Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Braunol 75 mg/g Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient
100 g solution contain:
7.5 g Iodinated Povidone, with a content of 10 % available iodine.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution
Clear, brown, aqueous 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 to the affected area.

4.3 Contraindications

Hypersensitivity to iodine or any of the other excipients.
Use before radio-iodine therapy.

4.4 Special warnings and precautions for use

Should evidence of local irritation or sensitivity occur, use of the product should cease.
If no improvement occurs, the doctor should be consulted.

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.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Allergic reactions are very rare, even in iodine sensitive patients.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiseptics and Disinfectants – Iodine products, ATC code: D08 AG02.

Iodinated povidone (povidone iodine) is an iodophor used for disinfection and antisepsis. Iodophors are loose complexes of iodine and complexing polymers. Solutions of povidone iodine gradually release iodine. Povidone iodine is thus less toxic than preparations of uncomplexed iodine.

5.2 Pharmacokinetic properties

Iodine is poorly absorbed when applied to the skin. After accidental oral uptake povidone iodine-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 placental barrier and are excreted in breast milk.

5.3 Preclinical safety data

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

The toxicity of povidone iodine 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 iodine 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

Purified water
Sodium dihydrogen phosphate dihydrate
Nonoxinol 9
Sodium hydroxide (for pH-adjustment)

6.2 Incompatibilities

Iodine reacts with mercury compounds forming strongly caustic mercurous iodide.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

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

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA 179/27/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 June 1986

Date of last renewal: 05 June 2006

10 DATE OF REVISION OF THE TEXT

September 2006