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

¹⁸ रिकॉम्बीनेन्ट ह्युमन एपीडर्मल ग्रोथ फेक्टर ज्एल Recombinant Human Epidermal Growth Factor Gel

REGEN-D 60 ਈजੇ**न-**डੀ[°] ६०

For Quick Wound Healing

DESCRIPTION:

REGEN-D[™]60 is Human Epidermal growth factor produced by recombinant DNA technology 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-DTM**60** is presented in the form of gel packaged in sizes of 7.5, 15, 30, 60 gm and 150 gms tubes in concentration of $60 \mu g/gm$.

Composition :

Each gram of gel contains

Recombinant Human Epidermal Growth Factor : 60 µg

INDICATIONS :

REGEN-D[™]60 is indicated for use for the healing of

- 1. Donor site Skin grafts
- 2. 1^{st} and 2^{nd} 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 in cases of treatment with immunosuppressive or immuno stimulant therapy.

PREGNANT AND LACTATING MOTHERS:

REGEN-D[™]60 is contraindicated in cases of pregnant woman, Immunocompromised individuals.

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 ADMINSTRATION:

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.

PRECAUTIONS:

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

REGEN-DTM60 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.

REGEN-D^m60 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-DTM60 has proven low reactogenicity and is well tolerated. Clinical trials did not show adverse reactions to the patient.

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) The patient should ensure that the product has not crossed the shelf life.

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

PHARMACEUTICAL PARTICULARS:

Category	: Growth factor.
Storage	: Store at 2° C to 8° C. Do not freeze.
Shelf life	: Two years from the date of manufacture.

Manufactured & Marketed by



Genome Valley, Shameerpet, Hyderabad - 500 078. India.

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