URICALM MAXIMUM STRENGTH- phenazopyridine hydochloride tablet, film coated
Alva-Amco Pharmacal Companies, 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.

Uricalm

Active ingredient (in each tablet)

Phenazopyridine hydrochloride, 99.5 mg

Purpose

Urinary Analgesic

Uses

Prompt temporary relief of:
- pain during urination
- burning
- sensation of urgency
- increased frequency

associated with urinary tract infections.

Warnings

Do not use if you have
- liver or kidney problems
- allergies to foods, preservatives or dyes
- had a hypersensitive reaction to phenazopyridine hydrochloride.

When using this product
- stomach upset may occur; taking this product with or after meals may reduce stomach upset
- you may experience a reddish-orange discoloration of the urine which is a non-harmful temporary effect.

Ask a doctor or pharmacist before use if you are taking any other medications.

Stop use and ask a doctor if

- your symptoms do not go away after two days or become worse
- you experience fever, chills, back pain or bloody urine
- you suspect you are having an adverse reaction to this medication.

If pregnant or breastfeeding, 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.

Directions

- Read all package directions and warnings before use.
- Use only as directed.
- Do not exceed recommended dosage.
- Adults: Swallow two (2) tablets with water after meals as needed up to 3 times daily for 2 days maximum.
- Swallow whole. Do not crush or chew.
- Do not use more than 12 tablets in 2 days.
- Drink 6 to 8 eight glasses of water daily.
- For use by normally healthy adults only. Persons under 18 years of age should use only as directed by a doctor.

Other information

WARNING: this product contains a chemical known to the State of California to cause cancer. **Precaution:** Carcinogenesis: Long-term administration of phenazopyridine HCl has induced neoplasia in rats (large intestine) and mice (liver) . Although no association between phenazopyridine HCl and human neoplasia has been reported, adequate epidemiological studies along these lines have not been conducted. ****Contents sealed:** Each URICALM MAX dark red colored, round shaped tablet bears the identifying mark "ALVA" and a "1" on the reverse side, and is sealed in a clear plastic blister with with foil backing. Do not use if seal appears broken or if product contents do not match product description. This product may stain soft contact lenses. This product can interfere with laboratory tests including urine, glucose (sugar) and ketones. You may report serious side effects to the phone number provided under *Questions?* below.

Inactive ingredients

Cornstarch, Cranberry Fruit Powder, Croscarmellose Sodium, FD&C Red No. 40 Lake, FD&C Yellow No. 6 Lake, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Mineral Oil, Polyethylene Glycol, Polyvinylpyrrolidone, Pregelatinized Starch, Silicon Dioxide, Talc, Titanium Dioxide and Triacetin.

Questions? 1-800-792-2582.

Product Insert

DOCTOR RECOMMENDED

Uricalm Max

199 mg Strong per dose

The Highest Dose of Clinically Proven Phenazopyridine Hydrochloride Available Over the Counter, Plus Cranberry

URICALM MAX provides the maximum non-prescription strength of clinically proven Phenazopyridine Hydrochloride to relieve pain, burning, increased frequency, and sensation of urgency associated with urinary tract infections. URICALM MAX has 99.5 mg of Phenazopyridine Hydrochloride per tablet - no other OTC brand contains more. Plus, URICALM MAX contains cranberry, which is used extensively by those concerned about urinary tract health.

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- burning
- sensation of urgency
- increased frequency associated with urinary tract infections.

Warnings

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- had a hypersensitive reaction to phenazopyridine hydrochloride

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Stop use and ask a doctor if
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- you experience fever, chills, back pain or bloody urine.
- you suspect you are having an adverse reaction to this medication

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Inactive ingredients:Corn starch, cranberry fruit powder, croscarmellose sodium, FD&C Red No. 40 Lake, FD&C Yellow No. 6 Lake, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, polyethylene glycol, polyvinylpyrrolidone, pregelatinized starch, silicon dioxide, talc, titanium dioxide and triacetin.

Questions? **1-800-792-2582**

www.URICALM.com

RECOMENDADO POR MÉDICOS

Uricalm Max

199 mg de concentración por dosis

Contiene la dosis más alta de phenazopyridine hydrochloride clínicamente comprobado disponible en venta sin receta, además de arándano

URICALM MAX ofrece la dosis más alta de phenazopyridine hydrochloride clínicamente comprobado de venta sin receta para aliviar el dolor, el ardor, el aumento en la frequencia y la sensación de necesidad urgente de orinar asociados con las infecciones del tracto urinario. URICALM MAX tiene 99.5 mg de phenazopyridine hydrochloride por tableta; ninguna otra marca de venta sin receta contiene más. Además, URICALM MAX contiene arándano, que es usado ampliamente por quienes se preocupan por la salud del tracto urinario.

