

FLANADOL PRONTO BISMUTH- bismuth subsalicylate liquid
Jomex International Llc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

FLANADOL PRONTO BISMUTH

Drug Facts

Active ingredient (in each 15mL Tablespoonful = TBSP)

Bismuth Subsalicylate 262 mg

Purposes

Upset stomach reliever and antidiarrheal

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Uses relieves • diarrhea • heartburn • indigestion • nausea • upset stomach

Warnings

Reye's Syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behaviour with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Contains salicylate. Do not take if you are

- allergic to salicylates (including aspirin)
- taking other salicylate products

Do not use if you have • an ulcer • a bleeding problem • bloody or black stool

Ask a doctor before use if you have • fever • mucus in the stool

Ask a doctor or pharmacist before use if you are taking any drug for • anticoagulation (thinning the blood) • diabetes • gout • arthritis

When using this product a temporary, but harmless darkening of the stool and/or tongue may occur

Stop use and ask a doctor if • symptoms get worse or last more than 2 days • diarrhea lasts more than 2 days • ringing in the ears or loss of hearing occurs

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

Directions • shake well before use

- use dose cup or tablespoon (TBSP)
- adults and children 12 years and over:
1 dose (30 mL or 2 TBSP) every 1/2 to 1 hour as needed
- do not exceed 8 doses (240 mL or 16 TBSP) in 24 hours

- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Inactive ingredients benzoic acid, flavor, magnesium aluminium silicate, methylcellulose, purified water, red 22, red 28, saccharin sodium, salicylic acid, simethicone emulsion, sodium salicylate, sorbic acid, xanthan gum

Other information

- **each 15 mL tablespoonful contains:** sodium 6 mg
- salicylate 130 mg • protect from freezing • low sodium • sugar free
- avoid excessive heat (over 104°F or 40°C)
- visit www.info-xtra.com for health information
- **TAMPER EVIDENT:** Do not use if imprinted neckband is missing or broken

Questions? 1-866-838-7456

Regular Strength

Manufactured for:
Jomex Pharmaceuticals, LLC
Fairfax Station, VA 22039 USA

Manufactured by:
GCP Laboratories, Inc.
Gulfport, MS 39501

www.jomexusa.com
www.flanadolusa.com

Packaging

Drug Facts (continued)

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← Levante la tapa posterior para ver los datos del medicamento en español.

ALIVIA EL
MALESTAR
ESTOMACAL

FLANADOL PRONTO BISMUTH

BISMUTH SUBSALICYLATE 262 mg/15 mL
Regular Strength
Antidiarrheal/Antidiarréico

5 SYMPTOM RELIEF

- Heartburn
- Indigestion
- Upset Stomach
- Diarrhea
- Nausea

ALIVIA 5 SÍNTOMAS

- Acidez estomacal
- Indigestión
- Malestar estomacal
- Diarrea
- Nausea

Compare to the Active Ingredient of
PEPTO-BISMOL®
NDC 69458-713-08



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(in each 15 mL Tablespoonful = TBSP)

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Levante la tapa posterior para ver los
datos del medicamento en español.

389-02112-0 REV GC-0915

*This product is not
manufactured or
distributed by the
owner of the registered
trademark Pepto-Bismol®

PBR004C

EXP 08/17

12 FL OZ (355 mL)

SPANISH LABEL

Datos del medicamento

Ingrediente activo **Propósitos**
(en cada cucharada de 15 mL = CDA)
 Subsalicilato de Bismuto 262 mg.....
Alivio del malestar estomacal y antidiarréico

Usos alivia • diarrea • acidez • indigestión • náusea
 • malestar estomacal

Advertencias
Síndrome de Reye: Niños y adolescentes con varicela o recuperándose de la misma o con síntomas parecidos a la influenza no deben usar este producto. Cuando use este producto, consulte con su médico si hay cambios de comportamiento con náusea y vómitos ya que estos pueden ser síntomas tempranos del síndrome de Reye, una enfermedad rara pero grave.

Alerta de alergias: Contiene salicilato. No tomar este medicamento
 • si es alérgico a salicilatos (incluyendo aspirina)
 • si está tomando otros productos con salicilato

No usar si tiene • úlceras • problemas de sangramiento
 • heces ensangrentadas o negras

Consultar con un médico si tiene
 • fiebre • mucosidad en las heces

Consultar con el médico o farmacéutico si está tomando medicamentos • anticoagulantes • para diabetes
 • para gota • para artritis

El uso de este producto puede causar oscurecimiento temporal pero inofensivo de las heces o la lengua

Suspender el uso y consultar con el médico si
 los síntomas empeoran o duran más de 2 días

Datos del medicamento *(continuación)*

- la diarrea dura más de 2 días
- le zumban los oídos o experimenta pérdida de audición

Si está embarazada o dando de lactar, consulte con un profesional de salud antes de usar.
Mantener lejos del alcance de los niños. En caso de sobredosis, buscar ayuda médica o comunicarse con un Centro de Control de Envenenamiento inmediatamente.

Instrucciones • Agitar bien antes de usar
 • usar un vaso dosificador o cuchara (CDA)
 • adultos y niños de 12 años o más:
 1 dosis (30 mL o 2 cdas) cada ½ hora a 1 hora según sea necesario
 • no exceder 8 dosis (240 mL o 16 cdas) en 24 horas
 • usar hasta que se detenga la diarrea pero por no más de 2 días
 • niños menores de 12 años: Consultar con un médico
 • tomar abundantes líquidos claros para evitar deshidratación causada por la diarrea.

Información adicional
 • cada cucharada de 15 mL contiene: sodio 6 mg
 • salicilato 130 mg • proteger de temperaturas heladas
 • bajo en sodio • sin azúcar
 • evitar excesos de calor (más de 104°F ó 40°C)
 • visitar www.info-xtra.com para información de salud
 • **CIERRE DE SEGURIDAD:** No utilizar si el sello impreso falta o está roto.

Ingredientes inactivos
 ácido benzoico, sabor, silicato de aluminio magnesio, hipromelosa, agua purificada, rojo 22, rojo 28, sacarina sódica, ácido salicílico, emulsión de simeticona, salicilato de sodio, ácido sórbico, goma de xantán

¿Preguntas? 1-866-838-7456

FLANADOL PRONTO BISMUTH

bismuth subsalicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69458-713
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	262 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
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BENZOIC ACID (UNII: 8SKN0B0MM)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
METHYLCELLULOSE (100 CPS) (UNII: 4GFU244C4J)
WATER (UNII: 059QF0KO0R)
D&C RED NO. 22 (UNII: 1678RKX8RT)
D&C RED NO. 28 (UNII: 767IP0Y5NH)
SACCHARIN SODIUM (UNII: SB8ZUX40TY)
SALICYLIC ACID (UNII: O414PZ4LPZ)
DIMETHICONE (UNII: 92RU3N3Y1O)
SODIUM SALICYLATE (UNII: WIQ1H85SYP)
SORBIC ACID (UNII: X045WJ989B)
XANTHAN GUM (UNII: TTV12P4NEE)
METHYL SALICYLATE (UNII: LAV5U5022Y)

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69458-713-08	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part335	04/15/2016	

Labeler - Jomex International Llc (833120707)

Establishment

Name	Address	ID/FEI	Business Operations
Geri-Care Pharmaceuticals, Corp		611196254	manufacture(69458-713)