

ESTOMAQUIL POLVO- bismuth subsalicylate powder
ProMex LLC

Estomaquil® Polvo

Drug Facts

Active ingredient (in each pouch)

Bismuth Subsalicylate 262 mg

Purpose

Upset stomach reliever / Antidiarrheal

Uses

relieves:

- travelers' diarrhea
- diarrhea
- upset stomach due to overindulgence in food and drink, including:
 - heartburn
 - indigestion
 - nausea
 - gas
 - belching
 - fullness

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 behavior with nausea or 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 salicylate (including aspirin)
- taking other salicylate products

Do not use if you have

- an ulcer
- a bleeding problem

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
- ringing in the ears or loss of hearing occurs
- diarrhea lasts more than 2 days

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

Keep out of the reach of children. In case of overdose, seek professional help or contact a poison control center immediately

Directions

- **Adults & Children 12 yrs and older:** Dissolve 2 pouches (1 dose) in 1/2 glass of water. Repeat every 1/2 to 1 hour as needed, to a maximum of 8 doses in a 24-hour period
 - use until diarrhea stops, but not more than 2 days. If symptoms persist, consult a doctor
 - drink plenty of clear fluids to help prevent dehydration which may accompany diarrhea
- **Children under 12 yrs:** ask a doctor

Other information

- **each pouch contains:** calcium 210 mg, magnesium 190 mg, sodium 206 mg
- avoid excessive heat

Inactive ingredients

anhydrous citric acid, calcium carbonate, magnesium hydroxide, maltodextrin, silicon dioxide, sodium bicarbonate, tartaric acid

Distributed By:

PRO-MEX®

P.O. Box 63-0716

Miami, FL. 33163

PRINCIPAL DISPLAY PANEL - 3.0 g Pouch Carton

ESTOMAQUIL®

Bismuth Subsalicylate 262 mg

Relief for:

- Nausea
- Heartburn
- Diarrhea
- Fullness

Maximum Strength

10 Pouches

0.1 oz (3.0 g) Each

ESTOMAQUIL®

Maximum Strength | Fuerza Maxima

Tamper evident: Do not use if pouch is torn or broken.
Prueba de manipulación: No use si el sobre impreso está roto.

ESTOMAQUIL®

Bismuth Subsalicylate 262 mg

Relief for: Alivio para:

- Nausea • Náuseas
- Heartburn • Acidez Estomacal
- Diarrhea • Diarrea
- Fullness • Llenura

Maximum Strength | Fuerza Maxima



10 Pouches

0.1 oz (3.0 g) Each

10 Sobres

Distributed By:

PRO-MEX®

P.O. Box 63-0716
Miami, FL. 33163

Manufactured and packaged in the USA using domestic and imported ingredients. Active ingredient is a product of Mexico.



Datos Acerca del Medicamento (continuado)

Al utilizar este producto un temporal, pero inofensivo oscurecimiento de las heces y / o la lengua pueden ocurrir

Suspenda el uso y consulte a un médico si:

- los síntomas empeoran ■ zumbido en los oídos o pérdida de la audición ■ si la diarrea dura más de 2 días

Si está embarazada o en periodo de lactancia, consulte con un médico antes de usar. Mantenga fuera del alcance de los niños. En caso de sobredosis, busque ayuda profesional o contacte un centro de control de envenenamiento inmediatamente

Instrucciones: Adultos y Niños de 12 años o más: Disolver 2 sobres (1 dosis) en medio vaso de agua. Repetir cada ½ a 1 hora según sea necesario, hasta un máximo de 8 dosis en 24 horas. ■ use hasta que cese la diarrea, pero no más de 2 días, si los síntomas persisten, consulte con un médico. ■ bebe abundante líquido claro para ayudar a prevenir la deshidratación que puede acompañar a la diarrea. ■ **Niños menores de 12 años:** consulten a su médico

Otra Información: cada sobre contiene: calcio 210 mg, magnesio 190 mg, sodio 206 mg ■ evite el calor excesivo

Ingredientes Inactivos: ácido cítrico anhidro, carbonato de calcio, hidróxido de magnesio, maltodextrina, dióxido de silicio, bicarbonato de sodio, ácido tartárico



R51451
PC-138.01

Drug Facts

Active ingredient (in each pouch) **Purpose**
Bismuth Subsalicylate 262 mg Upset stomach reliever / Antidiarrheal

Uses relieves: ■ travelers' diarrhea ■ diarrhea ■ upset stomach due to overindulgence in food and drink, including: ■ heartburn ■ indigestion ■ nausea ■ gas ■ belching ■ fullness

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 behavior with nausea or 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 salicylate (including aspirin) ■ taking other salicylate products

Do not use if you have ■ an ulcer ■ a bleeding problem

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 ■ ringing in the ears or loss of hearing occurs ■ diarrhea lasts more than 2 days

If pregnant or breast-feeding, ask a health professional before use. **Keep out of the reach of children.** In case of overdose, seek professional help or contact a poison control center immediately

Directions

■ **Adults & Children 12 yrs and older:** Dissolve 2 pouches (1 dose) in 1/2 glass of water. Repeat every 1/2 to 1 hour as needed, to a maximum of 8 doses in a 24-hour period ■ use until diarrhea stops, but not more than 2 days. If symptoms persist, consult a doctor ■ drink plenty of clear fluids to help prevent dehydration which may accompany diarrhea ■ **Children under 12 yrs:** ask a doctor

Other information

■ each pouch contains: calcium 210 mg, magnesium 190 mg, sodium 206 mg ■ avoid excessive heat

Inactive ingredients

anhydrous citric acid, calcium carbonate, magnesium hydroxide, maltodextrin, silicon dioxide, sodium bicarbonate, tartaric acid



Datos Acerca del Medicamento

Ingrediente Activo (cada sobre contiene)
Bismuto Subsalicilato 262 mg **Propósito**
Alivia Malestar Estomacal/Antidiarreico

Indicaciones alivia: ■ diarrea del viajero ■ diarrea ■ malestar estomacal debido al exceso de comida y de bebida, incluyendo: ■ acidez ■ indigestión ■ náuseas ■ gases ■ eructos ■ llenura

Advertencias

Síndrome de Reye's: Los niños y adolescentes que tienen o se están recuperando de la varicela o de síntomas parecidos a la gripe no deben usar este producto. Al utilizar este producto si se producen cambios en el comportamiento con náuseas o vómito, consulte con un médico, estos síntomas podrían ser una señal temprana del síndrome de Reye's, una enfermedad rara pero grave

Alerta de alergia: Contiene salicilato. No tome si usted es ■ alérgico al salicilato (como la aspirina) ■ toma otros productos con salicilato

No use si tiene ■ úlceras ■ problemas de sangrado

Pregúntele a su médico antes de usar si usted tiene ■ fiebre ■ moco en las heces

Pregúntele a su médico o farmacéutico antes de usar si usted está tomando medicamentos para: ■ anticoagulación (adelgazamiento de la sangre) ■ diabetes ■ gota ■ artritis

ESTOMAQUIL POLVO

bismuth subsalicylate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58988-1080
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

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
TARTARIC ACID (UNII: W4888I119H)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58988-1080-1	10 in 1 CARTON	01/02/2004	
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:58988-1080-2	20 in 1 CARTON	01/02/2004	
2		1 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:58988-1080-3	50 in 1 CARTON	01/02/2004	
3		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M008	01/02/2004	

Labeler - ProMex LLC (789974388)

Revised: 11/2023

ProMex LLC