1. NAME OF THE MEDICINAL PRODUCT

Bismuth Subnitrate and Iodoform Paste Impregnated Gauze.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

A lemon yellow paste impregnated gauze with characteristic antiseptic odour.

The gauze is impregnated with a paste of composition.

Bismuth Subnitrate	BPC 1973	20% w/w.
Iodoform	BPC 1954	40% w/w.
Paraffin Liquid	BP	40% w/w.

3. PHARMACEUTICAL FORM

A paste impregnated gauze.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

a) *Post ENT Surgical Procedures*

As an antiseptic gauze used to prevent infection and thus assist healing following ENT procedures.

It is not recommended that the impregnated gauze be placed into open wounds.

b) *Acute Epistaxis*

To pack the nasal cavity in order to reduce/stop the flow of blood.

4.2 Posology and Method of Administration

a) In ENT surgical procedures

Sufficient impregnated gauzes should be packed into the cavity to protect the operation site from bacterial challenge. The gauze is left in place until the wound has healed or graft taken.

It is not recommended that the impregnated gauze be placed into open wounds.

b) Acute epistaxis

Sufficient impregnated gauze(s) is packed up in the nose to stop the blood flow. The gauze is removed the following day or when clinical judgement dictates.

4.3 Contra-Indications

Known hypersensitivity to Iodoform, iodine and bismuth.

4.4 Special Warnings and Special Precautions for Use

Use with caution with patients suffering from hyperthyroidism.

4.5 Interaction with other Medicinal Products and other Forms of Interaction

None known.

4.6 Pregnancy and Lactation

There is insufficient evidence of safety in pregnancy, as with all drugs it is not recommended the product is used in pregnancy.

4.7 Effects on the Ability to Drive or use Machines

Not applicable.

4.8 Undesirable Effects

Hypersensitivity to iodine can result in an erythematous rash, which subsides on removal of the gauze.

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.

4.9 Overdose

Severe iodine poisoning is characterised by headache, somnolence, delirium and rapid feeble pulses. General supportive procedures are required. Overdose is not usually a problem when gauzes are packed in small cavities associated with the middle ear and mastoid operations.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Iodoform:-

Has a marked anaesthetic and antiseptic action due to the release of iodine.

Bismuth subnitrate:-

Bismuth subnitrate action is both as an astringent and absorbent.

5.2 Pharmacokinetic Properties

Pharmacokinetic particulars are not applicable since the active constituents are not systemically absorbed.

5.3 Pre-clinical Safety Data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Paraffin Liquid BP
X-Ray detectable Fast Edge Ribbon Gauze
May also contain Purified water BP.

6.2 Incompatibilities

The paste is incompatible with oxidising agents - lead, silver and mercuric salt.

6.3 Shelf-Life

2 years

6.4 Special Precautions for Storage

Store between 2-8^{o}C.
Protect from light.

6.5 Nature and Content of the Container:

An Aluminium laminated pouch of composition:

Polyester	12 micron
Polythene	20g/m2

Aluminium	9 micron
Surlyn	50g/m2

6.6 Instructions for Use, Handling and Disposal

Discard any unused gauze at the end of a procedure or session. Do not use if the pouch is damaged.

7. MARKETING AUTHORISATION HOLDER

Aurum Pharmaceuticals Limited
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8. MARKETING AUTHORISATION NUMBER

PL 12064/0002

9. DATA OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12th January 1995

10. DATA OF PARTIAL REVISION OF THE TEXT

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