Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Braunoderm Non-Coloured, Isopropyl Alcohol 500mg/g and Iodinated Povidone 10mg/g Cutaneous Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:
100 g solution contains:
50.0 g Isopropyl Alcohol Ph. Eur.
1.0 g Iodinated Povidone Ph. Eur., with a content of 10% available iodine.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous solution.
Clear, brown solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a topical antiseptic for disinfection of intact skin.

4.2 Posology and method of administration

Apply undiluted Braunoderm non-coloured to the skin area to be disinfected and spread with sterile swab. Wet the skin to be treated completely and then let dry.

4.3 Contraindications

Use in patients with hypersensitivity to iodine or the other excipients.
Before and after radio-iodine-therapy (until complete healing).

4.4 Special warnings and precautions for use

None stated.

4.5 Interaction with other medicinal products and other forms of interaction

Iodine reacts with mercury compounds forming strongly caustic mercurous iodide.

4.6 Pregnancy and lactation

Care must be taken in the case of pregnant women and infants up to the age of 6 months, as well as patients suffering from non-infected nodular strumae or latent hyperthyreosis.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Allergic reactions.

4.9 Overdose

Because the preparation is only applied locally, no overdose can result.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Alcoholic solutions with povidone, iodinated combine the advantages of fast antimicrobial action due to the alcohol with a broad spectrum of activity due to iodine.

Although alcohols are studied extensively as a group, their mode of action is not clearly understood. The most plausible explanation for the antimicrobial action of alcohols is denaturing of proteins.

5.2 Pharmacokinetic properties

Alcoholic povidone, iodinated preparations are used as disinfectants for skin (that means only for local application). Iodine and isopropyl alcohol are poorly absorbed through intact skin. After application the preparation evaporates readily from skin surface and therefore a systemic action of such a preparation is unlikely.

In case of systemic action, e.g. after accidental oral uptake, a part of isopropyl alcohol is metabolised slowly by oxidation to acetone and the remainder is excreted unchanged by the kidneys and the lungs.

After accidental oral uptake povidone, iodinated preparations (which are converted to iodide) and iodides are trapped by the thyroid gland after resorption. Excess iodides are excreted mainly in the urine, with smaller amounts appearing in the faeces, saliva and sweat. They cross the placenta barrier and are excreted in breast milk.

5.3 Preclinical safety data

Application of isopropyl alcohol to the skin may cause dryness and irritation. The lethal dose by mouth is reported to be 250 mL, but even 20 mL produce toxic symptoms like ketonacidosis and ketonuria due to the major metabolite acetone. Inhalation of isopropyl alcohol vapour has been reported to produce coma.

Due to the very good local tolerance of povidone, iodinated preparations accidental oral uptake does not cause the same severe corrosive effects as written for not complexed iodine preparations.

The toxicity of povidone, iodinated is mainly defined from the intake of iodine as iodide and its effect on the thyroid:

The thyroid is sensitive to an excess of iodine. Goitre and hypothyroidism (as can occur with iodine deficiency) as well as hyperthyroidism can result from this.

The normal daily requirement ranges from 100 to 300 micrograms, quantities of 500 micrograms to 1 mg daily probably have no effects on thyroid function in most cases. Larger doses cause an initial rise in thyroid hormone production, but at still higher doses, production decreases (Wolff-Chaikoff effect). The fall in thyroid hormone production is normally transient, adaptation occurring on repeated administration. A lack of adaptation may produce a chronic inhibition of thyroid hormone synthesis leading to goitre and hypothyroidism in certain cases. Congenital goitre and hypothyroidism have followed maternal ingestion. Neonates have been affected following maternal application of povidone, iodinated as well as following direct application to the neonate.

Excess iodine may also induce hyperthyroidism (Iod-Basedow phenomenon). Elderly subjects and those with nodular goitres have been found to be at greatest risk.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium iodide
Sodium dihydrogen phosphate dihydrate
Purified water

6.2 Incompatibilities

Iodine reacts with mercury compounds forming strongly caustic mercurous iodide.

6.3 Shelf Life

Shelf life of the medicinal product as packed for sale
2 years

In-use shelf -life: 12 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

150 ml, 500 ml, 1000 ml:	Bottle of polyethylene (HDPE), closed with a screw cap of polypropylene.
5l:	Bottle of polyethylene (HDPE), closed with a seal and a screw cap of polyethylene.

Bottled may be accompanied by a mechanical pump-spray-head. Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

B. Braun Medical Limited
3 Naas Road Industrial Park
Naas Road
Dublin 12

8 MARKETING AUTHORISATION NUMBER

PA0179/025/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 April 1987
Date of last renewal: 08 April 2007

10 DATE OF REVISION OF THE TEXT

May 2007