PACKAGE LEAFLET: INFORMATION FOR THE USER D05309

Bismuth Subnitrate & Iodoform Paste Impregnated 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.
- 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 & Iodoform Gauze is and what it is used for
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3. How Bismuth & Iodoform Gauze is used
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1. What Bismuth and Iodoform Gauze is and what is it 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 Gauze is an antiseptic gauze used to prevent infection and reduce bleeding.The impregnated gauze is used to pack cavities after ear, nose or throat surgery or to reduce or stop a severe nosebleed.

2. Before Bismuth & Iodoform Gauze is used

Bismuth & Iodoform Gauze should not be used if:
- you are allergic (hypersensitive) to Bismuth Subnitrate or Iodoform.

Take special care with Bismuth & Iodoform 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 Gauze should be used.

3. How Bismuth & Iodoform Gauze is used

After ear, nose or throat surgical procedures:
Enough impregnated gauze should be packed into the cavity 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 nosebleed:
Enough impregnated gauze should be packed into the nostril(s). The gauze can be removed the following day or at a time advised by your doctor.

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

Continued overleaf

4. Possible Side Effects

Like all medicines Bismuth & Iodoform Gauze can cause side effects, although not everybody gets them.

- A rash may appear where the gauze is applied but this should disappear when the gauze is removed.
- In the case of large wounds where a large gauze 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 & Iodoform Gauze

Keep out of the reach and sight of children.

Do not use Bismuth & Iodoform 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 & Iodoform Gauze contains
The active ingredients are 20% w/w Bismuth Subnitrate & 40% w/w Iodoform in Liquid Paraffin.
The other ingredients are Liquid Paraffin, X-Ray detectable Fast Edge Ribbon Gauze and may contain Purified Water.

What Bismuth & Iodoform Gauze looks like and contents of the pack:
Bismuth Subnitrate & Iodoform Paste Impregnated Gauze is supplied in laminated pouches containing 1.25 x 100cm, 2.5 x 100cm, 1.25 x 200cm, 2.5 x 200cm, 1.25 x 300cm or 2.5 x 300cm strips of impregnated gauze.

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 12064/0002
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D05309

TECHNICAL PRESCRIBING INFORMATION D05309

Bismuth Subnitrate & Iodoform Paste Impregnated Gauze

Bismuth Subnitrate
Iodoform

Product:	**Bismuth Subnitrate and Iodoform Paste Impregnated Gauze. (X-ray detectable gauze)**
Indications:	As an antiseptic gauze 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 impregnated gauze should be 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 impregnated gauze should be packed up the nose to stop the flow of blood. The gauze may be removed the following day or when clinical judgement dictates.
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

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.
Incompatabilities:	Oxidising agents, lead, silver and mercury salts.
Shelf life:	24 months. Store between 2-8°C protect from light
Handling and Use:	Do not use if packaging is damaged. Discard any unused gauze at the end of the session.
Authorisation Holder:	Aurum Pharmaceuticals Ltd Bampton Rd, Romford, RM3 8UG, England

Date of revision: May 2002
Licence number: PL12064/0002

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100mm Measurement Verification Bar