# ESTOMAQUIL POLVO- bismuth subsalicylate powder All Natural Dynamics

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®**

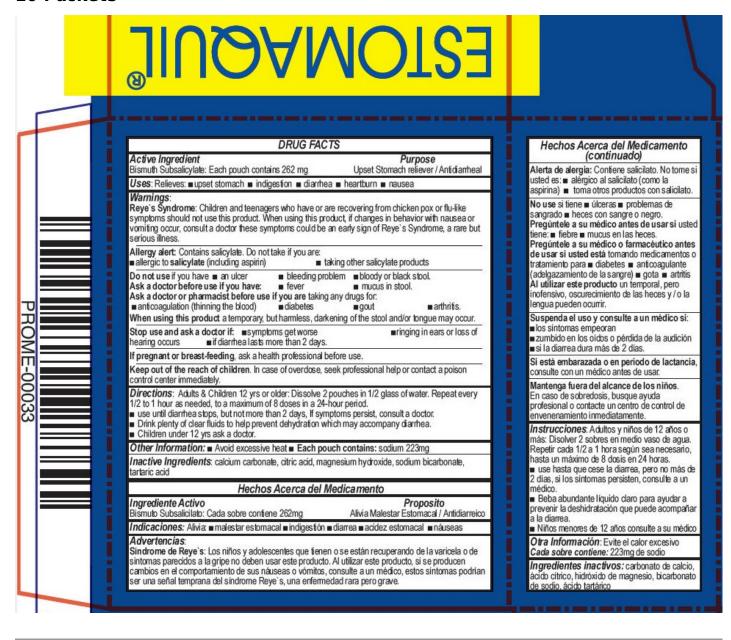
#### Relief for:

- Nausea
- Heartburn

- Diarrhea
- Fullness

#### **Maximum Strength**

#### 10 Packets



### **ESTOMAQUIL POLVO**

bismuth subsalicylate powder

<b>Product Information</b>					
Product Type	HUMAN OTC DRUG	Item Code (Sou	rce)	NDC:5176	9-108
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingredient Name		Basis of S	trength	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)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:51769-108- 20	20 in 1 CARTON	06/27/2022			
1		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	06/27/2022		

# Labeler - All Natural Dynamics (962732892)

# Registrant - All Natural Dynamics (962732892)

Revised: 6/2022 All Natural Dynamics