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)]

Please read this leaflet before you start taking REGEN-D[®] 150. Also, read it each time you renew your prescription, just in case anything has changed. Remember, this leaflet does not take the place of careful discussions with your doctor. You and your doctor should discuss REGEN-D[®] 150 when you start taking your medication and at regular checkups.

What is REGEN-D[®] 150?

REGEN-D $^{\circledR}$ 150 (Recombinant Human Epidermal Growth Factor) is a topical gel, for faster healing of Diabetic Foot Ulcers.

REGEN-D[®] 150 acts by, enhancing the wound healing process thereby reducing the healing time drastically over the natural course. Severe complications of foot ulcer can lead to amputation (removal of body extremity by surgery); REGEN-D[®] 150 facilitates to prevent this.

What are the various applications of REGEN-D $^{\textcircled{R}}$ 150 ?

- Faster healing of diabetic foot ulcers (DFU)
- Regeneration therapy in the management of bed sores & vascular ulcers.

Consult your Doctor for further information.

What are the storage guidelines for REGEN-D $^{(\!R\!)}$ 150 ?

Store at 2-8⁰C.

Do not Freeze

Avoid keeping outside for long time

What are the general guidelines for REGEN-D $^{\textcircled{R}}$ 150 application ?

Basic diabetic wound management procedures should be strictly followed while using $REGEN-D^{\circledR}$ 150 gel

- Proper glycemic control has to be maintained as recommended by your physician.
- Proper diabetic foot care and ulcer management guidelines should be adhered while using REGEN-D[®] 150 gel

Note: REGEN-D[®] 150 gel is a wound healing agent and it has no role in curing/treating diabetes.

How does Diabetes affect the feet?

Diabetes can affect your feet in two ways:

1) Diabetic Neuropathy

Uncontrolled diabetes has shown to damage the nerves. Damaged nerves in the legs and feet, may cause loss of sensation such as heat, cold, or pain. This lack of sensation is called "sensory diabetic neuropathy." Foot ulcers occur because of nerve damage and peripheral vascular disease.

2) Peripheral Vascular Disease

Poor blood flow in the arms and legs is called "peripheral vascular disease." Diabetes affects the flow of blood. Without proper blood flow, it takes longer for a sore, wound or cut to heal. Peripheral vascular disease is a circulation disorder that affects blood vessels away from the heart. An infection that does not heal due to poor blood flow increases the risk of developing ulcers or gangrene (death of tissue due to a lack of blood).

What common foot problems do diabetic patients face?

The following are the common foot problems:

<u>Foot ulcers</u>: A foot ulcer is a break in the skin or a deep sore, which can become infected. Foot ulcers can result from minor scrapes, cuts that heal slowly or from the rubbing of shoes that do not fit well. Early intervention is important in treatment.



<u>Fungal infection of nails</u>: Nails that are infected with a fungus may become discolored (yellowish-brown or opaque), thick and brittle, and may separate from the rest of the nail. The dark, moist and warm environment of shoes can promote fungal growth. In addition, an injury to the nail can put you at risk for a fungal infection. Fungal nail infections are difficult to treat.



<u>Calluses</u>: A callus is a build-up of hard skin, usually on the underside of the foot. Calluses are caused by an uneven distribution of weight, generally on the bottom of the forefoot or heel. Calluses also can be caused by improperly fitting shoes or by a skin abnormality.



<u>Corns</u>: A corn is a build-up of hard skin near a bony area of a toe or between toes. Corns may be the result of pressure from shoes that rub against the toes or cause friction between the toes.



<u>Blisters</u>: Blisters can form when your shoes rub the same spot on your foot. Wearing shoes that do not fit properly or wearing shoes without socks can cause blisters, which can become infected.



<u>Ingrown toenails</u>: Ingrown toenails occur when the edges of the nail grow into the skin. They cause pressure and pain along the nail edges. The edge of the nail may cut into the skin causing redness, swelling, pain, drainage and infection.

What are the common myths & facts on diabetes, concerning public health?

MYTH 1: Diabetes is contagious.

