

DIUREX WATER PILLS- caffeine, magnesium salicylate tablet, coated
Alva-Amco Pharmacal Companies, Inc.

Diurex Water Pills

Active ingredients (in each pill)

Caffeine, 50 mg

Magnesium Salicylate (NSAID)*, 162.5 mg

(Present as 202 mg of the Tetrahydrate)

*Non-steroidal anti-inflammatory drug

Purpose

Diuretic

Analgesic (pain reliever)

Uses

For temporary relief of

- temporary water retention
- bloat
- swelling
- full feeling
- fatigue
- minor aches and pains

associated with the premenstrual and menstrual periods.

Warnings

Reye's Syndrome: Children and teenagers should not use this product for chicken pox or flu symptoms before a doctor is consulted about Reye's Syndrome, a rare but serious illness reported to be associated with aspirin.

Allergy alert: Magnesium Salicylate may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Stomach bleeding warning: This product contains a non-steroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed.

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer.

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you are taking a diuretic.

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout or arthritis
- taking any other drug

When using this product, limit the use of caffeine containing medications, foods or beverages because too much caffeine may cause:

- nervousness
- irritability
- sleeplessness
- occasional rapid heart beat

The recommended dose of this product contains about as much caffeine as one cup of coffee.

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- pain gets worse or lasts more than 10 days.
- fever gets worse or lasts more than 3 days.
- redness or swelling is present.
- ringing in the ears or loss of hearing occurs.
- any new symptoms appear.
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better.

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 and use only as directed.
- Adults: Two (2) pills every 4 to 6 hours while symptoms persist, not to exceed eight (8) pills per day.
- Start taking 5 or 6 days before onset of period and continue until desired relief is obtained or end of period.
- Drink 6 to 8 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.
- Note: DIUREX Water Pills will not discolor urine.

Other information

Magnesium content: 15 mg/pill, Calcium content: 10 mg/pill ****Contents sealed:** Each DIUREX blue colored, round shaped pill bears the identifying mark "ALVA" and is sealed in a clear plastic blister with a foil backing. Do not use if seal appears broken or if product contents do not match product description. You may report serious side effects to the phone number provided under *Questions?* below.

Inactive ingredients

Acacia, calcium carbonate, corn starch, croscopovidone, FD&C Blue #1 Lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, mineral oil, polyethylene glycol, polysorbate 80, silica, sodium starch glycolate, stearic acid, talc, titanium dioxide, triacetin.

Questions? 1-800-792-2582

Datos farmacológicos

Ingredientes activos (en cada comprimido)

	Propósito
Cafeína 50 mg.	Diurético
Salicilato de magnesio (AINE)‡ 162.5 mg.	Analgésico (alivia el dolor)

(Presentación en 202 mg de tetrahidrato)
‡Fármaco antiinflamatorio no esteroideo

Usos Para el alivio temporal de ■ retención temporal de líquidos ■ distensión abdominal ■ hinchazón ■ sensación de saciedad ■ fatiga ■ dolores menores asociados con los períodos menstruales y premenstruales.

Advertencias

Síndrome de Reye: este producto no debe usarse en niños y adolescentes para los síntomas de varicela o gripe sin antes consultar con un médico acerca del síndrome de Reye, una enfermedad rara pero grave que, según se informa, está relacionada con la aspirina.

Alerta de alergias: el salicilato de magnesio puede causar una reacción alérgica grave que puede incluir: ■ urticaria ■ hinchazón facial ■ asma (sibilancias) ■ choque.

Advertencia de sangrado estomacal: Este producto contiene un fármaco

antinflamatorio no esteroideo (AINE), que puede causar sangrado estomacal grave. Las probabilidades son mayores si usted ■ tiene 60 años o más ■ ha tenido problemas de sangrado o úlceras estomacales ■ toma un fármaco diluyente de la sangre (anticoagulante) o esteroideo ■ toma otros fármacos que contienen AINE de venta con o sin receta [aspirina, ibuprofeno, naproxeno u otros] ■ bebe 3 o más bebidas alcohólicas cada día mientras usa este producto ■ toma más cantidad o durante un tiempo más prolongado que el indicado.

No use el producto si alguna vez tuvo una reacción alérgica a cualquier otro analgésico o fármaco para reducir la fiebre.

Consulte a un médico antes de usarlo si ■ la advertencia de sangrado estomacal se aplica a usted ■ tiene antecedentes de problemas estomacales, como acidez ■ tiene presión arterial alta, cardiopatía, cirrosis hepática o nefropatía ■ toma diuréticos.

Consulte a un médico o farmacéutico antes de usarlo si ■ toma un fármaco de venta con receta para la diabetes, gota o artritis ■ toma algún otro fármaco.

Cuando use este producto, limite el uso de medicamentos, alimentos o bebidas que contengan cafeína ya que demasiada cafeína puede provocar: ■ nerviosismo ■ irritabilidad ■ insomnio ■ latidos cardíacos rápidos ocasionales. La dosis recomendada de este producto contiene aproximadamente la misma cantidad de cafeína que una taza de café. ▼

Datos farmacológicos (continuación)

Advertencias (continuación)

Interrumpa el uso y consulte a un médico si ■ se produce una reacción alérgica, y busque ayuda médica de inmediato ■ el dolor empeora o dura más de 10 días ■ la fiebre empeora o dura más de 3 días ■ se produce enrojecimiento o hinchazón ■ aparecen zumbidos en los oídos o pérdida de la audición ■ aparecen síntomas nuevos ■ experimenta cualquiera de los siguientes signos de sangrado estomacal: ■ sensación de desmayo ■ vómitos con sangre ■ heces negras o con sangre ■ dolor estomacal que no mejora.

