



1. Generic Name

Papain and Urea

2. Qualitative and Quantitative composition

Papain.....521700 units

Urea.....100 mg

3. Dosage form and strength

Topical ointment containing 521700 units of Papain and 100mg of Urea.

4. Clinical particulars

4.1 Therapeutic indication

DEBRIVOID is indicated for debridement of necrotic tissue and liquefaction of slough in acute and chronic lesions such as pressure ulcers, varicose and diabetic ulcers, burns, postoperative wounds, pilonidal cyst wounds, carbuncles and miscellaneous traumatic or infected wounds.

4.2 Posology and method of administration

Apply DEBRIVOID ointment directly to the wound. Before each use of ointment, clean the affected area with saline or another mild wound cleansing solution recommended by doctor. Then cover the treated area with bandaging or other dressing. Ointment is usually applied two times each day.

4.3 Contraindication

DEBRIVOID is contraindicated in patients with a history of hypersensitivity to any of the components in the preparation.

4.4 Special warnings and precautions for use

- Avoid cleansing wound with hydrogen peroxide solution as it may inactivate the papain.
- Avoid getting DEBRIVOID in eyes, mouth, and nose, or on lips. If it does get into any of these areas, wash with water.
- Do not use other medicated skin products unless recommended by doctor.

4.5 Drug interactions

DEBRIVOID has potential interactions with:

- Hydrogen peroxide
- Medicines that contain heavy metals such as lead, silver and mercury

4.6 Use in special population

- Pediatric: No data available.
- Geriatric: No data available.
- Liver impairment: No data available.
- Renal failure: No data available.
- Pregnancy and lactation: DEBRIVOID should be applied during pregnancy only if the potential benefit justifies the potential risk to the foetus. It is not known DEBRIVOID is found in breast milk. If patient is or will be breast-feeding while using DEBRIVOID ointment, consult with doctor.

4.7 Effects on ability to drive and use machine

Patient must take precautions till effect of Debrivoid is known.

4.8 Undesirable effects

DEBRIVOID Ointment is generally well-tolerated and non-irritating. A transient "burning" sensation may be experienced by a small percentage of patients upon applying Ointment. Occasionally, the profuse exudate from enzymatic digestion may irritate the skin.

In such cases, more frequent dressing changes will alleviate discomfort until exudate decreases.

4.9 Overdose

Seek emergency medical attention if an overdose of DEBRIVOID is suspected or if the medication has been ingested. Symptoms of an overdose of papain-urea topical are not known.

5. Pharmacological properties

5.1 Mechanism of action

DEBRIVOID ointment is used to remove dead tissues and thinning the pus in lesions such as ulcers, burns, bed sores, surgical wounds, cysts and carbuncles. Papain is a substance from the papaya fruit. Papain breaks down certain proteins. Urea also breaks down protein.

Papain-urea combination is a debriding agent. It works by helping the breakdown of dead skin and pus, which helps improve the recovery time of open wound.

5.2 Pharmacodynamic properties

Papain has been used for the treatment of inflammation and pain via topical administration, papain has also shown to have anthelmintic and tooth-whitening properties. Present in over-the-counter mixture products consisting of different digestive enzymes, its active site contains a catalytic diad that plays a role in breaking peptide bonds. Papain is also used as an ingredient in various enzymatic debriding preparations.

Urea is used humectant; it draws water into the stratum corneum.

5.3 Pharmacokinetic properties

Papain is active over a pH range of 3 to 12. It is relatively ineffective when used alone as a debriding agent and requires the presence of activators to stimulate its digestive potency. The combination of papain and urea promotes two supplemental chemical actions. First, it exposes by solvent action, the activators of papain. Secondly, it denatures the nonviable protein matter in lesions; thereby rendering it more susceptible to enzymatic digestion. The

combination of papain and urea has been shown in pharmacologic studies to result in twice as much digestive activity as papain alone.

6. Nonclinical properties

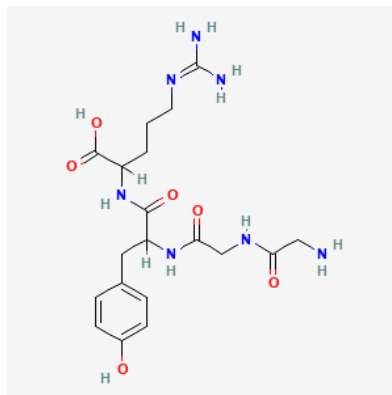
6.1 Animal Toxicology or Pharmacology

NA.

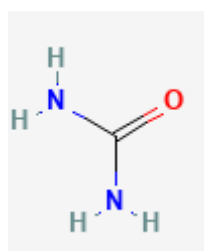
7. Description

Papain, also known as papaya proteinase I, is a cysteine protease enzyme that is found in species of papaya, *Carica papaya* and *Vasconcellea cundinamarcensis*. The enzyme is found to be localized in the skin of papaya, and is collected from slashed unripe papayas as a crude latex. Papain is used in food, pharmaceutical, textile, and cosmetic industries.

Its empirical formula is $C_{19}H_{29}N_7O_6$ and its molecular weight is 451.5g/mol. Its structural formula is:



Urea is a keratolytic emollient used to treat hyperkeratotic lesions and moisturize the skin. Its empirical formula is NH_2CONH_2 and its molecular weight is 60.056 g/mol. Its structural formula is:



8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

24 months.

8.3 Packaging Information

Debrivoid is available in tube of 15gm.

8.4 Storage and handling instructions

Store below 30 °C in a dark and dry place.

9. Patient Counselling Information

9.1 Adverse Reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.5

9.3 Dosage

Refer part 4.2

9.4 Storage

Refer part 8.4

9.5 Risk Factors

Refer part 4.4

9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

10. Manufactured by

CENTAUR PHARMACEUTICALS PVT. LTD., Drug farm Laboratories and Goa Antibiotics

11. Details of permission or license number with date

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