SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Pepto-Bismol Chewable Tablets, 262.5mg/tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENT
Each tablet contains 262.5mg Bismuth subsalicylate

For excipients see 6.1

3 PHARMACEUTICAL FORM

Chewable Tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For fast relief of upset stomach, indigestion, heartburn and nausea.

Controls diarrhoea.

4.2 Posology and method of administration

Adults and children 16 years and over :

2 tablets

Repeat dose every 1/2 to 1 hour if needed. No more than 16 tablets to be taken in 24 hours.

One adult dose (2 tablets) contains 525mg of Bismuth Subsalicylate

Do not exceed the recommended dose.

Pepto-Bismol can be taken before or after meals, on either an empty or full stomach.

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 the 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.

The absorption of tetracycline antibiotics can be reduced when concurrently taken with products containing bismuth although 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 data 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

Overdose of Pepto-Bismol may also give symptoms of salicylate intoxification. 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.

If symptoms occur, use of Pepto-Bismol should be discontinued. Management of overdose is the same as that for salicylate overdose:

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 four years. In children aged four 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, thrombocytopaenia, 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 alkalinisation, 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 ten 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, campoylobacter (Helicobacter) and Yersina, 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

Mannitol

Calcium carbonate

Povidone

Magnesium stearate

Talc
Peppermint flavour
Saccharin sodium
Aspartame
Amaranth, aluminium lake (E123)
Vanilla cream flavour

6.2 Incompatibilities
None stated.

6.3 Shelf life
36 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container
12 or 24 tablets in a cellophane film, packed in an outer claycoat board carton

6.6 Special precautions for disposal
None

7 MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

PL 00129/0143

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/06/2010

10 DATE OF REVISION OF THE TEXT

31/03/2016