

TOPCARE MAXIMUM STRENGTH URINARY PAIN RELIEF- phenazopyridine hydrochloride tablet

TOPCO ASSOCIATES LLC

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.

DRUG FACTS

ACTIVE INGREDIENT

PHENAZOPYRIDINE HYDROCHLORIDE 97.5 MG

PURPOSE

URINARY ANALGESIC

WARNINGS

DO NOT EXCEED RECOMMENDED DOSAGE

ASK DOCTOR SECTION

ASK DOCTOR BEFORE USE

IF YOU HAVE KIDNEY DISEASE

ALLERGIES TO FOODS,PRESERVATIVES OR DYES

HAD A HYPERSENSITIVE REACTION TO PHENAZOPYRIDINE

WHEN USING SECTION

WHEN USING THIS PRODUCT

STOMACH UPSET MAY OCCUR,TAKING THIS PRODUCT WITH OR AFTER MEALS MAY REDUCE STOMACH UPSET

YOUR URINE WILL BECOME REDDISH ORANGE IN COLOR.THIS IS NOT HARMFUL,BUT CARE SHOULD BE TAKEN TO

AVOID STAINING CLOTHING OR OTHER ITEMS.

STOP USE SECTION

STOP USE AND ASK A DOCTOR

IF YOUR SYMPTOMS LAST FOR MORE THAN 2 DAYS

YOU SUSPECT YOU ARE HAVING AN ADVERSE REACTION TO THE MEDICATION

PREGNANCY OR BREAST FEEDING

ASK A HEALTH PROFESSIONAL BEFORE USE

KEEP OUT OF REACH OF CHILDREN

IN CASE OF OVERDOSE ,GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

INDICATIONS & USAGE

Use; fast relief from urinary pain, burning, urgency and frequency associated with urinary tract infections.

DOSAGE & ADMINISTRATION

Adults and Children 12 years of age and over; take 2 tablets 3 times daily with a full glass of water, with or after meals as needed.

Children under 12 years of age; consult a doctor.

Do not use for more than 2 days (12 tablets) without consulting a Doctor.

INACTIVE INGREDIENT

Lactose, magnesium silicate, magnesium stearate, microcrystalline cellulose, pharmaceutical glaze, and sodium starch glycolate.



TOPCARE MAXIMUM STRENGTH URINARY PAIN RELIEF
phenazopyridine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-103
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENAZOPYRIDINE HYDROCHLORIDE (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)	PHENAZOPYRIDINE HYDROCHLORIDE	97.5 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	975
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-103-01	1 in 1 CARTON	02/01/2011	
1	NDC:36800-103-12	12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/01/2011	

Labeler - TOPCO ASSOCIATES LLC (006935977)**Registrant** - Reese Pharmaceutical Co (004172052)**Establishment**

Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(36800-103) , repack(36800-103)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corp.		057795122	manufacture(36800-103)

