Becaplex® Gel
(rhPDGF-BB 0.01% W/W)

COMPOSITION
Each gram of gel contains Recombinant Human Platelet Derived Growth factor-BB (rhPDGF-BB): 100 mcg.
Excipients: Methylparaben, Propylparaben, Sodium acetate, Lysine Hydrochloride, Sodium chloride, M-cresol, Glacial acetic acid, Carboxy Methyl Cellulose Sodium.

PRESENTATION
Becaplex® is supplied as a clear, colorless to straw-colored gel. It is available in 7.5g and 15g polyethylene laminated tubes.

PROPERTIES
rhPDGF-BB is a dimeric protein with a molecular weight of approximately 24.500 Daltons. Native PDGF is a growth factor derived from blood platelets and mediates tissue repair.

PHARMACOLOGY
Native endogenous PDGF belongs to one of the five super families of growth factors that are known to initiate a cascade of processes that ensure healing. It is synthesized by megakaryocytes, macrophages, fibroblasts, smooth muscle cells, and endothelial cells and is released from platelets after tissue injury. This PDGF derived from blood platelets mediates tissue repair via:
-Mitogenesis of mesenchymal cells including dermal fibroblasts, smooth muscle cells, and also perhaps wound capillary endothelial cells;
-Chemoattraction of fibroblasts, smooth muscle cells, monocytes, and neutrophils;
-Induction of extra cellular matrix components in fibroblasts including collagen, fibronectin, and hyaluronic acid;
-Induction of metalloproteinases involved in wound remodeling.
Becaplex® gel has a biological activity similar to endogenous PDGF and has a high affinity for PDGF-β receptor. It promotes chemotactic recruitment and proliferation of cells like fibroblasts that are involved in wound repair thus enhancing formation of granulation tissue. Judging from the clinical trials the gel appears to be non-irritant to normal human skin. This well ensures the effectiveness of Becaplex® gel and probably reduces the incidence of amputation or other complications normally associated with diabetic foot.

PHARMACOKINETICS
Published literature indicates that daily application of rhPDGF-BB has only negligible systemic absorption; therefore only limited pharmacokinetic data is available. However rhPDGF-BB seems to have longevity in the presence of biological fluid of at least 12 hours in vivo and 24 hours in vitro supporting the daily dosing regimen.

INDICATIONS
Becaplex® gel is indicated for the treatment of full thickness, neuropathic, lower extremity diabetic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply (Stage III & Stage IV ulcers IAET*Staging classification). When used as an adjunct to, and not a substitute, for good ulcer care practices including: initial sharp debridement, pressure relief by a non weight bearing regimen, and adequate infection control with systemic antibiotics, Becaplex® gel increases the incidence of complete healing of diabetic ulcers.
The efficacy of Becaplex® gel for the treatment of diabetic neuropathic Stage I or Stage II ulcers (ulcers that do not extend through the dermis into subcutaneous tissue) or ischemic diabetic ulcers have not been evaluated.
*International Association of Enterostomal Therapy for staging of chronic wounds.
Stage III Ulcer: Full thickness loss extending through dermis to involve subcutaneous tissue.
Stage IV Ulcer: Full thickness loss involving the muscle, bone, or tendon.

CONTRAINDICATIONS
Becaplex® gel is contraindicated in patients with:
-Known hypersensitivity to any component of the excipients used in the product.
-Known neoplasm(s) at the site(s) of application.

DRUG INTERACTIONS
It is not known whether Becaplex® gel interacts with other topical medications applied to the ulcer site. The use of Becaplex® gel with other topical drugs has not been studied.

PREGNANCY
No studies in pregnant women have been conducted,therefore, Becaplex® gel could be used during pregnancy if the benefits outweigh the risks.

NURSING MOTHERS
Since the drug is secreted in breast milk, caution should be exercised when Becaplex® gel is administered to nursing women.

WARNINGS AND PRECAUTIONS
Becaplex® gel is a low bio burden preserved product. Therefore, it is not preferred for use in wounds that close by primary intention.
Becaplex® gel is intended for external use only.
If application site reactions occur, the possibility of sensitization or irritation caused by excipients like parabens or m-cresol should be considered.

SIDE EFFECTS
Commonly reported side effects are erythema, and rarely bullous eruption and edema.

DOSAGE
The intended dose is around 7µg/cm^2 of ulcer per day in an average man of 50kg weight . Thus the amount Becaplex® gel to be applied varies depending upon the size of the ulcer. For calculating the adequate dose of Becaplex® gel, the greatest length of the ulcer should be measured and multiplied by the greatest width of the ulcer in centimeters . Surface area of the ulcer thus obtained is to be divided by 4 to give the approximate length of the gel in cm to be squeezed out from the tube. Proper dose in centimeters: 0.25g of Becaplex® gel (containing about 25µg of rhPDGF-BB) per centimeter of gel length squeezed out.

Size	Formula
7.5g / 15g tube	Length (cm) x Width (cm)/4

OVERDOSAGE
Since absorption is insignificant from the site of topical application, no untoward systemic events are expected.

INSTRUCTIONS FOR USE
-A tube of Becaplex® gel should be used for a single patient only.
-Hands should be washed thoroughly before applying Becaplex® gel.
-The tip of the tube should not come into contact with the ulcer or any other surface.
-Before each application, the ulcer should be gently rinsed with saline solution or water to remove any residual gel and wound area cleaned.
-Becaplex® gel should only be applied once daily in a carefully measured quantity adjusted according to the size of ulcers (see Dosage section).
-The calculated dose of Becaplex® gel should be squeezed out onto a clean, firm, non-absorbable surface (e.g.wax paper) in a linear fashion.
-The use of a clean application aid like a cotton swab, tongue depressor, etc is recommended to apply Becaplex® gel.
-The measured quantity of gel should be spread evenly over the ulcerated area including the margins to yield a thin continuous layer of approximately 1.5mm thickness.
-The gel should be covered with a saline solution moistened gauze and a secondary dressing. After 12 hours the gel can be gently rinsed off using saline solution or water. DO NOT APPLY ANY BECAPLEX® GEL AT THIS TIME. Apply a new, moist dressing on the wound.
-The Becaplex® gel application should be repeated, as mentioned above, daily.
-The tube should be closed tightly after each use.
-After treatment is completed, any residual gel should be discarded.
-The amount of Becaplex® gel to be applied daily should be recalculated at weekly or biweekly intervals by the physician or assigned medical personnel.
-It is important to use Becaplex® gel together with a good ulcer care program, including a strict non weight-bearing program.
-Excess application of Becaplex® gel has not been shown to be beneficial.
-Becaplex® gel should be stored in the refrigerator. Becaplex® gel should not be frozen.
-Becaplex® gel should not be used after the expiration date.

STORAGE
Store between 2°C to 8°C.
Do not freeze.

Manufactured by
Virchow Biotech Private Limited - India
For
Benta S.A.L. **- Lebanon**

This is a medicament
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Medicament: keep out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

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