

Bismuth Subnitrate & Iodoform Paste for Gauze

Bismuth Subnitrate
Iodoform

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Bismuth Subnitrate & Iodoform Paste for Gauze is and what it is used for
2. Before Bismuth Subnitrate & Iodoform Paste for Gauze is used
3. How Bismuth Subnitrate & Iodoform Paste for Gauze is used
4. Possible side effects
5. How to store Bismuth Subnitrate & Iodoform Paste for Gauze
6. Further information

1. What Bismuth Subnitrate & Iodoform Paste for Gauze is and what it is used for

Bismuth Subnitrate is a substance that reduces blood flow from an open blood vessel and has a drying or absorbent action. Iodoform is an antiseptic (preventing infection) and anaesthetic.

Bismuth & Iodoform Paste for Gauze is an antiseptic paste used to prevent infection and reduce bleeding. The paste is spread evenly on a suitable length of ribbon gauze which is then used to pack cavities after ear, nose and throat surgery or to reduce or stop a severe nose bleed.

2. Before Bismuth Subnitrate & Iodoform Paste for Gauze is used

Bismuth & Iodoform Paste for Gauze should not be used if:

- you are allergic (hypersensitive) to Bismuth Subnitrate or Iodoform.

Take special care with Bismuth Subnitrate & Iodoform Paste for Gauze if:

- you have an overactive thyroid gland.
- you are pregnant.

If any of the above applies to you, please tell your doctor or nurse.

Pregnancy and breast-feeding:

If you are pregnant, trying for a baby or breast-feeding your doctor will decide whether Bismuth & Iodoform Paste for Gauze should be used.

3. How Bismuth Subnitrate & Iodoform Paste for Gauze is used

After ear nose and throat surgical procedures:

Enough gauze should be evenly spread with the paste and packed into the ear, nose or throat to protect the operation site from germs and to reduce or stop bleeding. The gauze is left in place until the wound has healed or the graft has taken. It is recommended that the gauze is not placed over open wounds.

To reduce or stop a severe nose bleed:

Enough gauze should be evenly spread with the paste and packed into the nostril(s). The gauze can be removed the following day or at a time advised by your doctor.

Continued overleaf



Bismuth Subnitrate & Iodoform Paste for Gauze

Bismuth Subnitrate
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Product: **Bismuth Subnitrate and Iodoform Paste.**

Indications: When spread evenly on gauze it is used to prevent infection and thus assist healing following ENT surgery or to pack the nasal cavity and thus stop or reduce the flow of blood following acute epistaxis.

Dose: ENT surgical procedures.
Sufficient gauze should be evenly spread with the paste and packed into the cavity to protect the operation site from infection. The gauze is left in place until the wound has healed or the graft has taken. It should not be placed into an open wound.

Acute Epistaxis.

Sufficient gauze should be evenly spread with the paste and packed up the nose to stop the flow of blood.

Contra-indications: Hypersensitivity to Iodoform, iodine and bismuth.

Pregnancy: Use is not recommended due to insufficient data.

Side effects: Hypersensitivity to iodine may produce an erythematous rash which should subside when the gauze is removed. Although rare, there are reports within the published literature of the development of encephalopathy associated with the application of BIPP, however, none of the cases reported have occurred following ENT procedures.

Continued overleaf

If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines Bismuth Subnitrate & Iodoform Paste for Gauze can cause side effects, although not everybody gets them. Possible side effects include:

- A rash may appear at the site that the gauze is applied. This should disappear when the gauze is removed.
- In the case of large wounds where a large quantity of paste has been used you may experience:
 - headaches
 - mental disorders
 - sleepiness
 - a weak pulse
 - clumsiness
 - difficulty sleeping
 - confusion
 - low moods
 - a general feeling of being unwell.

If any of the side effects gets serious, or you notice any side effects not listed in the leaflet, please tell your doctor, nurse or pharmacist.

5. How to store Bismuth Subnitrate & Iodoform Paste for Gauze

Keep out of the reach and sight of children.

Do not use Bismuth Subnitrate & Iodoform Paste for Gauze after the expiry date which is stated on the label. The expiry date refers to the last day of that month. The doctor or nurse will check that the product has not passed this date and that the paste does not show signs of deterioration.

Store between 2 and 8°C.

Store in the original pouch until it is administered.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Bismuth Subnitrate & Iodoform Paste for Gauze contains

The active ingredients are 20% w/w Bismuth Subnitrate & 40% w/w Iodoform in Liquid Paraffin. The other ingredients are Liquid Paraffin and Purified Water.

What Bismuth Subnitrate & Iodoform Paste for Gauze looks like and contents of the pack:

Bismuth Subnitrate & Iodoform Paste for Gauze is supplied in laminated pouches containing 15g, 30g, 45g or 60g of the paste.

Marketing Authorisation Holder:

Aurum Pharmaceuticals Ltd., Bampton Road, Harold Hill, Romford, RM3 8UG, United Kingdom.

Manufacturer:

University Hospitals of Derby and Burton NHS Foundation Trust

Queen's Hospital Burton, Pharmacy Manufacturing Unit, Belvedere Road, Burton-on-Trent, DE13 0RB, United Kingdom

Product Licence Number: PL 12064/0012

This leaflet was last revised in: July 2020



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Overdosage: Severe iodine poisoning is characterised by headache, somnolence, delirium and a rapid feeble pulse. Not usually a problem when the gauze is used to pack small cavities. General supportive therapy should be given.

Pharmacodynamics: **Iodoform** has a marked anaesthetic and antiseptic action due to the release of iodine. **Bismuth subnitrate** has both an astringent and an absorbent action.

Pharmacokinetics: Not applicable.

Incompatibilities: Oxidising agents, lead, silver and mercury salts.

Shelf life: 36 months. Store between 2 - 8°C

Handling and Use: Do not use if packaging is damaged. Discard any unused gauze at the end of the session. Do not attempt to sterilise. The pouch should be kneaded before opening.

Authorisation Holder: Aurum Pharmaceuticals Ltd
Bampton Rd, Romford, RM3 8UG, England

Date of revision: May 2002

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