

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Collagenase for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sterilized and lyophilized collagenase with moderate stabilizer and excipient

3 PHARMACEUTICAL FORM

White or nearly white lump or powder

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Collagenase for injection is indicated for the treatment of Herniated Lumbar Intervertebral Disc incase conservative therapy is not effective.

4.2 Posology and method of administration

Dissolve the contents with 2 ml Sodium Chloride Injection, and then inject 1200 units of collagenase into Intervertebral Disc or extradural space of Intervertebral Foramen.

Procedure:

Patient is placed in the lateral decubitus. Under the X-ray fluoroscopy, along the Lumbar vertebrae transverse process, the needle is entered from the side of the vertebrae into intervertebral foramen of the L4-L5 or L5-S1. Then 1200 units of collagenase is injected into intervertebral foramen extradural space or into intervertebral disc.

4.3 Contraindications

(1) Allergic diathesis. (2) Severe Angio cardiopathy. (3) Severe hepatic insufficiency and renal insufficiency. (4) Pregnancy.

4.4 Special warnings and precautions for use

Before using Collagenase for injection, inject 5 mg dexamethasoni natrii phosphas in 20 ml of 50% glucose solution intravenously as a prophylactic, procedure for allergic reaction. This product can only be used by trained doctors. Carefully find the accurate injection site. Avoid doing harms on nerve root and peripheral tissues.

4.5 Interaction with other medicinal products and other forms of interaction

The optimal pH range of collagenase is 6 to 8. Drugs with higher or lower pH will decrease the enzyme's activity and appropriate precautions should be taken.

Collagenase requires calcium ions both for full catalytic activity and binding to the collagen molecule. Drugs contained metal chelating agent or heavy metal ions will decrease the enzyme's activity and appropriate precautions should be taken.

4.6 Fertility, pregnancy and lactation

Due to lack of experience, Dipeptiven should not be administered during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

After injection, there is a higher incidence of post injection pain in some of the patients, inject analgesic to relieve patients from the pain if necessary.

4.9 Overdose

The phenomenon of overdosing without experiencing systemic or local reactions that has been confirmed in clinical investigations and applications.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Collagenase exists in the normal human body, and its metabolic pathway is general protein metabolism.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

sodium chloride, mannitol

6.2 Incompatibilities

Nor clear yet

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Protect from light. Store in dry place, at lower temperature

6.5 Nature and contents of container

10 ml vial

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

600 units: H10960177

1200 units: H10960178

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

November 23, 2007

10 DATE OF REVISION OF THE TEXT

December 7, 2021