SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Bismuth Subnitrate & Iodoform Paste For Gauze

2. Qualitative and Quantitative Composition

Iodoform BPC 1954	40%w/w
Bismuth subnitrate BPC 1973	20% w/w

3. Pharmaceutical Form

A paste of composition Iodoform 40% w/w, Bismuth Subnitrate 20% w/w and Paraffin Liquid 40% w/w. presented in a labelled aluminium laminated pouch.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The paste is spread evenly onto a suitable length of sterile ribbon gauze. The impregnated gauze is then used in the following:

ENT Surgical Procedures

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

It is not recommended that the gauze is placed into open wounds

Acute Epistaxis

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

4.2. Posology and Method of Administration

The paste is evenly spread onto a suitable length of sterile gauze and packed into the post surgical cavity or the nose.

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

4.3. Contra-indications

Hypersensitivity to iodoform, iodine or bismuth.

4.4 Special warnings and precautions for use

Use in caution with patients suffering from hyperthyroidism

4.5 Interaction with other medicinal products and other forms of interaction

Not Known

4.6. Pregnancy and Lactation

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

4.7. Effects on Ability to Drive and 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 pulse. General supportive procedures are needed. Over dosage is not usually a problem when the gauzes are used in small cavities associated with the middle ear and mastoid operations.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Iodoform has a marked anaesthetic effect and antiseptic action due to the release of iodine.

Bismuth Subnitrate has both an astringent and absorbent action.

5.2. Pharmacokinetic Properties

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

5.3. Preclinical Safety Data

Not Applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin Liquid BP

6.2. Incompatibilities

Oxidising agents. Lead silver and mercury salts

6.3. Shelf Life

36 Months.

6.4. Special Precautions for Storage

Store between 2-8°C

6.5. Nature and Contents of Container

A Bismuth Subnitrate & Iodoform paste for gauze is presented in a laminated Aluminium pouch of composition:-

Polyester	12 micron
Polythene	20 gsm
Aluminium	9 micron
Surlyn	50 gsm

Each pouch contains either 15, 30, 45 or 60g of paste.

6.6. Instructions for Use/Handling

Do not use if the pouch is damaged.
Discard any unused paste at the end of the session.

Do not attempt to sterilise the pouch by autoclaving or irradiation, as it will result in severe discolouring of the paste due to the release of Iodine.

The paste has a tendency to separate out on standing.
Before opening, the contents of the pouch must be gently kneaded to mix the contents.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBERS

PL 12064/0012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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