

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

Rx

# Recombinant Human Epidermal Growth Factor Gel

## REGEN-D® 60

For Quick Wound Healing

### DESCRIPTION:

**REGEN-D®60** 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®60** is presented in the form of gel packaged in sizes of 7.5, 15, 30 and 150 gm tubes in concentration of 60 µg / gm.

### Composition:

#### Each gram of gel contains

Recombinant Human Epidermal Growth Factor : 60 µg  
Methyl Paraben (sod.salt).....1.8mg (0.18% w/w)  
Propyl Paraben (sod.salt).....0.2mg (0.02% w/w)

### INDICATIONS:

**REGEN-D®60** is indicated for use in healing of

1. Donor site skin grafts
2. First and Second degree burns only

### CONTRAINDICATIONS:

**REGEN-D®60** 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 who are receiving immunosuppressive or immune-stimulant therapy, or in immune compromised individuals.

### PREGNANT AND LACTATING MOTHERS:

**REGEN-D®60** is contraindicated in cases of pregnant and lactating woman.

### DOSAGE:

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

### REGEN-D®60 ADMINISTRATION:

Provided in gel base, **REGEN-D®60** is to be spread evenly (topical application) on affected part using a sterile cotton swab twice a day till the wound / burn area heals. **REGEN-D®60** therapy should be continued up to a period of 2 to 3 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®60** 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®60** has proven low reactivity and is well tolerated. Rash at the application site may be seen in very few 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 wound / burn site .
- 3) The patient should ensure that the wound / burn area is kept very clean before the drug is applied. The patients can do this by washing the wound / burn area daily with mild soap or a saline solution and keeping the wound /burn 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 dry and cool place.

Shelf life : The expiry date of the product indicated on the carton

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Manufactured & Marketed by



**Bharat Biotech International Ltd.**

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