Ingrediente activo (in cada tableta): Phenazopyridine hydrochloride 99.5 mg

Propósito: Analgésico urinario

Usos: Alivio rápido y temporal del
- dolor durante la micción
- del ardor
- de la sensación de necesidad urgente de orinar
- del aumento en la frecuencia asociada con las infecciones del tracto urinario.

Advertencias:

No lo use si tiene
- problemos hepático o renales
- alergias a los alimentos, conservantes o colorantes
- ha tenido una reacción hipersensible al phenazopyridine hydrochloride

Cuando se use este producto
- puede presentarse malestar estomical; la ingestión de este producto con alimentos o después de comer puede reducir el malestar estomacal
- puede experimentar un color de rojizo a anaranjado en la orina, lo cual es un efecto temporal inofensivo.

Consulte con un médico o farmacéutico antes de usarlo si está tomando cualquier otro medicamento.

Interrumpa el uso y consulte con su médico si
- los síntomas no desaparecen o empeoran después de dos dias
- tiene fiebre, escalofríos, dolor de espalda o nota la presencia de sangre en la orina.
- sospecha que está experimentado una reacción adversa a este medicamento.

Si está embarazada o lactando, consulte con un profesional de la salud antes de usario.

Manténgalo fuera del alcance de los niños. En caso de sobredosis, obtenga ayuda médica o comuníquese de inmediato con un centro de toxicologia.

Indicaciones:
- Lea todos las indicaciones y advertencias en el envase antes de usarlos.
- Úselo únicamente como se indica.
- No exceda la dosis recomendada.
- Adultos: Ingiera dos (2) tabletas con agua después de las comidas según sea necesario hasta 3 veces al día por un máximo de 2 dias.
- Trague la tablets entera. No triture ni mastique la tableta.
- No use más de 12 tabletas en 2 días.
- Tome de 6 a 8 vasos de agua todos los dias.
- Para usarlo en adultos normalmente sanos únicamente. Las personas menores de 18 años deben usarlo solo según las indicaciones de un médico.

Información adicional: ADVERTENCIA: Este producto contiene una sustancia quimica que en el Estado de California se sabe que causa cáncer. Precaución: Carcinogénesis: La administración a largo plazo del phenazopyridine hydrochloride ha inducido neoplasia en ratas (intestino grueso) y en ratones (hígado). Aunque no ha sido informada una asociación entre el phenazopyridine hydrochloride y la neoplasia en seres humanos, no se han realizado estudios epidemiológicos adecuados sobre esto.

****El contenido está sellado** Cada tableta URICALM MAX de color rojo oscuro y redonda lleva la marca identificadora "ALVA" y un "1" en el dorso, y está sellada en un blíster de plástico transperente con un recubrimiento posterior de papel aluminio. No lo use si el sello parece estar roto o si el producto no coincide con la descripción del producto. Este producto puede causar manchas en los lentes de contacto blandos. Este producto puede interferir con las pruebas de laboratorio incluidas orina, glucosa (azúcar) y cetonas. Puede informar efectos secundarios graves al número de teléfono

que aparece en la sección **¿Tiene preguntas?** a continuación.

Ingredientes inactivos: Almidón de maíz, polvo de la fruta de arándano, croscarmelosa sódica, FD&C Rojo No. 40 Lake, FD&C Amarillo No. 6 lake, hipromelosa, estearato de magnesio, celulosa microcristalina, aceite mineral, polietilenglicol, polivinilpirrolidona, almidón pregelatinizado, dióxido de silicio, talco, dióxido de titanio y tracetino.

¿Tiene preguntas? 1-800-792-2582

www.URICALM.com

URICALM MAXIMUM STRENGTH

phenazopyridine hydochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52389-241
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	
CRANBERRY (UNII: 0MVO31Q3QS)	

Product Characteristics

Color	red	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	ALVA;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52389-241-24	1 in 1 CARTON	04/29/2008	
1	NDC:52389-241-01	24 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:52389-241-12	1 in 1 CARTON	08/01/2009	12/31/2011
2	NDC:52389-241-02	12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:52389-241-36	1 in 1 CARTON	07/15/2012	06/15/2013
3	NDC:52389-241-03	36 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:52389-241-28	1 in 1 CARTON	02/20/2014	
4	NDC:52389-241-04	28 in 1 BLISTER PACK; Type 0: Not a Combination Product		

5	NDC:52389-241-48	2 in 1 CARTON	10/18/2021	
5		24 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		04/29/2008	

Labeler - Alva-Amco Pharmacal Companies, Inc. (042074856)

Revised: 5/2024 Alva-Amco Pharmacal Companies, Inc.