1. NAME OF THE MEDICINAL PRODUCT

Pepto-Bismol 262.5mg Chewable Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 262.5mg Bismuth subsalicylate.

Excipients with known effect
- Each tablet contains 0.157 mg of sodium.
- Each tablet contains 0.75 mg of aspartame (E951).
- Each tablet contains 0.5 mg of amaranth (E123).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable Tablet

4.1 Therapeutic indications

Indicated in adults and adolescents aged 16 years and over for fast symptomatic relief of heartburn, indigestion, nausea and upset stomach (due to overindulgence in food and drink). Also controls diarrhoea.

4.2 Posology and method of administration

Posology
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.

Paediatric population
Contraindicated in children aged under 16 years (see section 4.3).

Method of administration
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 is contraindicated in the case of:
- patients hypersensitive to bismuth subsalicylate or to any of the excipients listed in section 6.1;
- patients hypersensitive to aspirin or other salicylates;

- patients in concomitant treatment with aspirin or other salicylates;
- patients with a peptic ulcer;
- patients with blood clotting disorders;
- patients with bloody or black stool;
- children under 16 years of age (see section 4.4).

4.4 Special warnings and precautions for use

- Pepto-Bismol use should be stopped if symptoms get worse, if they last more than 2 days, or if ringing in the ears appears (tinnitus).
- Pepto-Bismol should not be used if symptoms are severe or persist for more than 2 days.
- Pepto-Bismol should not be used by those aged under 16 years, due to a possible association between salicylates and Reye's syndrome, a rare but very serious disease (see section 4.3). This is particularly important in those who have or are recovering from a viral infection such as chicken pox or flu.
- 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 take with aspirin or other salicylates.
- 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.
- 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 severe side effects (notably bismuth and salicylate intoxication).
- Keep all medicines out of reach and sight of children.

Excipients with known effect:
Sodium: This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.
Aspartame: This medicine contains 0.75 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
Amaranth: May cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction.

Pepto-Bismol contains salicylates, therefore care should be exercised in patients taking:

- anti-coagulant therapy (blood thinners) as concomitant use may increase the risk and severity of bleeding;
- medicines for gout (e.g., probenecid, sulfinpyrazone) as concomitant use may increase the risk of hyperuricemia and worsening gout;
- sulfonylurea medicines for diabetes (e.g., chlorpropamide, glibenclamide) as concomitant use may increase the risk of hypoglycaemia;
- medicines for arthritis (e.g., methotrexate) due to potential drug interactions.

Special precautions with tetracycline antibiotics, as co-administration may alter the pharmacokinetics of some antibiotics such as tetracycline and doxycycline (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 although this interaction can be minimised by separating the doses of the two drugs by a couple of hours.

Do not use in patients taking aspirin or other salicylates due to the risk of overdose and salicylate toxicity.

4.6 Fertility, pregnancy, and breastfeeding

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 breastfeeding unless potential benefit outweighs the risks.

4.7 Effects on ability to drive and use machines

None expected.

4.8 Undesirable effects

Tabulated list of adverse reactions
Adverse reactions are listed in the below table by System Organ Class and in order of decreased seriousness within each frequency grouping. Frequencies are defined as: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

The most common AEs are benign and transient blackening of the faeces (~15%) and discoloration (blackening) of the surface of the tongue (~8%). This phenomenon is caused by the reaction of malodorous sulfide gases from fermentation of food residues with bismuth resulting in an odorless black insoluble bismuth sulfide salt.

System Organ class	Frequency	Adverse reaction
Gastrointestinal disorders	common	Black tongue
	very common	Black stool

Pepto-Bismol contains the colouring amaranth (E 123) which may cause allergic type reactions including asthma (see section 4.4).

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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.

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.

Treatment: activated charcoal may be considered especially 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.

5.1 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, i.e., 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

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) Ltd.
The Heights, Brooklands
Weybridge, Surrey
KT13 0XP, United Kingdom

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

18/12/2023