

Product Information

Bismuth Subnitrate, Iodoform and Paraffin Paste

(B.I.P. Paste) (tube formula)

Description:

B.I.P. Paste (Tube) is a bright yellow non-sterile paste of bismuth subnitrate 250mg/g, iodoform 500mg/g and liquid and white soft paraffin (total paraffins 250mg/g) in a tube.

Iodoform

CHI₃ MW= 393.7

CAS Number = 75-47-8

Iodoform is a greenish-yellow lustrous crystalline powder which is slightly volatile at ordinary temperatures. Iodoform is practically insoluble in water, sparingly soluble in alcohol, freely soluble in chloroform and ether.

Bismuth Subnitrate

Bismuth₅O(OH)₉(NO₃)₄ MW= 1462.0

CAS Number = 1304-85-4

Bismuth subnitrate contains not less than 71% of Bismuth, calculated with reference to the dried substance. It is a white powder which is practically insoluble in water and alcohol. It readily dissolves in nitric and hydrochloric acids.

Pharmacology:

Iodoform is used topically for its mild antiseptic action. It slowly releases elemental iodine when applied to the skin. Bismuth compounds have been used topically for their astringent properties.

Pharmacokinetics:

No data exists concerning the absorption of bismuth and iodoform following topical administration of B.I.P. Paste.

Bismuth compounds are poorly soluble and are only slightly absorbed after oral administration. Absorption is also likely to be low after topical application unless the product is extensively applied or used for prolonged periods.

Absorbed bismuth is distributed throughout the body, including bone, and slowly excreted in urine and bile. It has a plasma elimination half life of 5 days. Excretion continues for about 12 weeks after ceasing treatment. Unabsorbed bismuth is excreted in the faeces.

Indications:

B.I.P. Paste is indicated for packing cavities after ear, nose and throat surgery, to assist healing and prevent infection.

Contra-indications:

B.I.P. Paste is contra-indicated in individuals with a history of hypersensitivity to any of the ingredients in this formulation. It is also contra-indicated in individuals with known hypersensitivity to iodine.

Precautions:

B.I.P. Paste is for external use only.

B.I.P. Paste may cause redness and stinging of the eyes. Contact with the eyes should therefore be avoided. If contact with the eyes occurs, remove contact lenses if worn, hold eyes open and flush with running water for at least 15 minutes.

Prolonged or extensive application of B.I.P. Paste may give rise to iodoform absorption and poisoning. B.I.P. Paste should be used with caution in patients suffering from hyperthyroidism.

Prolonged use or extensive application of B.I.P. Paste may also result in encephalopathy or renal failure as a result of bismuth absorption.

Bismuth levels in the body may remain elevated for some weeks in patients with renal impairment. Use of bismuth compounds is not recommended in patients with moderate to severe renal impairment.

Use in Pregnancy: (Category D)

The safety of B.I.P. Paste during pregnancy has not been established. Therefore, B.I.P. Paste should not be used during pregnancy unless the benefits outweigh the potential risks. Caution is recommended as sufficient iodine may be absorbed to affect fetal thyroid development and function.

Use in Lactation:

The safety of B.I.P. Paste during lactation has not been established.

Iodine is excreted into the breast milk and may affect infant thyroid function. Topical preparations containing iodine should therefore not be used during lactation.

As B.I.P. Paste slowly release elemental iodine to the skin, its use during lactation should be avoided.

Bismuth is also excreted in breast milk, but it is not known if it is harmful to the newborn infant.

Use in Children:

The safety and efficacy of B.I.P. Paste in paediatric patients has not been established.

Interactions with Other Drugs:

No data exists concerning potential interactions of bismuth and iodoform paste with other drugs.

Effects on Laboratory Tests:

Use of B.I.P. Paste causes artefacts on X-rays because the bismuth component is radio-opaque.

Adverse Reactions:

Neurological:

Rare: encephalopathy, confusion, ataxia, myoclonus, delirium, coma, personality change, facial palsy and insomnia.

Musculoskeletal:

Rare: bone and joint pain.

Renal:

Rare: acute renal failure

Hepatobiliary:

Rare: liver damage.

Haematological:

Uncommon: methaemoglobinaemia.

Skin:

Common: contact allergy. The risk of allergic reactions is higher in patients previously exposed to B.I.P. products.

Eyes:

Common: redness and stinging if contact occurs.

General:

Common: pain at application site.

Dosage and Administration:

Apply the B.I.P. Paste to gauze and pack into the cavity. Leave in place until the wound has healed or graft taken.

Overdosage:

There is no human experience with overdosage of B.I.P. products.

Overdose of bismuth may cause acute renal failure and encephalopathy. Renal function should be monitored for 10 days after an overdose.

If swallowed, the patient should be given large amounts of water. Vomiting should not be induced.

Presentation:

Tube: 50 g

AUST R 21139

Storage:

Store below 25°C.

Protect from Light.

Schedule:

All States and A.C.T. - S.4 (Prescription only Medicine)

Sponsor:

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Revision Information

Date	Document Name	Superseded Document	Revision Information
11 th November 2003	BIP00051_1_PI		TGA approved:
3 rd September 2007	BIP00051_2_PI	BIP00051_1_PI	TGA Amendment: Delete jar presentation and change of address
August 2008	BIP00532_1_PI	BIP00051_2_PI	New document for B.I.P. Paste (tube)
November 2009	BIP00532_2_PI	BIP00532_1_PI	Formatting