APPROVED PACKAGE INSERT

SCHEDULING STATUS:

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PROPRIETY NAME (AND DOSAGE FORM):

IODOSORB (ointment)

COMPOSITION:

Each gram of ointment contains 0,500 g of cadexomer iodine equivalent to 0,491 g of cadexomer and 0,009 g of iodine.

PHARMACOLOGICAL CLASSIFICATION:

A 14.1: Wound disinfectants

PHARMACOLOGICAL ACTION:

On contact with the wound exudate, cadexomer iodine ointment absorbs fluid. This results in the formation of a gel over the wound surface. The formed gel possesses chromatographic properties and acts as an inverter column. As a result, exudate, pus and debris are removed from the wound surface into the gel matrix. In vitro the absorption of fluid increases the pore size of the carrier base and iodine held within the matrix in the elemental state is progressively released against the concentration gradient.

INDICATIONS:

Treatment of chronic exudative leg ulcers.

CONTRAINDICATIONS:

Known or suspected hypersensitivity to iodine. IODOSORB should not be used by persons who are allergic to iodine.

Cadexomer iodine should not be used on patients with Hashimoto's thyroiditis, thyroid disease, patients with a prior history of Grave's disease and non-toxic nodular goitre.

In children or neonates.

IODOSORB should not be used during pregnancy or by breastfeeding females.

Drug interactions:

There is a potential for interaction of iodine with lithium, sulphafurazoles and sulphonylureas and therefore co-administration is not recommended. IODOSORB ointment should not be used concomitantly with mercurial antiseptics, e.g. Mercurochrome and thiomersal, since there is a risk of metabolic acidosis.

DOSAGE AND DIRECTIONS FOR USE:

FOR EXTERNAL USE ONLY.

IODOSORB ointment is applied topically to the wound surface to a depth of approximately 3 mm (1/8 inch). A single application should not exceed 50 g. The total amount of IODOSORB ointment used in one week must not exceed 150 g. The preparation should be changed approximately three times per week or when the IODOSORB ointment has become saturated with wound exudate, indicated by

a loss of colour. Each time the dressing is changed at the end of the treatment, the remaining IODOSORB should be gently removed from the ulcer surface either with a stream of sterile water or saline, or with a sterile moist swab.

The duration of treatment should not exceed three months in any single course of treatment. When venous insufficiency is a contributory factor, support bandages or stockings can be applied in conjunction with the use of IODOSORB ointment.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Side effects:

A transient stinging or painful sensation may occur with IODOSORB ointment during the first hour after application. Mild erythema without sensation has also been reported. Hypersensitivity reactions, alteration in thyroid function and irritation of the skin may occur.

Special precautions:

Systemic absorption of iodine can occur especially when treating large wounds.

Adherent crusts may form when the ointment is not changed with sufficient frequency.

Thyroid disorders:

Patients with a history of any thyroid disorder are more susceptible to alteration in thyroid metabolism with chronic IODOSORB therapy.

Systemic absorption of iodine should be taken into consideration if the thyroid function of a patient is under investigation.

In endemic goitre there have been isolated reports of hyperthyroidism associated the IODOSORB.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

If accidental ingestion should occur, systemic toxicity may result, indicated by a metallic taste, vomiting, abdominal pain and diarrhoea. Metabolic acidosis, hypernatraemia, impairment of renal function and hyper- or hypothyroidism may occur following ingestion of large quantities of IODOSORB.

Victims of acute poisoning have been given copious draughts of milk or starch mucilage; lavage may be attempted if there is no oesophageal damage. Other treatments include activated charcoal, and sodium thiosulphate solution 1 % or 5 % to reduce iodine to the less toxic iodides.

IDENTIFICATION:

Dark brown paste, with a slightly grainy consistency.

PRESENTATION:

A single dose sterile aluminium tube containing 20 g of ointment.

Pack size: two tubes.

STORAGE INSTRUCTIONS:

Store in a dry place at or below 25 °C.

Keep out of reach of children.

REGISTRATION NUMBER:

37/14.1/0333

NAME AND BUSINESS ADDRESS OF APPLICANT:

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