

MEDICATION GUIDE

REGRANEX® (RE#-GRAN-IX)

(becaplermin)

Gel

Read this Medication Guide before you start using REGRANEX and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about REGRANEX?

People who use 3 or more tubes of REGRANEX may have an increased risk of death from cancer.

- You should talk with your healthcare provider about the possible benefits and risks to you if you use more than 3 tubes of REGRANEX.
- If you already have cancer, you and your healthcare provider should carefully consider whether you will use REGRANEX.

If you decide to use REGRANEX, your healthcare provider will tell you how to use REGRANEX. See the section "How should I use REGRANEX?" below.

What is REGRANEX?

REGRANEX is a man-made protein medicine that is used with other ulcer care practices (such as good wound care) to treat diabetic sores (ulcers) of your legs or feet that are deeper than just your skin, in people who have good blood supply to the legs.

It is not known if REGRANEX is effective for the treatment of pressure ulcers or ulcers that are due to poor blood flow (circulation).

It is not known if REGRANEX is safe and effective in children under 16 years of age.

Who should not use REGRANEX?

Do not use REGRANEX if you have a skin tumor at the area where you apply REGRANEX.

What should I tell my healthcare provider before using REGRANEX?

Before you use REGRANEX tell your healthcare provider if you:

- have cancer
- have poor blood flow to your lower legs and feet
- have allergies to any of the ingredients in REGRANEX. See the end of this Medication Guide for a complete list of ingredients in REGRANEX.
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if REGRANEX will harm your unborn baby.
- are breast-feeding or plan to breast-feed. It is not known if REGRANEX passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you apply other medicines to diabetic ulcers of your legs or feet. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use REGRANEX?

- Use REGRANEX together with good ulcer care, as prescribed by your healthcare provider. This includes following your healthcare provider's instructions about not putting weight on the affected leg and foot (non-weight bearing).
- Use REGRANEX exactly as your healthcare provider tells you to use it.
- REGRANEX is for use on skin ulcers only. Do not use REGRANEX in your mouth, eyes, or vagina.
- REGRANEX comes as a gel. Your healthcare provider should tell you how often to use REGRANEX and how much REGRANEX to use.
- Your healthcare provider should check the size of your ulcer every 1 to 2 weeks.

- Your healthcare provider may change the amount of REGRANEX to be applied to your ulcer as the size of your ulcer changes. So, the amount of REGRANEX to be squeezed from the tube may change as the size of your ulcer changes.
- Close your REGRANEX tube tightly after each use.
- Put the REGRANEX tube back in the refrigerator after each use.
- Use a cotton swab, tongue depressor, or other application aid when you apply your REGRANEX. Do not let the tip of your REGRANEX tube touch the ulcer or any other surface.
- Apply REGRANEX one time each day.

Apply REGRANEX as follows:

- Wash your hands well before you apply REGRANEX.
- Carefully measure the amount of REGRANEX that your healthcare provider tells you to use.
- Squeeze the amount of REGRANEX needed for your ulcer on to a clean, firm, non-absorbable surface, such as wax paper.
- Use a clean cotton swab, tongue depressor, or similar application aid, to spread the REGRANEX gel in a thin even layer over the surface of the ulcer on your foot or leg.
- Cover the area with a saline-moistened gauze dressing.
- After about 12 hours, gently rinse the ulcer with saline or water to remove the rest of the REGRANEX. Cover the ulcer with a new saline-moistened gauze dressing. Do not apply any more REGRANEX.

What are the possible side effects of REGRANEX?

REGRANEX may cause serious side effects.

• See the section, "What is the most important information I should know about REGRANEX?"

• Common side effects of REGRANEX include:

- Red skin rash
- Burning at the application site

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of REGRANEX gel. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Ortho-McNeil at 1-888-734-7263.

How should I store REGRANEX?

- Store REGRANEX in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Do not freeze REGRANEX.
- Do not use REGRANEX after the expiration date on the bottom (sealed end) of the tube.
- Throw away your REGRANEX that is out of date or no longer needed for your treatment.

Keep REGRANEX and all medicines out of the reach of children.

General information about REGRANEX

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use REGRANEX for a condition for which it was not prescribed. Do not give REGRANEX to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about REGRANEX. If you would like more information about REGRANEX, talk to your healthcare provider. You can ask your healthcare provider or pharmacist for information about REGRANEX that is written for health professionals.

What are the ingredients in REGRANEX?

Active ingredient: becaplermin

Inactive ingredients: carboxymethylcellulose sodium, glacial acetic acid, l-lysine hydrochloride, m-cresol, methylparaben, propylparaben, sodium acetate trihydrate, sodium chloride, and water for injection.

Manufactured by:

OMJ Pharmaceuticals, Inc.

U.S. License No. 1196

San German, Puerto Rico 00683

Manufactured for:

Ortho-McNeil, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Raritan, NJ 08869

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This Medication Guide has been approved by the U.S. Food and Drug Administration.