wash out thoroughty with water If the symptoms are servere, seek medical
advice immediately

2)This product is for exeternal use only. Do not use for internal use

4.Storage and handling precautions

1)If possible, avoid direct sunlight and store in cool and area of low humidity

2)In order to maintain the quality of the product and avoid misuse

3)Avoid placing the product near fire and store out in reach of children

for external use only

FEDORA

Primum Edition

CONCENTRATING
HYDRO
MOISTURIZER

45 ml / 1.5 FL.OZ.

glycerin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62620-4001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	12 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62620-4001-1	45 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
OTC monograph final	part347	10/26/2015	

Labeler - Fedora International Co., Ltd. (689049099)

Registrant - Fedora International Co., Ltd. (689049099)

Establishment

Name	Address	ID/FEI	Business Operations
Fedora International Co., Ltd.		689049099	manufacture(62620-4001)

Revised: 10/2015

Fedora International Co., Ltd.