

# UNITED AFRICAN LABORATORY LTD

Registered Office  
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Mailing Address:  
2 Modupeola Street,  
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## Summary of Product Characteristics

### NAME OF THE MEDICINAL PRODUCT

Pepto Bismuth Ultra

**2. QUALITATIVE AND QUANTITATIVE:** Bismuth Subsalicylate 525mg

**PHARMACEUTICAL FORM:** Liquid Suspension

**CLINICAL PARTICULARS:** Bismuth subsalicylate is an antidiarrheal and anti-inflammatory agent used for symptomatic treatment of nausea, indigestion, upset stomach, diarrhea, and other temporary discomforts of the stomach and gastrointestinal tract.

**3. Posology and method of administration:** 30ml to be taken. Repeat every 30 - 26 minutes if needed.

8 doses daily.

**4. Contraindications:** Hypersensitivity to any of the active ingredients or excipients.

**5. Special warnings and precautions:** 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 the 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.

#### **5.1 Interaction with other medicinal products and other forms of interaction with Antibiotics:**

The use of Bismuth Subsalicylate with other antibiotic such as Abciximab, Acarbose, Aceclofenac, Acenocoumarol, Acetaminophen, Acetazolamide, Acetohexamide, Acetyldigitoxin, Acetylsalicylic acid, Albiglutide can affect the effectiveness its effectiveness.

**5.2 Pregnancy and lactation:** Do not take Pepto-Bismol if you're pregnant as it might affect your baby, particularly if you take it regularly after 30 weeks of pregnancy.

**6. Effects on ability to drive and use machines:** No negative influence on the ability to drive and use machines.

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**7. Undesirable effects:** Administration of Simethicone You're unlikely to get any side effects from Pepto-Bismol if you follow the instructions for taking it. One common side effect is your poo or your tongue turning black. This is harmless. This happens when bismuth (the active ingredient in this medicine) comes into contact with small amounts of sulphur in your saliva and digestive system. They combine to form bismuth sulfide, a black substance. As it slowly makes its way out of your body you may see black poo.

**8. Overdose Symptoms:** If your baby has received more than the recommended dose, seek medical help right away.

**9. Treatment of toxicity following recent ingestion:** Overdose of bismuth subsalicylate over an extended period of time and consequently, bismuth toxicity, can lead to blackening of the tongue and teeth, fatigue, mood changes, deterioration of mental status, and neurotoxicity. Other signs and symptoms include impaired cognition, tremors, lethargy, somnolence, insomnia, delirium, myoclonus, seizures, depressed mood, anxiety, and a depressed mood. Salicylate toxicity can occur from chronic bismuth subsalicylate use : it mostly occurs from ingestion of more than 150 mg/kg of salicylates (or >6.5 g of aspirin equivalent). As there are no specific antidotes for bismuth salicylate toxicity, overdose should be managed with supportive care, with or without decontamination with activated charcoal.

**10. Pharmacological properties.** Bismuth subsalicylate is thought to produce its therapeutic actions in part by stimulating prostaglandin, mucus formation, and bicarbonate secretion.

**10.1. Volume of distribution:** Bismuth Subsalicylate is not systemically absorbed and so these data are not readily available.

**11. Preclinical safety data:** No data of relevance which is additional to that already included in other sections of the SmPC.

## 11. 1 PHARMACEUTICAL PARTICULARS

**12. List of excipients:** Water, methylene paraben, propyl paraben, corn starch, lactose, aerosol, PVP K30, magnesium stearate, sodium benzoate.

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## Marketing Authorisation Holder

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