Skip to main content

Becaplermin (Regranex)

??? ??????: 30 ??????/?????? 2017

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In a follow-up study from two randomized, controlled trials, an increased rate of cancer remote from the becaplermin treatment site was observed in subjects treated with REGRANEX Gel. [see **WARNINGS AND PRECAUTIONS**]

In clinical trials, erythematous rashes occurred in 2% of patients treated with REGRANEX Gel (and good ulcer care) or placebo (and good ulcer care), and none in patients receiving good ulcer care alone. Patients treated with REGRANEX Gel did not develop neutralizing antibodies against becaplermin.

Postmarketing Experience

An increased rate of mortality secondary to malignancy was observed in patients treated with 3 or more tubes of REGRANEX Gel in a postmarketing retrospective cohort study, [see **WARNINGS AND PRECAUTIONS** and **BOXED WARNING**]

Burning sensation at the site of application and erythema have been reported during post-approval use of REGRANEX Gel. Because post approval adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the drug.