

For use by a Registered Medical Practitioner or Hospital or Laboratory only.

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Recombinant Human Epidermal Growth Factor Gel

REGEN-D® 150

For Quick Wound Healing

DESCRIPTION:

REGEN-D®150 is Human Epidermal growth factor based gel produced by recombinant DNA technology and developed by Bharat Biotech International Limited, Hyderabad, India.

RECOMBINANT DNA TECHNOLOGY:

The primary structure of recombinant human EGF is a single chain polypeptide which is a 53 amino acids chain.

PHARMACEUTICAL FORM:

REGEN-D®150 is presented in the form of gel packaged in sizes of 7.5, 15, 30, and 150 gm tubes in concentration of 150 µg / gm.

Composition:

Each gram of gel contains

Recombinant Human Epidermal Growth Factor: 150µg

Methyl Paraben (sod.salt).....1.8mg (0.18% w/w)

Propyl Paraben (sod.salt).....0.2mg (0.02% w/w)

INDICATIONS:

REGEN-D®150 is indicated for topical healing of neuropathic and diabetic foot ulcers

CONTRAINDICATIONS:

REGEN-D® 150 is generally well tolerated. However, the product should not be administered or repeated to persons known to be hypersensitive to any of the components of the product. Also, it should not be administered to individuals receiving immunosuppressive or immune-stimulant therapy or in immune compromised individuals.

PREGNANT AND LACTATING MOTHERS:

REGEN-D®150 is contraindicated in cases of pregnant and lactating woman.

DOSAGE :

After cleaning ulcer area, apply the gel so as to cover the full ulcer area. The dosage of the gel depends on the specific size of the ulcer area of the particular patient as advised by the physician.

REGEN-D® 150 ADMINISTRATION:

Provided in gel base **REGEN-D®150** is to be spread evenly (topical application) on affected part using a sterile cotton swab twice daily till the ulcer area heals. **REGEN-D®150** therapy should be continued up to a period of 15 to 20 weeks. The continuation of the therapy is at the discretion of the physician.

PRECAUTIONS:

It is suggested that the medical practitioners ascertain the hypersensitivity status of the subject.

REGEN-D®150 can be administered at the same time with other general concomitant drugs but must not be used with other growth factor containing drugs.

ADVERSE REACTIONS:

REGEN-D®150 has proven low reactivity and is well tolerated. Rash, pain, and skin irritation at the application site may be seen in some cases.

INSTRUCTIONS FOR USE:

- 1) A single tube should be used for individual patient.
- 2) The required precautions should be taken to avoid direct contact with the ulcer site.
- 3) The patient should ensure that the ulcer area is kept very clean before the drug is applied. The patients can do this by washing the ulcer area daily with mild soap or a saline solution and keeping the ulcer area covered with clean, dry dressings.
- 4) It should be ensured that the product has not crossed its shelf life.

Any unwarranted use of the product is not the responsibility of the manufacturer.

PHARMACEUTICAL PARTICULARS:

Category : Growth factor.

Storage : Store in a cool and dry place

Shelf life : date of expiry printed on the carton.

Last revision date: October 2016

Manufactured & Marketed by



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