

# NECK DECOLLETE HAND ARM DAY REPARATIVE HYDRATION RESCUE AND REPROGRAM BROAD SPECTRUM SPF 35 SUNSCREEN- neck and decollete day cream

## Haute Custom Beauty

*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.*

### PACKAGE LABEL



- BLACK PANTONE (INK)
- GOLDEN METALLIC PANTONE 871 (INK)
- GOLD HOT STAMPING
- EMBOSSED
- PANTONE COOL GRAY 1 + DEBOSSED + UV COATING

NOTE: DO NOT SCALE NOR MANIPULATE TEXT. BY FDA REGULATIONS / LAW WE ARE REQUIRED TO HAVE ALL TEXT AT SPECIFIC FONT SIZE. IF ANYTHING IS MANIPULATED IN ANY FORM IT COULD CAUSE A BIG ISSUE FOR US.

Package Label Principal display panel

Active Ingredients

Product



**NECK DECOLLETE HAND ARM DAY REPARATIVE HYDRATION  
RESCUE AND REPROGRAM BROAD SPECTRUM SPF 35 SUNSCREEN**

neck and decollete day cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72414-007
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3 g in 100 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	6 g in 100 g
<b>ENSULIZOLE</b> (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	4 g in 100 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.4 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CETEARYL ETHYLHEXANOATE</b> (UNII: 9M64UO4C25)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>PANTHENOL</b> (UNII: WW9CM0O67Z)	
<b>DIMETHYLMETHOXY CHROMANOL</b> (UNII: XBH432G01F)	
<b>DECARBOXY CARNOSINE HYDROCHLORIDE</b> (UNII: 6X7K9I5QR7)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>PALMITOYL TRIPEPTIDE-5</b> (UNII: 2A3916MQHO)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE</b> (UNII: FJ1H6M2JG9)	
<b>SESAME OIL</b> (UNII: QX10HYY4QV)	
<b>CETEARYL ISONONANOATE</b> (UNII: P5O01U99NI)	
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)	
<b>BELLIS PERENNIS</b> (UNII: 2HU33I03UY)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>.ALPHA.-TOCOPHEROL ACETATE, D-</b> (UNII: A7E6112E4N)	
<b>FYTIC ACID</b> (UNII: 7IGF0S7R8I)	
<b>LIMOSILACTOBACILLUS FERMENTUM</b> (UNII: 2C1F12C6AP)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>ACEFYLLINE METHYLSILANOL MANNURONATE</b> (UNII: OI1T4Z23RZ)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>VIOLA ODORATA</b> (UNII: AET12U8B74)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:72414-007-60	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/18/2023	
2	NDC:72414-007-20	200 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/18/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/18/2023	

**Labeler** - Haute Custom Beauty (024442805)

**Registrant** - Haute Custom Beauty (466493781)

## Establishment

Name	Address	ID/FEI	Business Operations
Haute Custom Beauty SLU		466493781	manufacture(72414-007) , label(72414-007) , pack(72414-007)

Revised: 8/2023

Haute Custom Beauty