

AZO URINARY PAIN RELIEF MAXIMUM STRENGTH- phenazopyridine hydrochloride tablet
i-Health, Inc.

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.

AZO Urinary Pain Relief Maximum Strength

Active ingredient (in each tablet)

Phenazopyridine Hydrochloride 99.5 mg

Purpose

Urinary tract analgesic

Use Relief from urinary pain, burning, urgency and frequency associated with urinary tract infections.

Warnings

Please read insert for important precautions.

Ask a doctor before use if you have

- kidney disease
- allergies to foods, preservatives or dyes
- had a hypersensitive reaction to Phenazopyridine Hydrochloride

Do not use if you have Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency unless approved by your physician.

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 doctor if

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

If pregnant or breastfeeding, ask a professional before use. **A pregnancy test and consultation with a health professional if pregnancy is confirmed is recommended prior to 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 years and older: Take 2 tablets 3 times daily with or after meals as needed for up to two days. Take with a full glass of water. Do not use for more than 2 days (12 tablets) without consulting a doctor.

- Children under 12: Do not use without consulting a doctor.

Other Information

- This product can interfere with laboratory tests including urine, glucose (sugar), and ketones tests
- This product may stain soft contact lenses and other items if handled after touching tablets
- Store at room temperature (59-86 F) in a dry place and protect from light.

Tamper evident: Product is sealed within blisters. Do not use if any part of the blister is torn, open or damaged.

Inactive ingredients carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized corn starch. May also contain corn starch.

Distributed by i-Health, Inc., 25 Bacon Road, Enfield, CT 06082

Made in India. Size and color of tablets may vary.

For questions, concerns, or to report an adverse event, call (800) 722-3476

AZO Urinary Pain Relief[®] and OWN YOUR DAY[™] are trademarks of DSM.

Información y instrucciones en Español adjuntas

visit www.azoproducts.com to read customer reviews

AZO

Urinary Pain Relief[®]

MAXIMUM STRENGTH

Urinary Pain Relief Tablets

Active ingredient: Each analgesic tablet contains Phenazopyridine Hydrochloride 99.5 mg.

Fast relief of urinary discomfort including common urinary tract infection symptoms: Urinary pain, burning, urgency and frequency.

URINARY TRACT INFECTION (UTI)

Symptoms of urinary discomfort may indicate a urinary tract infection. If you experience symptoms such as urinary pain, burning, urgency and frequency, you need to call your doctor to get diagnosed and obtain a prescription to treat the infection. While you wait to get to the doctor and for the prescription to begin to work, you can get fast, symptomatic relief with **AZO Urinary Pain Relief Maximum Strength**.

WARNINGS

Ask a doctor before use if you have:

- liver or kidney trouble
- allergies to foods, preservatives or dyes
- had a hypersensitive reaction to Phenazopyridine Hydrochloride

Do Not Use:

if you have Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency unless approved by your physician.

When using this product

- stomach upset may occur. Taking 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 using this product and ask a doctor if you think you may be having an adverse reaction to the medication or if your symptoms last for more than two days.

If you are pregnant or breastfeeding, ask a healthcare professional before you use this product. **A pregnancy test and consultation with a health professional if pregnancy is confirmed is recommended prior to use.**

Keep this medication out of the reach of children.

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

DIRECTIONS

Adults and children 12 years and older: Take two (2) tablets three (3) times daily for up to two days. Take with a full glass of water, with or after meals as needed. Do not use for more than two days (12 tablets) without consulting a doctor.

Children under age 12: do not use without consulting a doctor.

OTHER INFORMATION & PRECAUTIONS

- This product can interfere with laboratory tests including urine, glucose (sugar) and ketones.
- This product may stain soft contact lenses and other items if handled after touching tablets.
- Size and color of tablets may vary.
- **Carcinogenesis:** Long-term administration of Phenazopyridine Hydrochloride 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.
- **Storage:** Store at room temperature (59° - 86°F) in a dry place and protect from light.
- **Tamper Evident:** Product is sealed within blisters. Do not use if any part of the blister is torn, open or damaged.

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AZO

Urinary Pain Relief ®

MAXIMUM STRENGTH

Alivio rápido para el dolor de las vías urinarias

Ingrediente activo: Cada tableta de analgésico contiene 99.5 mg

de hidrocioruro de fenazopiridina.

Alivio rápido de la incomodidad en las vías urinarias que incluye los síntomas comunes de infección en las vías urinarias: dolor al orinar, ardor, urgencia y frecuencia.

INFECCIÓN DE LAS VÍAS URINARIAS

Los síntomas de incomodidad en las vías urinarias pueden indicar la presencia de una infección. Si tiene síntomas como dolor, ardor, urgencia y frecuencia, necesita llamar a su médico para recibir un diagnóstico y que le dé una receta para tratar la infección. Mientras espera para ver al doctor y para que el medicamento que le recete comience a funcionar, puede obtener un alivio rápido de sus síntomas con AZO Urinary Pain Relief® Maximum Strength.

