SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Pepto-Bismol, 17.5mg/ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each ml of suspension contains 17.5mg Bismuth Subsalicylate
One 30ml dose contains 526mg Bismuth Subsalicylate
For excipients see 6.1

3 PHARMACEUTICAL FORM
Liquid suspension
Pink, viscous liquid suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
For upset stomach, indigestion, heartburn and nausea. Controls diarrhoea.

4.2 Posology and method of administration
Adults and children 16 years and over and children over:

30ml in dosing cup provided, or 6 x 5ml spoonfuls
Repeat dose every 1/2 to 1 hour if needed. No more than 8 doses to be taken in 24 hours.

Do not exceed the recommended dose, shake bottle before use

For Oral use only.

4.3 Contraindications
Pepto-Bismol should not be used by patients hypersensitive to Aspirin or other salicylates.

Pepto-Bismol should not be used by patients hypersensitive to any ingredient in the formulation.

Pepto-Bismol should not be used by children under 16 years of age.

4.4 Special warnings and precautions for use

Do not take with aspirin or other salicylates.

Pepto-Bismol should not be used by those aged under 16 due to a possible association between salicylates and Reye’s syndrome, a very rare but very serious disease.

Caution should be exercised by patients who have blood clotting disorders or gout or who are taking medicines for anti-coagulation (thinning of blood), diabetes or gout.

Pepto-Bismol should not be used if symptoms are severe or persist for more than 2 days.

In patients with diarrhoea, especially in frail and elderly patients, fluid and electrolyte depletion may occur. In such cases administration of appropriate fluid and electrolyte replacement therapy is the most important measure.

Do not exceed the recommended dose. Do not use for more than 2 days except on the advice of a doctor. Use at doses higher than recommended or for prolonged periods is associated with an increased risk of side effects (notably bismuth intoxication).

Keep all medicines out of reach and sight of children.
4.5 Interaction with other medicinal products and other forms of interaction

Pepto-Bismol contains salicylates therefore care should be exercised if receiving drugs to thin the blood (anticoagulant therapy) or oral therapy for diabetes or treatment for gout.

Use of Pepto-Bismol with tetracycline antibiotics can lead to reduced bioavailability of bismuth subsalicylate due to interaction with aluminium magnesium silicate in the formulation.

Additionally the absorption of tetracycline antibiotics can be reduced when concurrently taken with products containing bismuth. This interaction can be minimised by separating the doses of the two drugs by a couple of hours.

4.6 Pregnancy and lactation

There are no adequate date concerning the use of Pepto-Bismol in pregnant women.

Animal studies are insufficient with respect to effects on pregnancy, embryonal/foetal development, parturition and postnatal development. The potential risk for humans is unknown.

Pepto-Bismol should not be used during pregnancy and lactation unless clearly necessary.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Gastrointestinal disorders:
Black tongue is common (>1/100, <1/10)
Black stool is very common (>1/10)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.
4.9 Overdose

**Bismuth**

Bismuth intoxication may present as an acute encephalopathy with confusion, myoclonic movements, tremor, dysarthria and walking and standing disorders. Bismuth intoxication may also cause gastrointestinal disturbances, skin reactions, discolouration of mucous membranes, and renal dysfunction as a result of acute tubular necrosis. Treatment includes gastric lavage, purgation and hydration. Chelating agents may be effective in the early stages following ingestion and haemodialysis may be necessary.

**Salicylate**

Salicylate poisoning is usually associated with plasma concentrations >350 mg/L (2.5 mmol/L). Most adult deaths occur in patients whose concentrations exceed 700 mg/L (95.1 mmol/L). Single doses less than 100 mg/kg are unlikely to cause serious poisoning.

**Symptoms**

Common features include vomiting, dehydration, tinnitus, vertigo, deafness, sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases.

A mixed respiratory alkalosis and metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion concentration) is usual in adults and children over the age of 4 years. In children aged 4 years or less, a dominant metabolic acidosis with low arterial pH (raised hydrogen ion concentration) is common. Acidosis may increase salicylate transfer across the blood brain barrier.

Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopenia, increased INR/PTR, intravascular coagulation, renal failure and non-cardiac pulmonary oedema.

Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

**Management**

Give activated charcoal if an adult presents within one hour of ingestion of more than 250 mg/kg. The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account. Elimination is increased by urinary alkalisation, which is achieved by the administration of 1.26% sodium bicarbonate. The urine pH should be
monitored. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylate excretion and may cause pulmonary oedema.

Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations >700 mg/L (5.1 mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under 10 years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic code: ATC code A07B B

The demulcent base provides a protective coating of the lower oesophagus and a partial coating in the stomach which holds the bismuth subsalicylate in suspension.

Limited in vitro studies have shown BSS to have some activity against enteropathogens, ie Clostridium, Bacteroides, E. Coli, Salmonella Shigella, campylobacter (Helicobacter) and Yersinia, but not against anaerobes. There are insufficient data to determine whether these findings have any relevance to treatment outcomes in the patient population who may receive BSS.

5.2 Pharmacokinetic properties

Bismuth subsalicylate is converted to bismuth carbonate and sodium salicylate in the small intestine

The oral bioavailability of bismuth administered as Bismuth subsalicylate is extremely low. Very little is known about bismuth distribution in human tissue. Renal clearance is the primary route of elimination for absorbed bismuth, however biliary clearance may also have a role. The remainder is eliminated as insoluble bismuth salts in the faeces. Following the maximum recommended daily adult dose, the mean biological half life is approximately 33 hours and peak plasma bismuth levels remain below 35ppb.

Salicylate is absorbed from the intestine and rapidly distributed to all body tissues. Peak plasma levels after maximum recommended daily dosing are
about 110 micrograms/ml. Salicylate is rapidly excreted from the body and has a mean biological half life of approximately 4 - 5.5 hours.

5.3 Preclinical safety data

There are no pre-clinical safety data of relevance to health professionals, other than those already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium magnesium silicate  
Methylcellulose  
Methyl salicylate  
Salicylic acid  
Saccharin sodium  
Sodium salicylate  
Amaranth (E123)  
Sorbic Acid  
Benzoic Acid (E210)  
Purified water

6.2 Incompatibilities

None stated

6.3 Shelf Life

24 months
6.4 Special precautions for storage
Do not store above 25°C

6.5 Nature and contents of container
120 ml, 240 ml and 480 ml transparent, colourless polyethylene terephthalate (PET) bottles with opaque, white polypropylene (PP) child resistant closures. A transparent, colourless polypropylene CE marked dosing cup is shrink wrapped onto the sealed bottle.

6.6 Special precautions for disposal
Shake bottle well before use

7 MARKETING AUTHORISATION HOLDER
Procter & Gamble (Health & Beauty Care) Limited
The Heights
Brooklands
Weybridge
Surrey
KT13 0XP

8. MARKETING AUTHORISATION NUMBER(S)
PL 00129/0358

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26/03/2009

10 DATE OF REVISION OF THE TEXT