SUNMARK URINARY PAIN RELIEF MAXIMUM STRENGTH - phenazopyridine hydrochloride tablet
Bryant Ranch Prepack

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

PHENAZOPYRIDINE HYDROCHLORIDE 97.5 MG

PURPOSE

PHENAZOPYRIDINE HYDROCHLORIDE URINARY ANALGESIC

WARNINGS

DO NOT EXCEED RECOMMENDED DOSAGE

ASK DOCTOR

ASK DOCTOR BEFORE USE

IF YOU HAVE KIDNEY DISEASE

ALLERGIES TO FOODS,PRESERVATIVES OR DYES

HAD A HYPERSENSITIVE REACTION TO PHENAZOPYRIDINE

WHEN USING

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

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 US

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.

INACTIVE INGREDIENT

Lactose, magnesium silicate, magnesium stearate, microcrystalline cellulose,

pharmaceutical glaze, and sodium starch glycolate.

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.

HOW SUPPLIED

NDC: 71335-1661-1: 6 Tablets in a BOTTLE

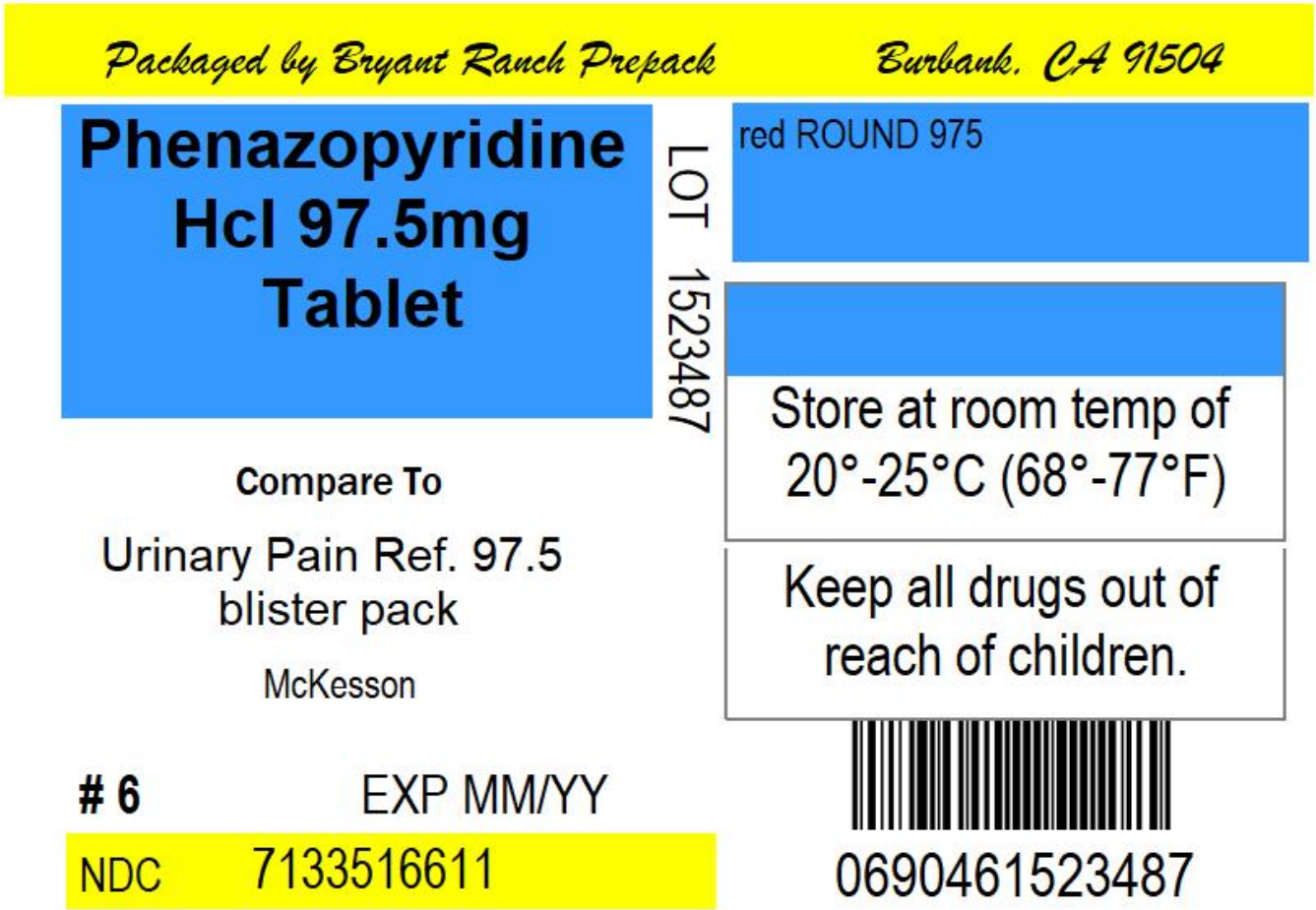
NDC: 71335-1661-2: 12 Tablets in a BOTTLE

NDC: 71335-1661-3: 36 Tablets in a BOTTLE

NDC: 71335-1661-4: 20 Tablets in a BOTTLE

NDC: 71335-1661-5: 10 Tablets in a BOTTLE

Phenazopyridine Hcl 97.5mg Tablet



SUNMARK URINARY PAIN RELIEF MAXIMUM STRENGTH

phenazopyridine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71335-1661(NDC:49348-941)
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, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

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:71335-1661-1	6 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2010	
2	NDC:71335-1661-2	12 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2010	
3	NDC:71335-1661-3	36 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2010	
4	NDC:71335-1661-4	20 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2010	
5	NDC:71335-1661-5	10 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/18/2010	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-1661) , RELABEL(71335-1661)