APPROVED PACKAGE INSERT

SCHEDULING STATUS:

S1

PROPRIETARY NAME (and dosage form):

IRUXOL® Mono Ointment

COMPOSITION:

Each 1 g of ointment contains:

Collagenase Clostridiopeptidase A	1,20 units
Proteases	0,24 units

PHARMACOLOGICAL CLASSIFICATION:

A 13.9 Special combinations

PHARMACOLOGICAL ACTION:

IRUXOL® Mono ointment produces a gentle, bloodless and practically pain-free enzymatic debridement of wounds.Sloughs are dissolved or separated, thereby facilitating their removal.

INDICATIONS:

For wound cleansing in various types of ulceration, including decubitus ulcers and in poorly healing necrotic wounds.

CONTRA-INDICATIONS:

Additional preparations for topical use should not be applied, since such preparations may influence the activity of IRUXOL® Mono ointment.

DOSAGE AND DIRECTIONS FOR USE:

If not otherwise prescribed by the physician, IRUXOL® Mono ointment is applied once daily in a layer of about 2 mm thickness. The ointment should be in close and even contact with the wound surface. In some cases it may be of advantage to apply the ointment twice daily. Completely dry and hard crusts should be softened by application of a moist dressing. Necrotic material which has separated should be removed when the dressing is changed. This can be done with gauze, forceps or bathing. As a matter of routine or for relief of irritation, it may be useful to cover the wound edge with zinc paste or a similar preparation. IRUXOL® Mono ointment should be applied according to medical prescription. The end of treatment is determined by the physician

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

At the beginning of treatment a burning sensation and pain may be felt in the wound surface. This, however, results only In rare cases in discontinuation of treatment. Some patients may show signs of local irritation which may be due to hypersensitivity. In such cases the physician should be consulted regarding the continuation of treatment.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

None known. Treatment is symptomatic and supportive

IDENTIFICATION:

A brownish ointment with a faint characteristic odour.

PRESENTATION:

Tubes of 10 g and 30 g.

STORAGE INSTRUCTIONS:

Store below 25°C.

Keep out of reach of children

REGISTRATION NUMBER

G1633 (Act 101/1965).

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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