

ESTOMAQUIL POLVO- bismuth subsalicylate powder
ProMex 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.

Estomaquil® Polvo

DRUG FACTS

Active Ingredient

Bismuth Subsalicylate: Each pouch contains 262 mg

Purpose

Upset Stomach reliever / Antidiarrheal

Uses

Relieves:

- upset stomach
- indigestion
- diarrhea
- heartburn
- nausea

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 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
- bleeding problem
- bloody or black stool.

Ask a doctor before use if you have

- fever
- mucus in stool.

Ask a doctor or pharmacist before use if you are taking any drugs 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 ears or loss of hearing occurs
- if 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 or older: Dissolve 2 pouches 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

- Avoid excessive heat
- **Each pouch contains:** sodium 223mg

Inactive Ingredients

calcium carbonate, citric acid, magnesium hydroxide, sodium bicarbonate, tartaric acid

PRINCIPAL DISPLAY PANEL - 10 Packet Carton

ESTOMAQUIL®

Relief for:

- Nausea
- Heartburn
- Diarrhea
- Fullness

Maximum Strength

10 Packets

ESTOMAQUIL[®]

Relief for: Alivio para:

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



Maximum Strength
| Fuerza Maxima

10 Packets 10 Sobres

PRO-MEX[®]

MIAMI, FL 33179

TOLL FREE: 1-855-877-6639



ESTOMAQUIL[®]

Maximum Strength | Fuerza Maxima

Maximum Strength | Fuerza Maxima

ESTOMAGUIL[®]

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

DRUG FACTS

Active Ingredient	Purpose
Bismuth Subsalicylate: Each pouch contains 262 mg	Upset Stomach reliever / Antidiarrheal

Uses: Relieves: ■ upset stomach ■ indigestion ■ diarrhea ■ heartburn ■ nausea

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 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 ■ bleeding problem ■ bloody or black stool.

Ask a doctor before use if you have: ■ fever ■ mucus in stool.

Ask a doctor or pharmacist before use if you are taking any drugs 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 ears or loss of hearing occurs ■ if 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 or older: Dissolve 2 pouches 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: ■ Avoid excessive heat ■ Each pouch contains: sodium 223mg

Inactive Ingredients: calcium carbonate, citric acid, magnesium hydroxide, sodium bicarbonate, tartaric acid

Hechos Acerca del Medicamento

Ingrediente Activo	Proposito
Bismuto Subsalicilato: Cada sobre contiene 262mg	Alivia Malestar Estomacal / Antidiarreico

Indicaciones: Alivia: ■ malestar estomacal ■ indigestión ■ diarrea ■ acidez estomacal ■ náuseas

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 de sus náuseas o vómitos, consulte a un médico, estos síntomas podrían ser una señal temprana del síndrome Reye's, una enfermedad rara pero grave.

Hechos Acerca del Medicamento (continuado)

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 ■ heces con sangre o negro.

Pregúntele a su médico antes de usar si usted tiene: ■ fiebre ■ mucus en las heces.

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

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 en medio vaso de agua. Repetir cada 1/2 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 a un médico.

■ Beba abundante líquido claro para ayudar a prevenir la deshidratación que puede acompañar a la diarrea.

■ Niños menores de 12 años consulte a su médico

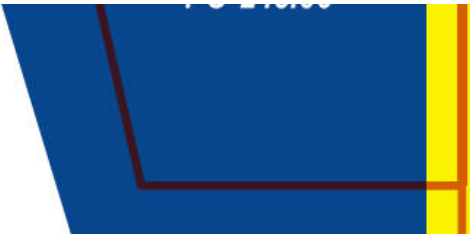
Otra Información: Evite el calor excesivo

Cada sobre contiene: 223mg de sodio

Ingredientes inactivos: carbonato de calcio, ácido cítrico, hidróxido de magnesio, bicarbonato de sodio, ácido tartárico

PROME-00033

PC-249.00



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: W48881119H)	

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 FINAL	part335	01/02/2004	

Labeler - ProMex LLC (789974388)

