

CVS PHARMACY MAXIMUM STRENGTH FEMININE WIPES- pramoxine hydrochloride cloth

CVS Pharmacy

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.

CVS Pharmacy Feminine Wipes - Drug Facts Label

Active ingredient

Pramoxine Hydrochloride 1.0% w/w

Purpose

ANALGESIC

Uses

- Temporarily relieves itching

Warnings

For external use only

When using this product

- Avoid contact with eyes

Stop use and ask a doctor if

- Condition worsens or does not improve within 7 days or clears up and reoccurs within a few days

Keep out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Direction

- Adults: unfold wipe and cleanse the area by gently wiping or patting external vaginal area from front to back. Use each towel only once and discard.
- Use up to 4 times daily.
- Children under 12: consult a doctor

Other information

- Store at room temperature
- Discard within 2 months of opening

Inactive ingredients

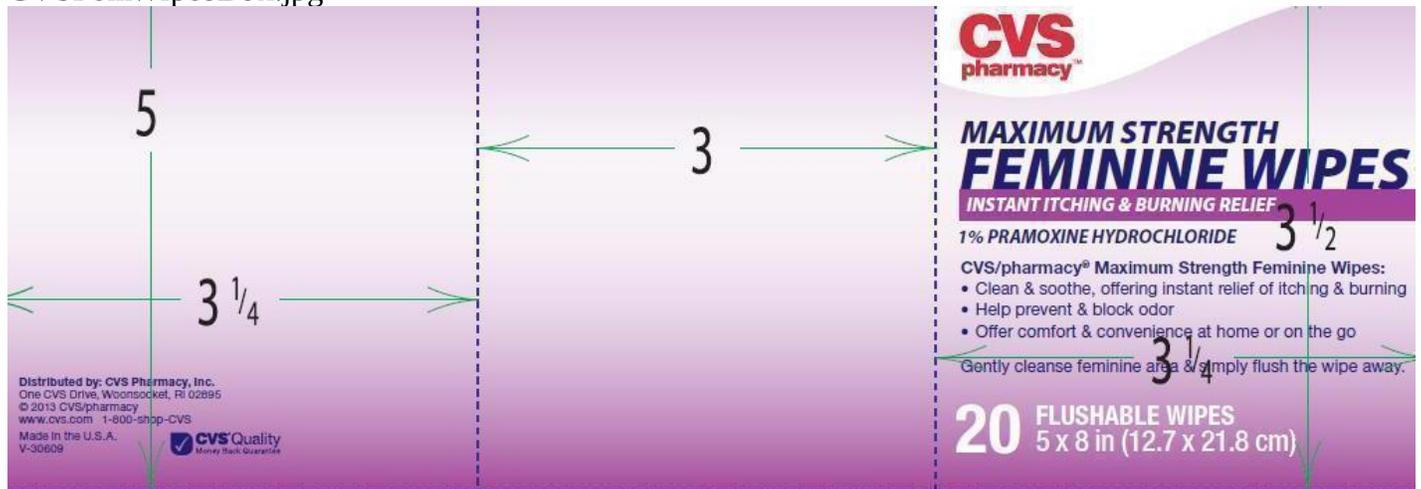
purified water, glycerin, propylene glycol, cocoamphodiacetate, polysorbate 20, aloe vera barbadensis leaf juice, citric acid, fragrance, diazolidinyl urea, iodopropynyl butylcarbamate.

Questions or comments?

Call weekdays 8am-5pm CST 1-800-325-5358

Images of representative packaging

CVSFemWipesBox.jpg



CVSFemWipesLabel.jpg



1% PRAMOXINE HYDROCHLORIDE

- **Cleans while soothing itch**
- **Helps prevent & block odor**

20 FLUSHABLE WIPES
5 x 8 in (12.7 x 21.8 cm)

*Peel here to open
Reseal after each use*

| | |
|--|-----------------------|
| <u>Drug Facts</u> | <u>Purpose</u> |
| <u>Active ingredient</u> Pramoxine Hydrochloride 1.0% w/w..... | ANALGESIC |
| <u>Uses</u> • Temporarily relieves itching | |
| <u>Warnings</u> For external use only When using this product <ul style="list-style-type: none">• Avoid contact with eyes Stop use and ask a doctor if <ul style="list-style-type: none">• Condition worsens or does not improve within 7 days or clears up and reoccurs within a few days Keep out of the reach of children <small>If you have had a medical procedure...</small> | |

if swallowed, get medical help or contact a Poison Control Center right away.

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CVSFemWipesDrugFactsPanel.jpg

CVS PHARMACY MAXIMUM STRENGTH FEMININE WIPES

pramoxine hydrochloride cloth

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59779-993 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056) | PRAMOXINE HYDROCHLORIDE | 10 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------|-----------------|
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |

| | |
|--|--|
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) | |
| IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:59779-993-01 | 89 g in 1 PACKAGE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part346 | 03/21/2013 | |

Labeler - CVS Pharmacy (062312574)

Registrant - Guy & O'Neill, Inc. (962567264)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|------------------------|
| Guy & O'Neill, Inc. | | 037838844 | manufacture(59779-993) |

Revised: 3/2013

CVS Pharmacy