

# **SHOPKO MAXIMUM STRENGTH MEDICATED WITH ALOE AND WITCH HAZEL- witch hazel cloth**

**Shopko Stores Operating Co., LLC.**

*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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## **SHOPKO Maximum Strength Medicated wipes**

### **Active Ingredient**

Witch hazel 50%

### **Purpose**

Astringent

### **Uses**

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporary relief of irritation and burning.
- aids in protecting irritated anorectal areas.

### **Warnings**

**For external use only.**

### **When using this product**

- do not exceed the recommended daily dosage unless directed by a doctor
- do not put this product into the rectum by using fingers or any mechanical device or applicator.

### **Stop use and ask a doctor if**

- bleeding occurs
- condition worsens or does not improve within 7 days

### **Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away.(1-800-222-1222)

### **Directions**

- adult: unfold wipe and cleanse the area by gently wiping, patting or blotting. If necessary, repeat until all matter is removed from the area.
- use up to 6 times daily or after each bowel movement and before applying hemorrhoidal treatments, and then discard
- Dispose of wipe in trash.
- For best results, only flush one or two wipes at a time.

### **Other information**

- store at room temperature 20-25°C (68-77°F)

- for vaginal care - cleanse the area by gently wiping, patting, or blotting. Repeat as needed.
- for use as moist compress - if necessary, first cleanse the area as previously described. Fold wipe to desired size and place in contact with tissue for a soothing and cooling effect. Leave in place for 15 minutes and repeat as needed.

## Inactive Ingredients

Aloe, citric acid, Decyl Glucoside, Glycerin, Phenoxyethanol, Potassium Sorbate, Propylene Glycol, Sodium Benzoate, Water.

## Principal Display Panel

SHOPKO

Maximum Strength

Medicated Wipes

with Aloe and Witch Hazel

Cools, Soothes and Comforts

For Hemorrhoidal and vaginal Care

Convenient, Easy to use, Flushable Wipes

48 Wipes

6 in. x 5 in. (15.2 cm x 12.7 cm)

### Drug Facts (continued)

#### Warnings

**Stop use and ask a doctor if** ■ bleeding occurs ■ condition worsens or does not improve within 7 days

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

### Drug Facts (continued)

**Directions** ■ adult: unfold wipe and cleanse the area by gently wiping, patting or blotting. if necessary, repeat until all matter is removed from the area. ■ use up to 6 times daily or after each bowel movement and before applying hemorrhoidal treatments, and then discard ■ children under 12 years of age: consult a doctor ■ Dispose of wipe in trash. ■ For best results, only flush one or two wipes at a time.

### Drug Facts (continued)

**Other Information** ■ store at room temperature 20 – 25°C (68 – 77°F) ■ for vaginal care – cleanse the area by gently wiping, patting, or blotting. repeat as needed. ■ for use as moist compress – if necessary, first cleanse the area as previously described. fold wipe to desired size and place in contact with tissue for a soothing and cooling effect. leave in place for 15 minutes and repeat as needed.

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with Aloe & Witch Hazel

Cools, Soothes and Comforts  
For Hemorrhoidal and Vaginal Care  
Convenient, Easy to Use, Flushable Wipes

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By Refund Or Exchange

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## SHOPKO MAXIMUM STRENGTH MEDICATED WITH ALOE AND WITCH HAZEL

witch hazel cloth

### Product Information

|                         |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:370 12-121 |
| Route of Administration | TOPICAL        |                    |                |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength      |
|--|-------------------|---------------|
| WITCH HAZEL (UNII: 10 1I4J0 U34) (WITCH HAZEL - UNII:10 1I4J0 U34) | WITCH HAZEL       | 50 g in 100 g |

## Inactive Ingredients

| Ingredient Name                            | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R)                   |          |
| GLYCERIN (UNII: PDC6A3C0OX)                |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)        |          |
| DECYL GLUCOSIDE (UNII: Z17H97EA6Y)         |          |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)          |          |
| SODIUM BENZOATE (UNII: OJ245FE5EU)         |          |
| ALOE ARBORESCENS LEAF (UNII: 09TD8L5SQV)   |          |

## Packaging

| # | Item Code         | Package Description | Marketing Start Date | Marketing End Date |
|---|-------------------|---------------------|----------------------|--------------------|
| 1 | NDC:370 12-121-50 | 48 in 1 PACKAGE     |                      |                    |
| 1 |                   | 2.9 g in 1 PACKET   |                      |                    |

## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part346                                  | 07/16/2013           |                    |

**Labeler** - Shopko Stores Operating Co., LLC. (023252638)

Revised: 7/2013

Shopko Stores Operating Co., LLC.