HEISCLEAN FOR WOMAN- alcohol gel HEISCLEAN.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.

ACTIVE INGREDIENT

Active Ingredient: Alcohol 1.0%

INACTIVE INGREDIENT

Inactive Ingredients: Water, Rose Extract, Onsen-Sui, Decyl Glucoside, 1,2-Hexanediol, Hamamelis Virginiana (Witch Hazel) Extract, Hydroxyethylcellulose, Arginine, Lactic Acid, Polyglyceryl-4 Caprate, Salicornia Herbacea Extract, Phragmites Communis Extract, Lactuca Indica Extract, Corydalis Ochotensis Extract, Draba Nemorosa Extract, Chenopodium Album Flower Extract, Punica Granatum Fruit Extract, Ficus Carica (Fig) Fruit Extract, Morus Alba Fruit Extract, Ginkgo Biloba Nut Extract, Soy Isoflavones, Cimicifuga Racemosa Root, Polygonum Cuspidatum Root Extract, Pueraria Lobata Root Extract, Angelica Polymorpha Sinensis Root Extract, Punica Granatum Extract, Trifolium Pratense (Clover) Flower Extract, Pueraria Mirifica Root Extract, Butylene Glycol, Larix Sibirica Wood Extract, Chrysanthellum Indicum Extract, Rheum Palmatum Root/Stalk Extract, Asarum Sieboldi Root Extract, Quercus Mongolia Leaf Extract, Persicaria Hydropiper Extract, Illicium Verum (Anise) Fruit Extract, Corydalis Turtschaninovii Root Extract, Coptis Japonica Root Extract, Machilus Thunbergii Bark Extract, Pyridoxine HCl, Rosa Damascena Flower Oil, Sapindus Mukurossi Fruit Extract, RH-Oligopeptide-1, Disodium EDTA, Menthol

PURPOSE

Purpose: Sanitizer

WARNINGS

Warnings:

For external use only

- 1. Please discontinue use immediately in the event that you experience any of the following side effects from using this product, and consult a dermatologist as the symptoms may get worse with continued use. (a) Adverse skin reactions occur upon its application which may involve red spots, swelling, itchiness, and other skin irritation. (b) The applied part shows signs of any of the symptoms mentioned above after exposure to the direct sunlight.
- 2. Do not apply to wounds and the area affected by dermatitis, eczema, and other irritations.
- 3. Precautions for handling and storage (a) Always close the cap after each use. (b) Always keep the product out of the reach of infants. (c) Do not store the product in high and low temperatures. It should also be kept out of direct sunlight.
- 4. Vulvar Cleanser (a) It should only be used on the vulva. (b) It should not be used for long periods of time. (c) It should be used with extreme caution when there are affected areas on the (vulvar) skin or the surrounding area has become contaminated. (d) It should not be used on children under 3 years of age. (e) It is not recommended for use during pregnancy and it is advised that you discontinue its use on the vulva until you deliver a baby as it may get into the eyes of the newborn baby.

KEEP OUT OF REACH OF CHILDREN

Always keep the product out of the reach of infants.

Uses

Uses:

It keeps women's sensitive and precious area safe and fresh by relaxing the unpleasant smell of women.

Directions

Directions:

Wet your vulva thoroughly with running water (preferably mild in temperature). Apply a suitable amount (2-3g) evenly to the region and massage gently. Rinse thoroughly in clean, lukewarm water.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





alcohol gel

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Pro	auct	Inioi	rmation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:42979-160

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Alcohol (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	Alcohol	2 g in 200 g

Inactive Ingredients

inactive ingredicines				
Ingredient Name	Strength			
Water (UNII: 059QF0KO0R)				
Witch Hazel (UNII: 101I4J0U34)				

Packaging

#	# Item Code Package Description		Marketing Start Date	Marketing End Date
1	NDC:42979-160-01	200 g in 1 CARTON: Type 0: Not a Combination Product	0.7/0.1/20.15	

37/01201

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/01/2015	

Labeler - HEISCLEAN.CO.,LTD (694730019)

Registrant - HEISCLEAN.CO.,LTD (694730019)

Establishment				
Name	Address	ID/FEI	Business Operations	
HANSOLBIOTECH		694455165	manufacture(42979-160)	

Revised: 12/2017 HEISCLEAN.CO.,LTD