

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Collagenase ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Collagenase Ointment is available as a sterile ointment in a white petrolatum base packaged in 15 gram tubes.

3 PHARMACEUTICAL FORM

This product is like white or slightly yellow ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Collagenase ointment is a sterile ointment indicated for the enzymatic debridement of burn wound and promoting the wound healing.

4.2 Posology and method of administration

once a day or every other day. The use method is as follows:

- (1) Before using medication, gently wash the affected area with normal saline.
- (2) In case of infection, use appropriate antibiotics and then apply the product. If the infection continues, suspend the application after the infection is eliminated.
- (3) This product can be directly applied to the affected area, or applied on the gauze, applied to the affected area.

4.3 Contraindications

Not for local and systemic allergies to the ingredients contained in this product.

4.4 Special warnings and precautions for use

The optimal pH range of collagenase is 6-8. Too high or too low pH reduces the activity of this product, so appropriate attention should be paid. The enzyme activity is also affected by decontamination agents, heavy metal ions, for example, by the mercury and silver used in some preservatives. When it is suspected that these things have been exposed, the affected area should be carefully washed with normal saline before using this product. Soaking containing metal ions and acid solutions should also be avoided because such solutions with metal ions and low pH.

Cleaners such as hydrogen peroxide solution, sodium hypochlorite solution, or normal saline can be used in combination with this product.

Because enzymatic debridement may theoretically increase the risk of bacterial infection, close attention should be paid to the systemic bacterial infection in critically ill patients.

When applying this product to surrounding tissues outside of the wound, slight temporary redness may occasionally occur, so the ointment should be carefully applied to the wound.

4.5 Interaction with other medicinal products and other forms of interaction

Silver and mercury found in detergents and preservatives can reduce the activity of this product.

4.6 Fertility, pregnancy and lactation

Not yet clear

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

This product is well tolerated. Potential adverse reactions are local pain, burning, or tingling sensation.

4.9 Overdose

It has been confirmed in clinical investigation and clinical application that no systemic or local reactions occur in overdose. Sometimes, if necessary, the affected area is cleaned with polyethylene pyrrolidone iodine to inactive collagenase.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacology and Toxicology

This product is an enzyme drug. Because collagen accounts for 75% of the dry skin weight, collagenase has the role of hydrolyzing natural collagen at physiological pH and temperature, and it has the unique digestive role of natural and denatured collagen in necrotic tissue. If the necrotic tissue fixed by its own collagen in the base of the wound is removed, the healing of the wound is accelerated. Collagenase is the only proteolytic enzyme capable of resolving their own collagen. Collagenase decomposes the necrotic tissue of the wound and promotes the formation of granulation tissue and epithelial tissue of the wound, and healthy tissue such as normal epithelium, granulation tissue, adipose tissue and muscle around the wound will not be damaged. In the bacterial infectious wounds, the necrotic tissue is enzymatically degraded to lose the bacterial medium for growth, thus alleviating the wound infection. During wound healing, the amount and activity of endogenous collagenase are affected, so it is necessary to supplement the exogenous collagenase. The decomposition of collagenase can not only make the necrotic tissue loose and easy to remove, so that the wound can grow and repair normally. At the same time, the peptide chain molecules produced after collagen degradation can further degenerate into fibrocyte, inflammatory cells, which can accelerate the proliferation and movement of keratinocytes and thus accelerate the wound healing.

5.2 Pharmacokinetic properties

Not yet clear.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White petrolatum, liquid paraffin

6.2 Incompatibilities

Nor yet clear.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Shaded, sealed and stored in cold (2-10°C).

6.5 Nature and contents of container

(1) Aluminum medicinal ointment tube: 15g / tube / box

(2) Aluminum medicinal ointment tube: 5g / tube / box

6.6 Special precautions for disposal and other handling

7 MARKETING AUTHORISATION HOLDER

Liaoning Weibang BioPharma. Co., Ltd

No.1 Xiyi Road, Teng'ao Economic Development Zone, Haicheng City, Anshan City,
Liaoning Province, China.

8 MARKETING AUTHORISATION NUMBER

H20090366

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

March 12, 2010

10 DATE OF REVISION OF THE TEXT

December 1, 2019