# 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.

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#### 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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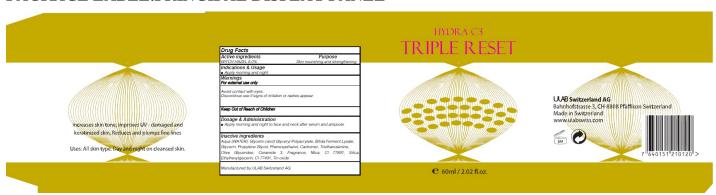
### **INDICATIONS & USAGE**

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



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

mactive 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

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

Revised: 3/2017 ULAB