

## DEBRIFREE

**For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.**

Abbreviated Prescribing information for DEBRIFREE (Papain - Urea Ointment)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**Mechanism of action:** Papain is proteolytic enzyme derived from fruit of Carica Papaya, is a potent digestant of non-viable protein matter, but is harmless to viable tissue. Papain is active over a wide range of pH (3-12). Papain is relatively ineffective when used alone as debriding agent and requires the presence of activators to stimulate its digestive potency. In DEBRIFREE, papain is combined with urea, a denaturant of proteins to provide two supplemental chemical actions. -To expose the sulfhydryl groups (activators of papains) by solvent action -To denature the non-viable tissue in the lesions and render it more susceptible to enzymatic digestions. Pharmacological studies have shown that the combinations of papain and urea results in twice as much digestive activity as papain alone.

**DOSAGE AND ADMINISTRATION:** The ointment should be applied directly to the lesion and the covered with appropriate dressing. Daily or twice daily changes of dressings preferred.

**CONTRAINDICATION:** DEBRIFREE is contraindicated in patients with known hypersensitivity to the active substance or to any of the excipient of this product.

**WARNINGS & PRECAUTIONS:** Avoid contact with the eyes and mucous membranes. If irritation occurs, discontinue use temporarily and consult a physician. Apply with caution only to damaged or inflamed skin or to the face. The product should be used under medical supervision in babies.

**DRUG INTERACTION:** Hydrogen peroxide solution may inactivate the papain. Precautions to avoid hydrogen peroxide during the wound cleansing process. Urea may enhance the efficacy of topical formulations of 5-fluorouracil and dithranol, and increase the release and the permeation into the skin of active ingredients from other topical products such as corticosteroids. The salts of heavy metals such as lead, silver, and mercury may inactivate papain. Therefore, contact with topical medications containing these metals should be avoided on the wound treated with Papain-Urea.

**ADVERSE REACTIONS:** DEBRIFREE is generally a well-tolerated and non-irritating formulation. A transient burning sensation may be experienced by a small percentage of patients upon apply DEBRIFREE. Occasionally, the profuse exudates from enzymatic digestion may irritate the skin. In such cases, more frequent dressing changes will alleviate discomfort until exudates decreases. There were no product related adverse events observed during study period in efficacy evaluable population during reported clinical trial.

**Marketed BY:**



**IN/DEBRIFREE-  $\geq$  521700 Units and 100 mg /Mar -21/01 /ABPI**  
(Additional information is available on request)