smith&nephew

IRUXOL® MONO

Ointment

Important information, read carefully!

For enzymatic wound debridement.

Composition

IRUXOL® mono is an enzyme preparation of Clostridium histolyticum containing the collagenase clostridioptidase A (EC 3.4.24.3) as the active constituent and other proteases as associated enzymes.

1 g of ointment contains not less than 1.2 units of clostridiopeptidase A and at least 0.24 units of its associated proteases in a lipophilic anhydrous ointment base.

Mode of action

The process of wound healing is speeded up if the wound base is free from necrotic tissue which may be anchored to the wound surface by strands of native collagen.

Collagenases are the only proteolytic enzymes capable of breaking down native collagen. The synergistic action of collagenase and the associated proteases allows the decomposition of necrotic components of the wound, thus intensifying the wound cleaning effect.

IRUXOL® mono does not affect intact epithelium, granulation tissue, fatty tissue and muscle so that healthy tissue is not damaged.

In bacterial wound infections the bacteria are deprived of a medium by enzymatic degradation of the necrotic tissue.

Therapeutic indications

IRUXOL® mono is indicated for enzymatic debridement of necrotic tissue in cutaneous as well as subcutaneous ulceration.

Contraindications

IRUXOL® mono must not be used in patients hypersensitive to any of the ingredients.

Do not use in major burns.

Undesirable effects

IRUXOL® mono is generally well tolerated. Side effects include local pain, burning or irritation, localised skin reactions (including contact dermatitis), Erythema.

For all of the undesirable effects, in severe cases discontinuation of treatment should be considered.

Interactions with other medicaments and compatibility

1. Antiseptics, heavy metals, detergents and soaps used concomitantly will inhibit the activity of the collagenase.
2. Tyrothricin, gramicidin and tetracyclines should not be used locally with IRUXOL® mono.
3. Chloramphenicol, neomycin, framycetin, bacitracin, polymyxin B and macrolides, eg. erythromycin have been shown to be compatible. IRUXOL® mono is not stable over longer periods in the presence of moisture.

Special warnings and precautions for use

Do not store IRUXOL® mono at temperatures above 25°C (77°F).

Avoid contact with eyes and mucosa.

In diabetic patients, dry gangrenes should be moistened with caution in order to avoid conversion to moist gangrene.

Use in pregnancy and lactation

Although no evidence of teratogenic effect has been reported, Iruxol mono should only be administered during the first three months of pregnancy when strictly indicated.

Since collagenase does not enter the systemic circulation, excretion in breast milk is unlikely.

Overdose

Inadvertent intake of the drug is unlikely, but if it occurs it should be removed from the stomach (vomiting or gastric lavage if required).

Pharmacodynamics

IRUXOL® mono can be used for the debridement of wounds, with necrotic tissue remnants being broken down and removed, which promotes wound-healing. Necrotic tissue can be anchored to the surface of the wound by unaltered collagen fibres, and these can only be removed by enzymatic action once the unaltered collagen fibres have been broken down. Unaltered collagen is resistant against the action of proteases.

The collagenases in IRUXOL® mono are proteolytic enzymes, which are able to break down the collagen fibres. When the non-polar region splits off, the collagen fibre disintegrates into high-molecular peptides, which can then be broken down further by collagen peptidases and non-specific proteases.

GIF 022
164 x 192 mm

Because of the substrate-specificity, the action of collagenase alone is not sufficient for the debridement of wounds, since the fibrous or globurular proteins remain unaffected. The combined action of collagenase and related proteases ensures that all protein components in the wound are broken down, improving the wound-cleaning effect.

IRUXOL® mono has no effect on intact epithelial, granulation, fat and muscle tissue, so healthy tissue is not damaged. In addition, collagenase has been shown to improve the healing rates of necrotic wounds by increasing the proliferation and migration of fibroblasts and macrophages, and to accelerate the migration rates of endothelial cells to the wound.

Activation of these cell types results in the production of cytokines and growth factors.

Pharmacokinetics

Results from immunological studies (both from human and animal experiments) have made it clear that here is no systemic absorption of collagenase following administration to intact skin, or following administration to ulcerous plaques.

Neither anti-collagenase antibodies nor collagenase could be found in the blood of patients treated for skin lesions.

It seems that inactivation and breakdown also takes place in the necrotic area itself. The breakdown products of collagenase probably go to make up part of the endogenous stock of peptides and amino acids.

Dosage and mode of administration

To guarantee successful enzymatic wound treatment with IRUXOL® mono, sufficient moisture must be present in the wound area during therapy. In dry wounds the wound base must therefore be moistened with physiological saline (0.9% NaCl) or other solutions which are well tolerated by the tissue (eg. glucose).

Dry and hard crusts should be first softened by applying a moist dressing.

A layer of approximately 2 mm of ointment should be applied directly to the slightly moistened area to be treated once daily. Occasionally twice daily use may be required.

In general it will suffice to change the dressing once daily. An increase of activity may possibly be obtained by applying the ointment twice daily.

The treatment of varicose ulcers with IRUXOL® mono will be usefully supplemented by a pressure bandage and, in arterial circulatory disorders, by appropriate drug treatment.

Whenever infection is present, an appropriate antibiotic treatment should be considered. Chloramphenicol, neomycin, framycetin, bacitracin, gentamicin, polymyxin B and macrolides eg. erythromycin have been shown to be compatible with IRUXOL® mono.

Presentation

15 g and 30 g IRUXOL® mono.
Store the drug carefully!
Keep out of reach of children!

EXPIRY DATE

Do not use IRUXOL® mono beyond the expiry date indicated on the carton.

Manufacturer

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