

Patient Product Information

REGEN D[®]150

(India's First Recombinant Human Epidermal Growth Factor (rhEGF) Gel for Diabetic Foot Ulcers)

Generic name: [Recombinant Human Epidermal Growth Factor (rhEGF)]

Read this information with care before using Regen D[®]150

- Keep this leaflet with you. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This drug has been prescribed for you only. Do not pass it on to others.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is there in this leaflet?

1. What are characteristics of foot ulcers?
2. What is Regen D[®]150 and what is its use?
3. What are the important aspects to note before using Regen D[®] 150?
4. How is Regen D[®] 150 administered?
5. What are the possible side effects from using Regen D[®] 150?
6. How is Regen D[®] 150 stored?

1. What are characteristics of foot ulcers?

Foot ulcers (foot ulcerations) are serious complications in poorly controlled diabetes which are caused by the breakdown of the tissue underneath the skin layer. The common sites of Diabetic foot ulcers (DFUs) are big toes and heel of the foot. DFU occurs because of poor blood circulation to the affected area, impairment in sensation due to nerve impairment and impaired immune system functioning; all of which are related to high blood sugar level in diabetes. Risk factors for DFUs are lack proper foot care which include poor hygiene, poor-quality shoes, improper trimming of toenails, alcohol consumption, eye disease from diabetes, heart disease, kidney disease, obesity, tobacco use (inhibits blood circulation) are responsible for DFU. If neglected, infected foot ulcers can result in amputation.

It can be prevented by foot baths, disinfecting the skin around an ulcer, keeping the ulcer dry with frequent dressing changes, enzyme treatments and dressings containing calcium alginates to inhibit bacterial growth, seeking a podiatrist advice for corn and callus removal and wearing proper-fitting shoes.

2. What is Regen D[®]150 and what is its use?

Regen D[®] 150(recombinant human epidermal growth factor) is a topical gel, manufactured by Bharat Biotech International Limited. It is used for faster healing of the following types of ulcers:

- Diabetic foot ulcer
- Bedsore
- Vascular ulcer
- Chronic leg ulcer

An epidermal growth factor is a small mitogenic protein that is involved in mechanisms such as normal cell growth, wound healing, and reduces the healing time.

3. What are the important aspects to note before using Regen D[®] 150?

Regen D[®] 150 should not be applied if

- You are allergic to any of the components
- You are pregnant woman or a nursing mother
- You are immune-compromized individual
- You are receiving immunosuppressive or immunostimulant medications

4. How is Regen D[®]150 administered?

The dose of the gel depends on the specific size of the ulcer area of the particular patient as advised by the physician.

Provided in gel base, **REGEN-D[®]150** is to be spread evenly (topical application) on the affected part using a sterile cotton swab twice a day till the ulcer area heals. **REGEN-D[®]150** 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.

- a) A single tube should be used for individual patient.
- b) Avoid direct contact of the tube with the wound area.
- c) The patient should ensure that the wound area is cleaned with sterile cotton or a saline solution before the gel is applied. 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.

5. What are the possible side effects from using Regen D[®]150?

The following side effects may occur:

Dizziness, headache, nausea, abdominal pain, rash and pruritus.

6. How is Regen D[®] 150 stored?

- Keep Regen D[®]150 out of the reach and sight of children.
- Store Regen D[®]150 at room temperature (25°C).
- Do not use Regen D[®]150 after the expiry date (EXP) which is stated on the package containing the tube.