Si está embarazada o amamantando, consulte a un profesional de la salud antes de usarlo. **Mantener fuera del alcance de los niños.** En caso de sobredosis, obtenga ayuda médica o comuníquese de inmediato con un centro de toxicología.

Indicaciones ■ Lea todas las indicaciones y advertencias del envase antes de usar el producto y úselo solo según las indicaciones. ■ Adultos: dos (2) comprimidos cada 4 a 6 horas mientras los síntomas persistan, sin exceder los ocho (8) comprimidos por día. ■ Comience a tomarlo 5 o 6 días antes del inicio del período y continúe hasta que se obtenga el alivio deseado o hasta el final del período. ■ Tome de 6 a 8 vasos de agua todos los días. ■ Para uso por parte de adultos normalmente sanos únicamente. ■ Las personas menores de 18 años deben usarlo solo según las indicaciones de un médico. ■ Nota: Los comprimidos contra la retención de líquido DIUREX no tiñen la orina.

Información adicional Contenido de magnesio: 15 mg/comprimido, contenido de calcio: 10 mg/comprimido ****Contenido sellado:** cada comprimido DIUREX, de color

azul y forma redonda lleva la marca identificatoria "ALVA" y está sellado en un blíster de plástico transparente con un recubrimiento posterior de papel aluminio. No lo use si el sello parece estar roto o si el contenido del producto no coincide con la descripción del producto. ■ Puede informar efectos secundarios graves al número de teléfono que aparece en la sección *¿Tiene preguntas?* a continuación.

Ingredientes inactivos Acacia, carbonato de calcio, almidón de maíz, crospovidona, FD&C azul n.º 1 Lake, hipromelosa, estearato de magnesio, maltodextrina, celulosa microcristalina, aceite mineral, polietilenglicol, polisorbato 80, sílice, glucolato de almidón sódico, ácido esteárico, talco, dióxido de titanio, triacetina.

¿Tiene preguntas? 1-800-792-2582



Drug Facts (continued)
Inactive Ingredients Acacia, calcium carbonate, corn starch, croscopolone, FD&C Blue #1 Lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, mineral oil, polyethylene glycol, poly sorbate 80, silica, sodium starch glycolate, stearic acid, talc, titanium dioxide, triacetin.
Questions? 1-800-792-2582
www.DIUREX.com

Drug Facts
Active Ingredients (in each pill)
 Caffeine 50 mg.....Diuretic
 Magnesium Salicylate (NSAID)† 162.5 mg.....Analgesic (pain reliever)
 †Non-steroidal anti-inflammatory drug
Uses For temporary relief of ■ temporary water retention ■ bloating ■ swelling ■ full feeling
 ■ fatigue ■ minor aches and pains associated with the premenstrual and menstrual periods.
Warnings
Reye's Syndrome: Children and teenagers should not use this product for chicken pox or flu symptoms before a doctor is consulted about Reye's Syndrome, a rare but serious illness reported to be associated with aspirin.
Allergy alert: Magnesium Salicylate may cause a severe allergic reaction which may include:
 ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock.
Stomach bleeding warning: This product contains a non-steroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed.
Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer. Ask a doctor before use if ■ stomach bleeding warning applies to you ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis or kidney disease ■ you are taking a diuretic.
Ask a doctor or pharmacist before use if you are ■ taking a prescription drug for diabetes, gout or arthritis ■ taking any other drug.
When using this product, limit the use of caffeine-containing medications, foods or beverages because too much caffeine may cause: ■ nervousness ■ irritability ■ sleeplessness ■ occasional rapid heart beat. The recommended dose of this product contains about as much caffeine as one cup of coffee.
Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away. ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ ringing in the ears or loss of hearing occurs ■ any new symptoms appear ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better.
If pregnant 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.
Directions ■ Read all package directions and warnings before use and use only as directed. ■ Adults: Two (2) pills every 4 to 6 hours while symptoms persist, not to exceed eight (8) pills per day. ■ Start taking 5 or 6 days before onset of period and continue until desired relief is obtained or end of period. ■ Drink 6 to 8 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. ■ Note: DIUREX Water Pills will not discolor urine.
Other information Magnesium content: 15 mg/pill, Calcium content: 10 mg/pill
****Contents sealed:** Each DIUREX blue colored, round shaped pill bears the identifying mark "ALVA" and is sealed in a clear plastic blister with a foil backing. Do not use if seal appears broken or if product contents do not match product description. ■ You may report serious side effects to the phone number provided under **Questions?** below.

*Based on independent syndicated market research data.



DIUREX WATER PILLS

caffeine, magnesium salicylate tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52389-306
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

MAGNESIUM SALICYLATE (UNII: 41728CY7UX) (SALICYLIC ACID - UNII:O414PZ4LPZ)	MAGNESIUM SALICYLATE	162.5 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	50 mg

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (UNII: 2S7830E561)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	blue	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	ALVA
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52389-306-84	2 in 1 CARTON	05/02/2012	
1	NDC:52389-306-01	42 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:52389-306-42	1 in 1 CARTON	05/15/2005	
2	NDC:52389-306-01	42 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:52389-306-22	2 in 1 CARTON	05/15/2005	11/30/2018
3	NDC:52389-306-02	11 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:52389-306-21	2 in 1 CARTON	09/15/2014	10/31/2018
4		21 in 1 BLISTER PACK; Type 0: Not a Combination		

4		Product		
5	NDC:52389-306-36	2 in 1 CARTON	02/14/2020	
5		18 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
OTC Monograph Drug	M027	05/15/2005	

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

Revised: 4/2024

Alva-Amco Pharmacal Companies, Inc.