

LEADER AZO TABS URINARY TRACT ANALGESIC - phenazopyridine hydrochloride tablet
Cardinal Health

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 95 mg

Purpose;

Urinary Analgesic

Uses

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

Do not exceed recommended dosage

Ask a Doctor before use if you have

kidney disease,
allergies to foods, preservatives or dyes,

had a hypersensitive reaction to phenazopyridine.

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 and ask a doctor if

if your symptoms last for more than 2 days

you suspect you are having an adverse reaction

to the medication.

If pregnant or breast feeding, ask a health professional before use.

Keep out of reach of children

in case of an overdose, get medical help or contact

a Poison Control Center right away.

Directions

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

Children under 12 consult a doctor.

Do not use for more than 2 days ;12 tablets; without consulting a doctor.

magnesium stearate, microcrystalline cellulose. May also contain carnauba wax, croscarmellose sodium, hypromellose, lactose, magnesium silicate, maize starch, pharmaceutical glaze, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate.

For the prompt temporary relief of
• Minor Pain • Urinary Burning
• Discomfort of Urination

LEADER®

Azo Tabs

Urinary Tract Analgesic

For the prompt temporary relief of • Minor Pain
 • Urinary Burning • Discomfort of Urination



Distributed By: Cardinal Health
 Dublin, Ohio 43017
 www.myleader.com
 1-800-200-6313
 CIN 3318375

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

LEADER®

Compare to AZO Standard® *
 active ingredient

Azo Tabs

Phenazopyridine Hydrochloride 95mg

Urinary Tract Analgesic

For the prompt temporary relief of • Minor Pain
 • Urinary Burning • Discomfort of Urination



32 TABLETS

*This product is not manufactured or distributed by AmeriLit Nutrition, Inc., owners of the registered trademark Azo Standard®.



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Drug Facts

| Active ingredient (in each tablet) | Purpose |
|--|-------------------|
| Phenazopyridine Hydrochloride 95 mg..... | Urinary Analgesic |

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

Warnings Do not exceed recommended dosage

Ask a doctor before use if you have
 ■ kidney disease
 ■ allergies to foods, preservatives or dyes
 ■ had a hypersensitive reaction to Phenazopyridine

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 and ask a doctor if

■ your symptoms last for more than 2 days
 ■ you suspect you are having an adverse reaction to the medication

If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children.

Hechos Acerca Del Medicamento

| Ingrediente Activo (en cada tableta) | Propósito |
|---|---------------------|
| Hidrocloruro de Fenazopiridina 95 mg..... | Analgesico Urinario |

Usos alivio rápido del dolor urinario, ardor, urgencia y frecuencia asociados con las infecciones del tracto urinario

Advertencias No exceda la dosis recomendada

No lo use y consulte a un Médico si:

■ usted tiene enfermedad de los riñones
 ■ alergias a ciertos alimentos, preservativos o colorantes
 ■ ha tenido alguna reacción de hipersensibilidad a la Fenazopiridina

Quando use este producto
 ■ puede tener molestias estomacales. tomando este producto durante o después de los alimentos puede reducir las molestias estomacales

■ su orina cambiará a un color rojo anaranjado. esto no es anormal, pero debe tener cuidado de no manchar la ropa u otros objetos.

Deje de usarlo y consulte a un Médico si
 ■ sus síntomas duran más de 2 días
 ■ usted sospecha que tiene una reacción adversa al medicamento

Si está embarazada o lactando, pregunte a un profesional de la salud antes de tomarlo. Manténgalo fuera del alcance de

in case of an overdose, get medical help or contact a Poison Control Center right away.

Directions ■ Adults and children 12 and over: take 2 tablets 3 times daily with a full glass of water, with or after meals as needed

- Children under 12: consult a doctor
- Do not use for more than 2 days (12 tablets) without consulting a doctor

Other Information ■ this product can interfere with laboratory tests including urine, ▼

los niños. En caso de sobredosis, obtenga asistencia médica o póngase en contacto de manera inmediata con el Centro de Control de Envenenamientos.

Instrucciones ■ Adultos y niños mayores de 12 años: tome 2 tabletas 3 veces al día con un vaso de agua, durante o después de los alimentos.

- Niños menores de 12 años: consultar a un doctor
- No lo use por más de 2 días (12 tabletas) sin consultar a un Doctor

Otra Información ■ este producto puede ▼

Drug facts (continued)

glucose (sugar), and ketones tests
 ■ this product may stain contact lenses
 ■ long term administration of phenazopyridine HCl has induced neoplasia in rats (large intestine) and mice (liver). Although no association between phenazopyridine hydrochloride and human neoplasia has been reported, adequate epidemiological studies along these lines have not been conducted.

■ store at room temperature 15°-30°C (59°-86°F) in a dry place and protect from light

Caution: do not use if cellophane is open or damaged

Inactive Ingredients magnesium stearate, microcrystalline cellulose. May also contain carnauba wax, croscarmellose sodium, hypromellose, lactose, magnesium silicate, maize starch, pharmaceutical glaze, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate.

Hechos Acerca Del Medicamento (cont.)

interferir con pruebas de laboratorio que incluyen pruebas de la orina, glucosa (azúcar) y pruebas de cetonas

■ este producto puede manchar los lentes de contacto
 ■ la administración a largo plazo del Hidrocloruro de Fenazopiridina ha inducido neoplasias en ratas (Intestino grueso) y en ratones (Hígado) Aunque no se ha reportado la asociación entre el Hidrocloruro de Fenazopiridina y neoplasias humanas, no se han llevado al cabo estudios epidemiológicos adecuados relativos a este caso ■ guárdese a temperatura ambiente 15°-30°C(59°-86°F) en un lugar seco y protéjalo de la luz

Precaución: no las use si el celofán ha sido abierto o dañado

Ingredientes inactivos estearato de magnesio, celulosa microcristalina. También puede contener cera de carnauba, croscarmelosa de sodio, hipromelosa, lactosa, silicato de magnesio, almidón de maíz, esmalte farmacéutico, polietilenglicol, povidona, almidón pregelatinizado, glicolato de almidón de sodio.

REV 4/09 RELDR

LEADER AZO TABS URINARY TRACT ANALGESIC

phenazopyridine hydrochloride tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:37205-308 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------------|----------|
| PHENAZO PYRIDINE HYDRO CHLORIDE (UNII: 0 EWG668 W17) (PHENAZO PYRIDINE - UNII:K2J09EMJ52) | PHENAZO PYRIDINE HYDRO CHLORIDE | 95 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| LACTOSE (UNII: J2B2A4N98G) | |
| MAGNESIUM SILICATE (UNII: 9B9691B2N9) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | red | Score | no score |
| Shape | ROUND | Size | 7mm |
| Flavor | | Imprint Code | CPC64;A5 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:37205-308-01 | 1 in 1 CARTON | | |
| 1 | NDC:37205-308-64 | 32 in 1 CELLO PACK | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| unapproved drug other | | 11/05/2004 | |

Labeler - Cardinal Health (097537435)**Registrant** - Reese Pharmaceutical Co (004172052)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| Reese Pharmaceutical Co | | 004172052 | relabel, repack |

Revised: 1/2011

Cardinal Health