Diabetes is an endocrine disease and is caused by a problem with the amount of insulin produced by the beta cells in the pancreas. Diabetes tends to be an inherited trait that runs in families - it is not contagious.

<u>MYTH 2</u>: People with diabetes (kids, adolescents, and adults) should avoid parties. There is no reason to do this since everyone needs to relax and socialize. In fact, parties are a great way to lower or avoid stress which can affect blood sugar levels. People with diabetes just need to be careful about the amount and type of food they take.

MYTH 3: Insulin cures diabetes.

When used properly, insulin is a medicine that helps to keep the levels of blood sugar in the near-normal range. In Type 1 (insulin dependent) diabetes, insulin must be used because the

pancreas is not producing enough insulin. In Type 2 diabetes - diet, exercise, and oral diabetes medications are used, with insulin sometimes used for additional control. Insulin itself does not cure diabetes.

MYTH 4: Pills for diabetes are oral insulin.

Pills for diabetes (oral hypoglycemic agents) work to affect the ability of the body to use insulin better - they are not oral insulin.

MYTH 5: People with diabetes can't eat carbohydrates.

Not true. However, when a person is first diagnosed with diabetes it is important to meet with a dietitian who is aware of the medical treatment planned by your doctor. Proper balanced medication with physical activity, life-style, and the amount & types of food that you eat will help you keep blood sugar levels at near-normal levels, feel healthy, and prevent long-term complications.

MYTH 6: If my insulin dose is increased, my diabetes must be getting worse.

The most important goal for people with diabetes is keeping near normal blood sugar levels in order to feel well and avoid long-term diabetes complications. To do this, each person needs different amounts and types of food, physical activity, and medicines like insulin.

<u>MYTH 7</u>: There are many jobs that people with diabetes can't do.

Almost all jobs can be done by people with diabetes. In the past, some positions in the military, and occupations such as airplane pilot or interstate truck driver were not available to people with diabetes. Today, many of these professions are changing those requirements.

Can such foot problems be prevented?

Yes. When you have diabetes, taking good care of your feet is very important. Poor foot care can lead to serious problems, including amputation. A person with diabetes is more vulnerable to foot problems because the disease can damage nerves and reduce blood flow to the feet.

By taking proper care of the feet, most serious problems can be prevented. Proper foot care can help prevent foot problems and/or treat them before they cause serious complications. Here are few vital tips for good foot care:

- » Wash and dry feet daily
- » Examine feet everyday

- » Take Care of toenails
- » Be careful when exercising
- » Protect feet with good shoes and socks

Do's:

- Use mild soaps and warm water
- Thoroughly dry feet after washing and use a good moisturizing lotion on the feet to prevent cracking
- Look for blisters, cuts, scratches, sores, redness, increased warmth, or tenderness when touching any area of the feet
- Check for ingrown toenails, corns and calluses
- Cut toenails straight across after bathing, when they are soft
- Walk and exercise in comfortable shoes
- Always protect feet by wearing shoes or hard-soled slippers
- Wear natural-fiber socks (cotton or wool)

Don'ts:

- Do not put lotion between toes
- Blisters should not be popped. Apply a bandage and wear a different pair of shoes
- Avoid cutting into the corners of toes
- Do not exercise with open sores on your feet
- Never go barefoot
- Avoid shoes with high heels and pointed toes
- Avoid shoes that expose toes or heels

Vital Diabetic Foot Ulcer Precautions:

- Never put pressure by prolonged walking or standing on the affected foot
- Put feet up while sitting to facilitate proper blood flow
- Keep ulcers covered by dressing to keep them clean and warm
- Never let dressings get wet as this can lead dirt and germs to the ulcer







- Followed Standard wound Management as suggested by your Physician
- Inspect feet daily, including between toes
- Proper diet control i.e. glucose levels to be maintained
- Don't wait to treat a minor foot problem. Follow your physician's first aid and guidelines
- Do not use heating pads on feet
- Do not cross your legs
- Do not self-treat your corns, calluses, or other foot problems. Go to a doctor to treat these conditions