ADVERTENCIAS

Consulte a su médico antes de usar este producto si:

- tiene problemas renales o hepáticos.
- tiene alergias a alimentos, conservadores o tintes.
- ha tenido una reacción alérgica a el hidrocioruro de fenazopiridina.

No usar: si tiene una deficiencia de glucosa-6-fosfato deshidrogenasa (G6PD), a menos que su médico lo apruebe.

Al usar este producto:

- puede sentir malestar estomacal. Tómelo durante o después de las comidas para ayudar a disminuir el malestar.
- **la orina adquiere un color anaranjado rojizo.**

Esto no es dañino, pero debe tener cuidado para evitar manchar a ropa u otros artículos.

Deje de usar este producto y consulte a su médico si piensa que puede estar teniendo una reacción adversa al medicamento o si sus síntomas duran más de dos días.

Si usted está embarazada o lactando, consulte a un profesional médico antes de usar este producto. **Se recomienda una prueba de embarazo y una consulta con un profesional médico si se**

confirma un embarazo antes de usar el producto.

Mantenga este medicamento fuera del alcance de los niños.

En caso de una sobredosis, consiga atención médica o comuníquese con un centro de control de envenenamiento de inmediato.

INSTRUCCIONES

Adultos y niños mayores de 12 años: tome dos (2) tabletas tres (3) veces al día hasta dos días. Tome con un vaso de agua, durante o después de las comidas, según sea necesario. No lo utilice durante más de 2 días (12 tabletas) sin consultar a un médico.

Niños menores de 12 años: no se utilice sin consultar a un médico.

OTRA INFORMACIÓN y PRECAUCIONES

- Este producto puede interferir con los análisis de laboratorio, incluso los análisis de orina, glucosa (azúcar) y cetonas.
- Este producto puede manchar los lentes de contacto blandos y otros artículos si los manipula después de tocar las tabletas.
- El tamaño y el color de las tabletas puede variar.
- **Carcinogénesis:** la administración a largo plazo del hidrocloreto de fenazopiridina ha inducido neoplasia en ratas (intestino grueso) y ratones (hígado). Aunque no se ha informado acerca de ningún caso que relacione el hidrocloreto de fenazopiridina con la neoplasia en humanos, no se han efectuado estudios epidemiológicos adecuados al respecto.
- **Almacenaje:** almacénese a temperatura ambiental (15° a 30°C) en un sitio seco, y protéjase de la luz.
- Evidencia de alteraciones: el producto viene sellado en blísteres. No lo use si alguna parte del blíster está rota, abierta o dañada.

Para preguntas, dudas o para informar acerca de una reacción adversa, llame al (800) 722-3476 o visite www.azoproducts.com

Packaging

RELIEF That's Fast

AZO

Urinary Pain Relief®

MAXIMUM STRENGTH

- **STRONGEST UTI PAIN RELIEVER AVAILABLE+**
- **EVEN HIGHER DOSE TO RELIEVE PAIN, BURNING & URGENCY+**
- **TARGETS THE SOURCE OF PAIN**

#1 MOST TRUSTED BRAND*

__ TABLETS

99.5 mg

Phenazopyridine Hydrochloride

+Among AZO Urinary Pain Relief® products.

* #1 Most Trusted Brand based on Total AZO Brand Nielsen data through 10/04/25 and the 2025 Pharmacy Times Survey (Urinary Pain Relief and Cranberry Supplement categories).



AZO Urinary Pain Relief®
MAXIMUM STRENGTH

RELIEF That's Fast

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Urinary Pain Relief®

MAXIMUM STRENGTH

#1 MOST TRUSTED BRAND†

- ✓ STRONGEST UTI PAIN RELIEVER AVAILABLE
- ✓ EVEN HIGHER DOSE TO RELIEVE PAIN, BURNING & URGENCY*
- ✓ TARGETS THE SOURCE OF PAIN

12 TABLETS

99.5 mg Phenazopyridine Hydrochloride

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AZO Values:

- We believe in open, honest conversations about women's health
 - We believe in helping you take charge of your health
 - We believe in helping you live your life to the fullest
 - We believe in delivering the best urinary, vaginal, and bladder health products available
- We believe in helping you, OWN YOUR DAY.®

AZO

Urinary Pain Relief®

MAXIMUM STRENGTH



AMBM686

Drug Facts

Active ingredient (in each tablet)	Purpose
Phenazopyridine Hydrochloride 99.5 mg	Urinary tract analgesic

Use Relief from urinary pain, burning, urgency and frequency associated with urinary tract infections.

Warnings
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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 breastfeeding, ask a health professional before use. **A pregnancy test and consultation with a health professional if pregnancy is confirmed is recommended prior to use.**

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Other Information • This product can interfere with laboratory tests including urine, glucose (sugar), and ketones tests • This product may stain soft contact lenses and other items if handled after touching tablets • Store at room temperature (59°-86°F) in a dry place and protect from light. **Tamper evident:** Product is sealed within blisters. Do not use if any part of the blister is torn, open or damaged.

