DIUREX- pamabrom capsule, liquid filled 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.

Diurex Aquagels

Active ingredient (in each soft gel capsule)

Solubilized pamabrom, 50 mg

Purpose

Diuretic

Uses

For the relief of

- temporary water retention
- bloating
- swelling
- full feeling

associated with the premenstrual and menstrual periods.

Warnings

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

Stop use and ask a doctor if symptoms last for more than ten consecutive days.

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.
- Adults: One (1) soft gel capsule after breakfast with a full glass of water.
- Dose may be repeated after 6 hours, not to exceed four (4) soft gel capsules in 24 hours.
- 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.

Other information

**Contents sealed: Each Diurex Aquagel, clear translucent blue colored, oval shaped soft gel

capsule 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

FD&C Blue #1, gelatin, glycerin, hypromellose, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol and titanium dioxide.

Questions? 1-800-792-2582

Datos farmacológicos

Ingrediente activo (en cada cápsula blanda)

Propósito

Pamabrom solubilizado 50 mg Diurético

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

Advertencias

Consulte a un médico o farmacéutico antes de usar el producto si está tomando cualquier otro medicamento.

Interrumpa el uso y consulte a un médico si los síntomas duran más de diez días consecutivos.

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 usarlo. ■ Úselo solo de acuerdo con las indicaciones. ■ Adultos: una (1) cápsula blanda después del desayuno con un vaso lleno de agua. ■ La dosis puede repetirse después de 6 horas, sin exceder las cuatro (4) cápsulas en 24 horas.
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.

Información adicional **Contenido sellado: cada cápsula blanda DIUREX AQUAGEL, de color azul brillante translúcido y forma ovalada lleva la marca identificatoria "ALVA" y está sellada 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 FD&C azul n.º 1, gelatina, glicerina, hipromelosa, polietilenglicol, povidona, propilenglicol, agua purificada, sorbitol y dióxido de titanio.

¿Tiene preguntas? 1-800-792-2582



water bloat



36/20-7RG,

diureX aquagels

Water **Pills**

DOCTOR RECOMMENDED

NEW LOOK!

gentle diuretic

AQUAGELS®

Píldoras Diuréticas sin cafeína CAFFEINE FREE **Nater Pills**

/ea las instrucciones en español adentro

Feel Better & **Less Heavy**

Effective Bloat Relief

Water Pills CAFFEINE

20 **SOFTGELS**

diurex Aquagels Water Pills CAFFEINE

Relieves Periodic Water Bloat



80253 2/19

moo.X3RUIG.www

Contains no gluten ingredients

and effective by an FDA expert advisory panel when used as directed. The active ingredient in DIUREX AQUAGELS has been recognized to be safe

Questions? 1-800-792-2582

polyethylene glycol, povidone, propylene glycol, purified water, sorbitol and Inactive ingredients FD&C Blue #1, gelatin, glycerin, hypromellose,

phone number provided under Questions? below. match product description. • You may report serious side effects to the backing. Do not use if seal appears broken or if product contents do not clear translucent blue colored, oval shaped softgel capsule bears the identifying mark "ALVA" and is sealed in a clear plastic blister with a foil beating the street sealed in a clear plastic blister with a foil beating the sealed in a clear plastic blister with a foil beating the sealed in a clear plastic blister with a foil beating the sealed in a clear plastic blister with a foil beating the sealed in a clear plastic blister with a foil bl Other information **Contents sealed: Each DIUREX AQUAGEL

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*Based on independent syndicated market research data.





DIUREX

pamabrom capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52389-136
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PAMABROM (UNII: UA8 U0 KJM72) (BROMOTHEOPHYLLINE - UNII:FZG87K1MQ6)	PAMABROM	50 mg	

Inactive Ingredients		
Ingredient Name	Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
PO VIDO NE K29/32 (UNII: 390 RMW2PEQ)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE (oval soft gel capsule)	Size	8mm
Flavor		Imprint Code	ALVA
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52389-136-20	1 in 1 CARTON	04/15/2013	
1	NDC:52389-136-03	20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:52389-136-40	2 in 1 CARTON	07/17/2019	
2		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:52389-136-24	1 in 1 CARTON	09/18/2019	
3		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:52389-136-48	2 in 1 CARTON	09/18/2019	
4		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		04/10/2000	

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

Revised: 9/2019 Alva-Amco Pharmacal Companies, Inc.