

HYDRA C3 TRIPLE RESET- witch hazel cream ULAB

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

Active ingredients: WITCH HAZEL 5.0%

INACTIVE INGREDIENT

Inactive ingredients: Aqua (WATER), Glycerin (and) Glyceryl Polyacrylate, Bifida Ferment Lysate, Glycerin, Propylene Glycol, Phenoxyethanol, Carbomer, Triethanolamine, Olive Glycerides, Ceramide 3, Fragrance, Mica, CI 77891, Silica, Ethylhexylglycerin, CI 77491, Tin oxide

PURPOSE

Purpose: Skin nourishing and strengthening

WARNINGS

Warnings: For external use only Avoid contact with eyes. Discontinue use if signs of irritation or rashes appear.

KEEP OUT OF REACH OF CHILDREN

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INDICATIONS & USAGE

Indications & Usage: Apply morning and night

DOSAGE & ADMINISTRATION

Dosage & Administration: Apply morning and night to face and neck after serum and ampoule

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

**HYDRA C3
TRIPLE RESET**

Drug Facts	Purpose
Active Ingredients WITCH HAZEL 5.0%	Skin nourishing and strengthening
Indications & Usage • Apply morning and night	
Warnings For external use only Avoid contact with eyes. Discontinue use if signs of irritation or rashes appear.	
Keep Out of Reach of Children	
Dosage & Administration • Apply morning and night to face and neck after serum and ampoule	
Inactive Ingredients Aqua (WATER), Glycerin (and) Glyceryl Polyacrylate, Bifida Ferment Lysate, Glycerin, Propylene Glycol, Phenoxyethanol, Carbomer, Triethanolamine, Olive Glycerides, Ceramide 3, Fragrance, Mica, CI 77891, Silica, Ethylhexylglycerin, CI 77491, Tin oxide	
Manufactured by ULAB Switzerland AG	

Increases skin tone, improves UV - damaged and keratinized skin, Reduces and plumps fine lines
Use: All skin type. Day and night on cleansed skin.

ULAB Switzerland AG
Bahnhofstrasse 3, CH-8008 Pfaffikon Switzerland
Made in Switzerland
www.ulabswiss.com

60ml / 2.02 fl.oz.

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HYDRA C3 TRIPLE RESET

witch hazel cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71276-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 10 114J0 U34) (WITCH HAZEL - UNII:10 114J0 U34)	WITCH HAZEL	3.0 g in 60 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71276-100-02	1 in 1 CARTON	03/02/2017	
1	NDC:71276-100-01	60 mL in 1 BOTTLE, PUMP; 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	03/02/2017	

Labeler - ULAB (688976692)

Registrant - ULAB (688976692)

Establishment

Name	Address	ID/FEI	Business Operations
ULAB		688976692	relabel(71276-100)

Establishment

Name	Address	ID/FEI	Business Operations
U-LAB Switzerland AG		485958743	manufacture(71276-100)