Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Iodoflex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1g unit-dose paste contains:

Cadexomer iodine	600	mg	
equivalent to:			
Iodine	9	mg	Ph. Eur.
Cadexomer	591	mg	

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Impregnated dressing

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of chronic exuding wounds, e.g. leg ulcers. The underlying disease must also be treated.

When applied to wounds, Iodoflex reduces the bacterial count. In chronic leg ulcers it accelerates healing and reduces pain.

For topical application.

4.2 Posology and method of administration

In adults and the elderly, Iodoflex unit-dose paste is applied to the wound surface and then covered with a dry gauze dressing. The frequency of change depends on the exudation from the wound. Changes should be made when the Iodoflex unit-dose paste has become saturated with wound exudate, indicated by loss of colour, usually two to three times a week. If the wound is exuding heavily, daily changes may be needed.

Each time the unit dose paste is changed and at the end of the treatment the remaining Iodoflex should be gently removed from the wound surface with a stream of water or saline.

A single application should not exceed 50g. The total amount of Iodoflex used in one week should not exceed 150g.

The duration of treatment should not exceed three months in any single course of treatment.

There is no experience in children, therefore Iodoflex is not recommended.

4.3 Contraindications

Iodoflex is contraindicated in:

- patients with known or suspected iodine sensitivity.
- Hashimoto's thyroiditis.
- non-toxic nodular goitre.
- children.

Iodoflex should not be used:

- by pregnant or lactating women.

4.4 Special warnings and precautions for use

Iodine may be absorbed systemically, especially when large wounds are treated. Patients with severely impaired renal function or a past history of any thyroid disorder are more susceptible to alterations in thyroid metabolism with chronic Iodoflex therapy.

In endemic goitre there have been isolated reports of hyperthyroidism associated with exogenous iodine.

It has been observed occasionally that an adherent crust can form when Iodoflex is not changed with sufficient frequency.

4.5 Interaction with other medicinal products and other forms of interaction

There is a potential risk of interaction with lithium, resulting in an increased possibility of hypothyroidism.

Iodoflex should not be used concomitantly with mercurial antiseptics, e.g. mercurochrome and thiomersal.

Since iodine may be absorbed systemically, the result of tests of the thyroid function can be influenced.

4.6 Pregnancy and lactation

Iodine crosses the placental barrier and is secreted into breast milk. Clinical experience of use in pregnant women is limited. Insufficient animal data are available. Iodoflex should therefore not be used in pregnant or lactating women.

4.7 Effects on ability to drive and use machines

It is unlikely to have an effect.

4.8 Undesirable effects

About 5% of the patients treated with Iodoflex experience a transient smarting or pain within the first hour after application. Contact allergy, alteration in thyroid function and local oedema have been reported in rare cases. Minor reddening or swelling around the wound may occur without necessarily being an allergic reaction.

4.9 Overdose

There have been no reported overdosages. In case of excessive topical use of the Iodoflex paste, the treatment should be stopped, the area washed and symptomatic treatment introduced.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Iodoflex consists of cadexomer iodine in a macrogol base applied to a polyester gauze carrier. In contact with wound exudate Iodoflex absorbs fluid, removes exudate, pus and debris from the wound surface. One gram of cadexomer iodine can absorb up to 6ml of fluid. Iodine is physically immobilised within the matrix of the dry cadexomer iodine and is slowly released in an active form during uptake of wound fluid. This mechanism of release provides antibacterial activity both at the wound surface and within the formed gel. There is no evidence of the development of bacterial resistance to iodine. The formed gel can easily be removed without damaging the fragile new epithelium underneath.

5.2 Pharmacokinetic properties

Systemically absorbed iodine from Iodoflex is rapidly and almost exclusively excreted into the urine. Cadexomer is biodegradable by amylases, normally present in wound fluid.

5.3 Preclinical safety data

In preclinical studies, Iodoflex has been shown not to interfere with normal wound healing. Toxicity studies with daily skin applications of Iodoflex for 6 months in rabbits showed no evidence of local or systemic toxic effect. Iodoflex did not cause sensitisation in animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lanogen 1500 40%
Consisting in equal parts of:

Macrogol 300 Ph. Eur.
Macrogol 1500 Ph. Eur.

6.2 Incompatibilities

Iodoflex should not be used concomitantly with taurolidine, since there is a risk of metabolic acidosis.

6.3 Shelf Life

48 months.

6.4 Special precautions for storage

The product should be stored below 25^{o}C.

6.5 Nature and contents of container

Iodoflex is provided with a polyester gauze backing. Each unit is packed in a heat-sealed sachet of polyethylene or ionomer (inside), aluminium, polyethylene and paper (outside).

The following packages are available:

- 5 sterile unit-doses of 5 g (6x4 cm) in an outer carton.
- 3 sterile unit-doses of 10 g (8x6 cm) in an outer carton.
- 2 sterile unit-doses of 17 g (10x8 cm) in an outer carton.

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

1. Clean the wound and let the wound surface stay moist. Dry the surrounding area.
2. Remove the backing gauze and apply Iodoflex directly onto the wound surface. Cover with a suitable dressing.
3. Change the dressing when Iodoflex has lost its colour. Irrigate to remove as much remaining Iodoflex as possible.
4. Support bandages or stockings can be applied in conjunction with the use of Iodoflex.

7 MARKETING AUTHORISATION HOLDER

Smith & Nephew Pharmaceuticals Limited
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8 MARKETING AUTHORISATION NUMBER

PA 710/5/1

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