

PeptoFit®

Bismuth Subsalicylate BP

Description: PeptoFit® (Bismuth Subsalicylate) is 2-Hydroxybenzoic acid bismuth (3+) salt. It is a fine, white, odorless and tasteless powder that is stable and non-hygroscopic. It is highly insoluble in trivalent bismuth and salicylic acid.

Mode of action: *Antacid action:* Bismuth Subsalicylate coats ulcer surface, protecting it from acid and pepsin. It stimulates mucus and bicarbonate secretion and also reacts with HCl which produces Oxychloride & Salicylic acid and thus reduces HCl.

Anti-inflammatory action: Bismuth Subsalicylate is hydrolyzed to salicylic acid which inhibits prostaglandin G & H synthase 1 & 2. Thus reduces inflammation and coats irritated tissue to retard the expulsion of fluid.

Anti-diarrheal action: Bismuth Subsalicylate exerts an anti-diarrheal effect through several mechanisms (a) In vitro and human studies demonstrated an antimicrobial effect against a wide variety of enteric pathogens that cause diarrhea and food poisoning (b) Human and Animal studies demonstrated a binding and inactivation of bacterial toxins and bile acids (c) Animal studies demonstrated an inhibition of secretion and stimulation of absorption thereby reducing fluid in the intestine and (d) Human studies demonstrated a decreasing GI motility or transit time.

Composition: PeptoFit® Suspension: Each 5 ml oral suspension contain Bismuth Subsalicylate BP 87.5 mg.

Indications: PeptoFit® (Bismuth Subsalicylate) is indicated for upset stomach, indigestion, heartburn, nausea, gas, belching, hyperacidity, diarrhea & traveler's diarrhea. It has also mild anti-inflammatory effect.

Dosage & administration

Age	Dose
Adult (>12 years)	30 ml suspension in every ½ to 1 hour or as needed
Children (10 - 12 years)	15 ml suspension in every ½ to 1 hour or as needed
Children (5 - 9 years)	7.5 ml suspension in every ½ to 1 hour or as needed
Children (3 - 5 years)	5 ml suspension in every ½ to 1 hour or as needed
Children (2 months - 3 years)	2.5 ml suspension in every 4 hours
Do not exceed 8 doses in 24 hours	

Contraindications: Bismuth Subsalicylate should not be used by patients hypersensitive to Aspirin or other Salicylates or any ingredient in this formulation.

Side effects: Black stool and black tongue is common with use of Bismuth Subsalicylate. Bismuth Subsalicylate should not be used if symptoms are severe or persist for more than 2 days. Do not exceed the recommended dose, shake bottle before use.

Use in pregnancy & lactation: There are no adequate data concerning the use of Bismuth Subsalicylate in pregnant women. The potential risk for humans is unknown. Bismuth Subsalicylate should not be used during lactation unless clearly necessary.

Use in elderly patients: No special precaution is needed. Caution is needed in case of patients suffering from renal insufficiency.

Precautions: 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.

Drug interactions: Do not take with Aspirin or other Salicylates. Caution should be exercised by patients taking medicines for anti-coagulation (thinning of the blood), diabetes or gout.

Over dosage: Bismuth intoxication may cause acute encephalopathy with confusion, Myoclonic movements, Tremor, Dysarthria and walking and standing disorders etc. If symptoms occur, use of Bismuth Subsalicylate should be discontinued.

Storage: Store in a cool (below 25°C temperature) and dry place, protected from light. Keep away from the reach of children.

Packaging: PeptoFit® 200 ml Suspension: Each carton contains a bottle having 200 ml suspension.