# MIRACLE GYN (2 TABLETS)- allantoin tablet Haudongchun Co., Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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Miracle GYN (2 tablets)

## **Active Ingredients**

Allantoin (11%)

#### Purpose

Vaginal skin protectant

#### Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control right away. (1-800-222-1222)

#### Uses

Relieves the following symptoms: vaginal irritation, itching and burning, odor, vaginal dryness

#### Warnings

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Do not use if you have/are pregnant, hypersensitivity to any of the ingredients, scars on vagina, an allergic reaction or pain.

When using this product

			menstruati	

Use clean underwear.

Do not use tampons, douches, condoms, feminine cleansers, or other vaginal products.

Do not eat or swallow.

Stop use and ask a doctor if

- □ Symptoms get worsen or do not get better.
- ☐ Symptoms last more than 7 days
- I You get rashes or hives, abdominal pain, fever, chills, nausea, vomiting or foul-smelling vaginal odor or discharge.

If pregnant or breast-feeding, ask a health professional before use.

# **Directions & Dosage**

- Use it at bedtime preferably or during daytime without dynamic activites.
- Use Wash your finger and insert 2 pills into the vagina with first two knuckles of a finger. It will take 20-30 minutes until the pills are dissolved to relieve the symptoms and clean the vagina.
- ☐ Do not use within 6 hours prior to vaginal intercourse.
- ☐ This product is for adults and children age of 4 and up.
- ☐ Use 2 tablets at a time 2-4 consecutive days until symptoms are relieved.

□ After then, keep using 2 tablets every week

Other Information

☐ Store at cool temperature and dry place

## **Inactive Ingredients**

Sodium Chloride, Soluble Collagen, Glucose, Magnesium Stearate, Aloe Barbadensis Leaf Extract, Cereus Grandiflorus (Cactus) Extract, Ginkgo Biloba Leaf Extract, Mentha Piperita (Peppermint) Leaf Extract, Centella Asiatica Extract, Sophora Flavescens Root Extract, Angelica Gigas Root Extract

## Miracle GYN (2 tablets)



#### MIRACLE GYN (2 TABLETS) allantoin tablet **Product Information** Product Type HUMAN OTC DRUG Item Code (Source) NDC:55618-2002 **Route of Administration** VAGINAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z) ALLANTOIN 0.11 in 600 mg

Inactive Ingredients		
Ingredient Name	Strength	
Sodium Chloride (UNII: 451W47IQ8X)		
.ALPHAD-GLUCOPYRANOSE (UNII: 5J5I9EB41E)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
GINKGO (UNII: 19 FUJ2C58 T)		
MENTHA PIPERITA LEAF (UNII: A389O33LX6)		
CENTELLA ASIATICA (UNII: 7M867G6T1U)		
SOPHORA FLAVESCENS ROOT (UNII: IYR6 K8 KQ5K)		
ANGELICA GIGAS ROOT (UNII: 32766B2FHX)		

Product Characteristics				
Color	white	Score	no score	
Shape	capsule	Size	14mm	
Flavor		Imprint Code		
Contains				

]	Packaging					
3	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date		
:	NDC:55618-2002-3	1 in 1 PACKAGE	07/06/2016			
	NDC:55618-2002-2	2 in 1 BLISTER PACK				
	NDC:55618-2002-1	$600\mathrm{mg}$ in 1 CAPSULE; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		07/06/2016		

# Labeler - Haudongchun Co., Ltd. (688479464)

# Registrant - Haudongchun Co., Ltd. (688479464)

Establishment				
Name	Address	ID/FEI	Business Operations	
Haudongchun Co., Ltd.		688479464	manufacture (556 18 - 2002)	

Revised: 3/2017 Haudongchun Co., Ltd.