ASSURED FEMININE ANTI-ITCH- benzocaine resorcinol cream
Greenbrier International

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.

Drug Facts

Active ingredients

Benzocaine 5%

Resorcinol 2%

Purpose

External analgesic

External analgesic

Uses

■ temporarily relieves itching

Warnings

For external use only

Avoid contact with eyes

Stop use and ask a doctor if

condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days

Do not apply over large areas of the body

Keep out of reach of children

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

Directions

Adults and children 2 years of age and older: Apply a fingertip amount (approximately 1-inch strip) to affected area not more than 3 to 4 times daily. Children under 2 years of age: Consult a doctor

Other information

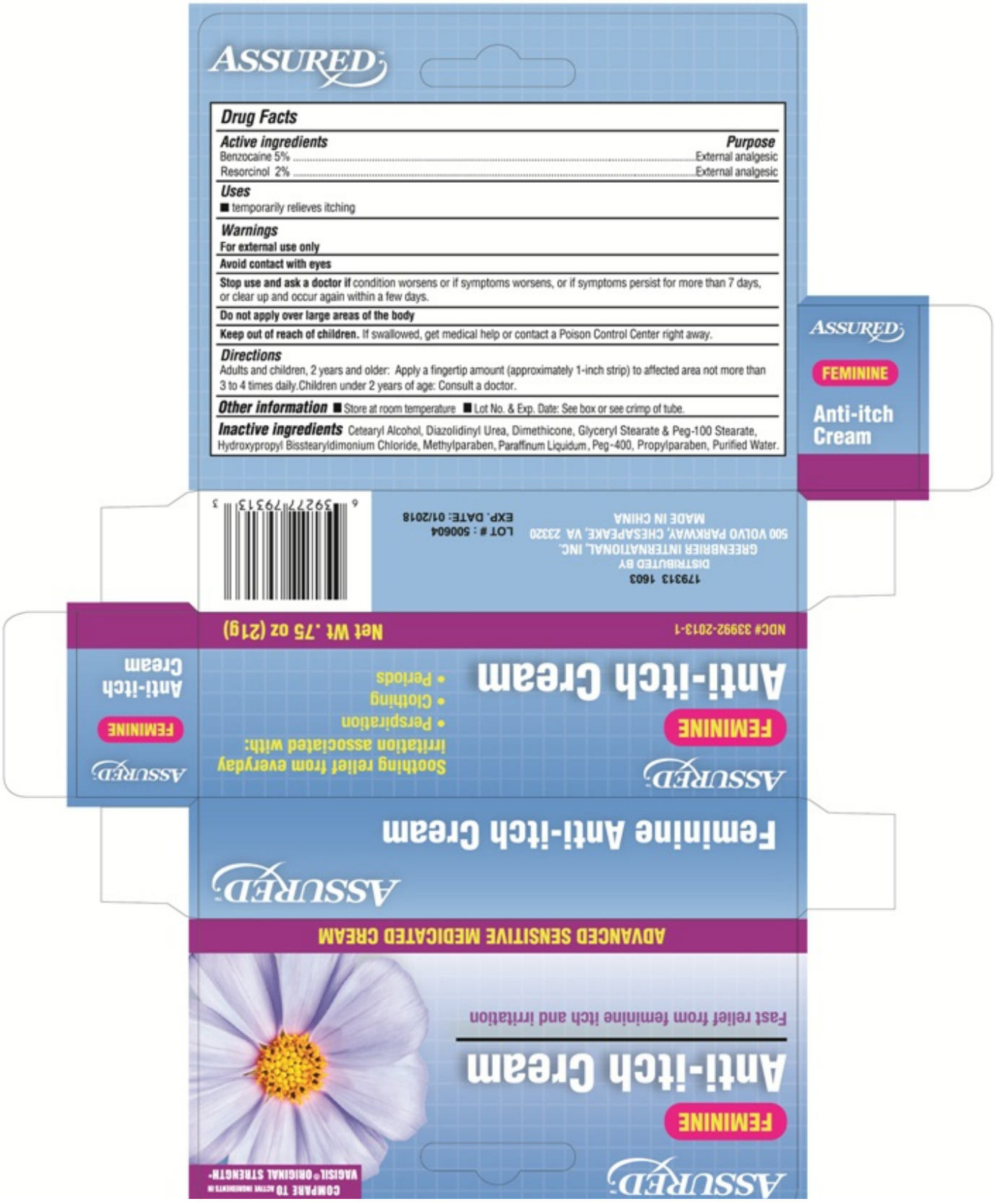
■ Store at room temperature ■ Lot. No. & Exp. Date: See box or see crimp of tube

Inactive ingredients

Cetearyl Alcohol, Diaziolidinyl Urea, Dimethicone, Glyceryl Stearate & Peg 100 Stearate, Hydroxpropyl Bisstearyldimonium Chloride, Methyparaben, Paraffinum Liquidum,Peg 400,

Propylparaben, Purified water

Package Label



ASSURED FEMININE ANTI-ITCH

benzocaine resorcinol cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:33992-2014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	5 g in 100 g
RESORCINOL (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK)	RESORCINOL	2 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
MINERAL OIL (UNII: T5L8T28FGP)	
HYDROXYPROPYL BISSTEARYLDIMONIUM CHLORIDE (UNII: OVB1E9X12I)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:33992-2014-1	21 g in 1 TUBE; Type 0: Not a Combination Product	03/31/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/31/2017	

Labeler - Greenbrier International (610322518)

Establishment

Name	Address	ID/FEI	Business Operations
FRONT PHARMACEUTICAL PLC		530897792	manufacture(33992-2014)

Revised: 4/2017

Greenbrier International