

Medication Guide
KALBITOR® (KAL-bi-tor)
(ecallantide)

Read this Medication Guide before you start receiving KALBITOR and before each treatment. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information that I should know about KALBITOR?

Serious allergic reactions may happen in some people who receive KALBITOR. These allergic reactions can be life-threatening and usually happen within 1 hour after receiving KALBITOR.

- KALBITOR should be given to you by a doctor or nurse in a healthcare setting where serious allergic reactions and hereditary angioedema (HAE) can be treated.
- Symptoms of a serious allergic reaction to KALBITOR can be similar to the symptoms of HAE, the condition that you are being treated for. Your doctor or nurse should watch you for any signs of a serious allergic reaction after treatment with KALBITOR.
- **Tell your doctor or nurse right away if you have any of these symptoms of a serious allergic reaction during or after treatment with KALBITOR:**
 - wheezing, shortness of breath, cough, chest tightness, or trouble breathing
 - dizziness, fainting, fast or weak heartbeat, or feeling nervous
 - reddening of the face, itching, hives, or feeling warm
 - swelling of the throat or tongue, throat tightness, hoarse voice, or trouble swallowing
 - runny nose or sneezing

What is KALBITOR?

KALBITOR is a prescription medicine used to treat sudden attacks of hereditary angioedema (HAE).

KALBITOR is not a cure for HAE.

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

Who should not receive KALBITOR?

Do not receive KALBITOR if you are allergic to KALBITOR.

What should I tell my doctor before I receive KALBITOR?

Before receiving KALBITOR, tell your doctor if you:

- have ever had an allergic reaction to KALBITOR. See “Who should not take KALBITOR?”
- are pregnant or plan to become pregnant. It is not known if KALBITOR will harm your unborn baby.
- are breast-feeding or plan to breast-feed. It is not known if KALBITOR passes into your breast milk.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.
Know the medicines you take. Keep a list of them to show to your doctor and pharmacist when you get a new medicine.

How will I receive KALBITOR?

For each dose, you will receive 3 injections just under the skin (subcutaneous or SC injections) of your abdomen, thigh, or upper arm.

What are the possible side effects?

KALBITOR can cause serious allergic reactions. See "What is the most important information I should know about KALBITOR?".

Common side effects of KALBITOR include:

- headache
- nausea
- diarrhea
- fever
- injection site reactions, such as redness, rash, swelling, itching, or bruising
- stuffy nose

Call your doctor for advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about KALBITOR

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This Medication Guide gives you the most important information about KALBITOR. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about KALBITOR that is written for health professionals.

What are the ingredients of KALBITOR?

Active Ingredient: ecallantide

Inactive ingredients: disodium hydrogen orthophosphate (dihydrate), monopotassium phosphate, potassium chloride, sodium chloride in water for injection.

Manufactured for: Dyax Corp.

300 Technology Square, Cambridge, MA 02139

Issued Month Year

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

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