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Distributed by I-Health, Inc., 55 Sebesthe Drive, Cromwell, CT 06416

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Información y instrucciones en Español adjuntas

AZO Urinary Pain Relief®
MAXIMUM STRENGTH

RELIEF That's Fast

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MAXIMUM STRENGTH

#1 MOST TRUSTED BRAND†

- ✓ STRONGEST UTI PAIN RELIEVER AVAILABLE
- ✓ EVEN HIGHER DOSE TO RELIEVE PAIN, BURNING & URGENCY*
- ✓ TARGETS THE SOURCE OF PAIN

24 TABLETS

99.5 mg Phenazopyridine Hydrochloride

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MAXIMUM STRENGTH



AMBM6968

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Información y instrucciones en Español adjuntas

AZO

Urinary Pain Relief[®]
**MAXIMUM
STRENGTH**

Urinary Pain Relief Tablets

Active ingredient: Each analgesic tablet contains Phenazopyridine Hydrochloride 99.5 mg.

Fast relief of urinary discomfort including common urinary tract infection symptoms: Urinary pain, burning, urgency and frequency.

URINARY TRACT INFECTION (UTI)

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AM16146

AZO

Urinary Pain Relief[®]
**MAXIMUM
STRENGTH**

Alivio rápido para el dolor de las vías urinarias

Ingrediente activo: Cada tableta de analgésico contiene 99.5 mg de hidrocloruro de fenazopiridina.

Alivio rápido de la incomodidad en las vías urinarias que incluye los síntomas comunes de infección en las vías urinarias: dolor al orinar, ardor, urgencia y frecuencia.

INFECCIÓN DE LAS VÍAS URINARIAS

Los síntomas de incomodidad en las vías urinarias pueden indicar la presencia de una infección. Si tiene síntomas como dolor, ardor, urgencia y frecuencia, necesita llamar a su médico para recibir un diagnóstico y que le dé una receta para tratar la infección. Mientras espera para ver al doctor y para que el medicamento que le recete comience a funcionar, puede obtener un alivio rápido de sus síntomas con AZO Urinary Pain Relief[®] Maximum Strength.

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ADVERTENCIAS

Consulte a su médico antes de usar este producto si:

- tiene problemas renales o hepáticos.
- tiene alergias a alimentos, conservadores o tintes.
- ha tenido una reacción alérgica a el hidrocloruro de fenazopiridina.

No usar: si tiene una deficiencia de glucosa-6-fosfato deshidrogenasa (G6PD), a menos que su médico lo apruebe.

Al usar este producto:

- puede sentir malestar estomacal. Tómelo durante o después de las comidas para ayudar a disminuir el malestar.
- **la orina adquiere un color anaranjado rojizo.**
- **Esto no es dañino, pero debe tener cuidado para evitar manchar a ropa u otros artículos.**

Deje de usar este producto y consulte a su médico si piensa que puede estar teniendo una reacción adversa al medicamento o si sus síntomas duran más de dos días.

Si usted está embarazada o lactando, consulte a un profesional médico antes de usar este producto. Se recomienda una prueba de embarazo y una consulta con un profesional médico si se confirma un embarazo antes de usar el producto.

Mantenga este medicamento fuera del alcance de los niños. En caso de una sobredosis, consiga atención médica o comuníquese con un centro de control de envenenamiento de inmediato.

INSTRUCCIONES

Adultos y niños mayores de 12 años: tome dos (2) tabletas tres (3) veces al día hasta dos días. Tome con un vaso de agua, durante o después de las comidas, según sea necesario. No lo utilice durante más de 2 días (12 tabletas) sin consultar a un médico.

Niños menores de 12 años: no se utilice sin consultar a un médico.

OTRA INFORMACIÓN Y PRECAUCIONES

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- Este producto puede manchar los lentes de contacto blandos y otros artículos si los manipula después de tocar las tabletas.
- El tamaño y el color de las tabletas puede variar.
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- **Almacenaje:** almacénese a temperatura ambiental (15° a 30°C) en un sitio seco, y protéjase de la luz.
- **Evidencia de alteraciones:** el producto viene sellado en blísteres. No lo use si alguna parte del blíster está rota, abierta o dañada.

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AZO URINARY PAIN RELIEF MAXIMUM STRENGTH

phenazopyridine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49973-247
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENAZOPYRIDINE HYDROCHLORIDE (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)	PHENAZOPYRIDINE HYDROCHLORIDE	99.5 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	red (Maroon)	Score	no score
Shape	CAPSULE	Size	9mm
Flavor		Imprint Code	99
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49973-247-12	6 in 1 BOX	07/02/2018	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:49973-247-24	12 in 1 BOX	07/02/2018	
2		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:49973-247-96	48 in 1 BOX	02/22/2019	01/31/2023
3		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:49973-247-06	3 in 1 BOX	06/15/2023	

4		2 in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:49973-247-48	24 in 1 BOX	12/08/2025	
5		2 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		07/02/2018	

Labeler - i-Health, Inc. (061427694)

Revised: 11/2025

i-Health, Inc.