TREDA ULTRA- bismuth subsalicylate tablet
Laboratorios Sanfer, S.A. de C.V.

Treda Ultra 44-749

Active ingredient (in each caplet)

Bismuth subsalicylate 525 mg

Purpose

Upset stomach reliever/antidiarrheal

Uses

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

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 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

- gout
- diabetes
- arthritis
- anticoagulation (thinning the blood)

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 reach of children.

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

Directions

- **do not take more than directed**
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- swallow with water; do not chew
- adults and children 12 years and over: 1 caplet every 1/2 to 1 hour as needed. Do not exceed 8 caplets in 24 hours.
- do not use for more than 2 days unless directed by a doctor
- use until diarrhea stops, but not more than 2 days
- children under 12 years: ask a doctor

Other information

- **each caplet contains:** calcium 45 mg, salicylate 206 mg, sodium 3 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive heat
- see end flap for expiration date and lot number

Inactive ingredients

calcium carbonate, corn starch, D&C red #27 aluminum lake, D&C red #30 aluminum lake, magnesium stearate, mannitol, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, stearic acid

Questions or comments?

Call 1-(833) 604-1084 (English and Spanish)
8:00 AM-5:00 PM CST, Monday-Friday

Principal display panel

Treda®
Ultra

Bismuth Subsalicylate 525 mg

UPSET STOMACH RELIEVER
ANTIDIARRHEAL

RELIEVES:

Diarrhea

Nausea

Heartburn

Upset Stomach

Indigestion

Actual Size

24
caplets

sanfer®

TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

50844
ORG032174908

Manufactured for: Laboratorios Sanfer S.A. de C.V.
Blvd. Adolfo López Mateos No. 314
Col. Tlacopac, CDMX, 01049. México

This product is produced in compliance with all United States regulatory and quality requirements for pharmaceutical product.

Treda Ultra 44-749

TREDA ULTRA

bismuth subsalicylate tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83393-749
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BISMUTH SUBSALICYLATE (UNII: 62TFY51PP1) (SALICYLIC ACID - UNII:O414PZ4LPZ	BISMUTH	

BISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (SALICYLIC ACID - UNII:O414PZ4LPZ, BISMUTH CATION - UNII:ZS9CD1I8YE)	BISMUTH SUBSALICYLATE	525 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	pink	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	44;749
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83393-749-08	1 in 1 CARTON	02/06/2024	
1		24 in 1 BOTTLE, PLASTIC; 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	02/06/2024	

Labeler - Laboratorios Sanfer, S.A. de C.V. (810007732)

Revised: 2/2024 Laboratorios Sanfer, S.A. de C.V.