

## **EQUALINE STOMACH RELIEF - bismuth subsalicylate tablet, chewable Supervalu Inc.**

*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.*

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### **Equaline Stomach Relief**

#### **ACTIVE INGREDIENT(in each tablet)**

Bismuth subsalicylate 262 mg

(total salicylate 102 mg per tablet)

#### **PURPOSE**

Upset stomach reliever and anti-diarrheal

#### **USE(S)**

relieves:

- diarrhea
- heartburn
- indigestion
- nausea
- upset stomach associated with these symptoms

#### **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**

- bloody or black stool
- 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 of 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 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 REACH OF CHILDREN**

In case of overdose, get medical help or contact a Poison Control Center immediately.

### **DIRECTIONS**

- chew or dissolve in mouth
- adults and children 12 years and over: 2 tablets every 1/2 to 1 hour as needed
- do not take more than 8 doses (16 tablets) in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor
- drink plenty of fluids to help prevent dehydration caused diarrhea

### **OTHER INFORMATION**

- **each tablet contains:**
- sodium less than 1 mg
- salicylate 102 mg

- very low sodium
- avoid excessive heat (over 104°F or 40°C)
- **TAMPER EVIDENT: Do not use if individual compartments are torn on open.**

## **INACTIVE INGREDIENTS**

calcium carbonate, D&C red 27 aluminum lake, flavor, magnesium stearate, mannitol, pregelatinized starch, saccharin sodium

## **PRINCIPAL DISPLAY PANEL**

NDC 41163-058-49

compare to Pepto-Bismol® Chewable Tablets active ingredient\*

EQUALINE

chewable

**stomach relief**

tablets

bismuth subsalicylate 262 mg  
(upset stomach reliever / anti-diarrheal)

relieves:

- heartburn
- indigestion
- nausea
- upset stomach
- diarrhea

GLUTEN FREE

30 chewable tablets



## EQUALINE STOMACH RELIEF

bismuth subsalicylate tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41163-058
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BISMUTH SUBSALICYLATE</b> (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ)	BISMUTH SUBSALICYLATE	262 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	

**MANNITOL** (UNII: 3OWL53L36A)

**STARCH, CORN** (UNII: O8232NY3SJ)

**SACCHARIN SODIUM** (UNII: SB8ZUX40TY)

### Product Characteristics

<b>Color</b>	PINK	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	G122
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-058-49	5 in 1 BOX	01/05/2022	
1		6 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
OTC MONOGRAPH FINAL	part335	01/05/2022	

**Labeler** - Supervalu Inc. (006961411)

### Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(41163-058)

Revised: 11/2022

Supervalu Inc.