HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use KALBITOR® safely and effectively. See full prescribing information for KALBITOR.
KALBITOR (ecallantide)
Injection for subcutaneous use
Initial U.S. Approval: 2009

WARNING: ANAPHYLAXIS
See full prescribing information for complete boxed warning

Anaphylaxis has been reported after administration of KALBITOR®. Because of the risk of anaphylaxis, KALBITOR should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema. Healthcare professionals should be aware of the similarity of symptoms between hypersensitivity reactions and hereditary angioedema and patients should be monitored closely. Do not administer KALBITOR to patients with known clinical hypersensitivity to KALBITOR [see *Contraindications (4), Warnings and Precautions (5.1), and Adverse Reactions (6)*].

INDICATIONS AND USAGE

- KALBITOR is a plasma kallikrein inhibitor indicated for treatment of acute attacks of hereditary angioedema (HAE) in patients 16 years of age and older. (1)

DOSAGE AND ADMINISTRATION

- 30 mg (3 mL), administered subcutaneously in three 10 mg (1 mL) injections. If an attack persists, an additional dose of 30 mg may be administered within a 24 hour period. (2.1)
- KALBITOR should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema. (2.2).

DOSAGE FORMS AND STRENGTHS

- Single use glass vial containing 10 mg/mL of ecallantide as a solution for injection. (3)

CONTRAINDICATIONS

- Do not administer KALBITOR to a patient who has known clinical hypersensitivity to KALBITOR. (4)

WARNINGS AND PRECAUTIONS

- Hypersensitivity Reactions Including Anaphylaxis: Anaphylaxis has occurred in 3.9% of treated patients. Administer KALBITOR in a setting equipped to manage anaphylaxis and hereditary angioedema. Given the similarity in hypersensitivity symptoms and acute HAE symptoms, monitor patients closely for hypersensitivity reactions (5).

ADVERSE REACTIONS

- The most common adverse reactions occurring in ≥3% of KALBITOR-treated patients and greater than placebo are headache, nausea, diarrhea, pyrexia, injection site reactions, and nasopharyngitis. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Dyax Corp. at 1-888-452-5248 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

To report SUSPECTED ADVERSE REACTIONS, contact at or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

See 17 for PATIENT COUNSELING INFORMATION and the FDA-approved Medication Guide

Revised: 02/2012

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FULL PRESCRIBING INFORMATION

WARNING: ANAPHYLAXIS

Anaphylaxis has been reported after administration of KALBITOR. Because of the risk of anaphylaxis, KALBITOR should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema. Healthcare professionals should be aware of the similarity of symptoms between hypersensitivity reactions and hereditary angioedema and patients should be monitored closely. Do not administer KALBITOR to patients with known clinical hypersensitivity to KALBITOR. [see *Contraindications (4), Warnings and Precautions (5.1), and Adverse Reactions (6)*]

1 INDICATIONS AND USAGE

KALBITOR® (ecallantide) is indicated for treatment of acute attacks of hereditary angioedema (HAE) in patients 16 years of age and older.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

The recommended dose of KALBITOR is 30 mg (3 mL), administered subcutaneously in three 10 mg (1 mL) injections. If the attack persists, an additional dose of 30 mg may be administered within a 24 hour period.

2.2 Administration Instructions

KALBITOR should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema.

KALBITOR should be refrigerated and protected from the light. KALBITOR is a clear, colorless liquid; visually inspect each vial for particulate matter and discoloration prior to administration. If there is particulate matter or discoloration, the vial should not be used.

Using aseptic technique, withdraw 1 mL (10 mg) of KALBITOR from the vial using a large bore needle. Change the needle on the syringe to a needle suitable for subcutaneous injection. The recommended needle size is 27 gauge. Inject KALBITOR into the skin of the abdomen, thigh, or upper arm. Repeat the procedure for each of the 3 vials comprising the KALBITOR dose. The injection site for each of the injections may be in the same or in different anatomic locations (abdomen, thigh, upper arm). There is no need for site rotation. Injection sites should be separated by at least 2 inches (5 cm) and away from the anatomical site of attack.

The same instructions apply to an additional dose administered within 24 hours. Different injection sites or the same anatomical location (as used for the first administration) may be used.

3 DOSAGE FORMS AND STRENGTHS

KALBITOR is a clear, colorless liquid free of preservatives. Each vial of KALBITOR contains ecallantide at a concentration of 10 mg/mL.

4 CONTRAINDICATIONS

Do not administer KALBITOR to a patient who has known clinical hypersensitivity to KALBITOR. [*see Warnings and Precautions (5.1)*].

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions, Including Anaphylaxis

Potentially serious hypersensitivity reactions, including anaphylaxis, have occurred in patients treated with KALBITOR. In 255 HAE patients treated with intravenous or subcutaneous KALBITOR in clinical studies, 10 patients (3.9%) experienced anaphylaxis. For the subgroup of 187 patients treated with subcutaneous KALBITOR, 5 patients (2.7%) experienced anaphylaxis. Symptoms associated with these reactions have included chest discomfort, flushing, pharyngeal edema, pruritus, rhinorrhea, sneezing, nasal congestion, throat irritation, urticaria, wheezing, and hypotension. These reactions occurred within the first hour after dosing.

Other adverse reactions indicative of hypersensitivity reactions included the following: pruritus (5.1%), rash (3.1%), and urticaria (2.0%).

Patients should be observed for an appropriate period of time after administration of KALBITOR, taking into account the time to onset of anaphylaxis seen in clinical trials. Given the similarity in hypersensitivity symptoms and acute HAE symptoms, patients should be monitored closely in the event of a hypersensitivity reaction.

KALBITOR should not be administered to any patients with known clinical hypersensitivity to KALBITOR [see *Contraindications (4)*].

6 ADVERSE REACTIONS

Hypersensitivity reactions, including anaphylaxis, have occurred in patients treated with KALBITOR [see *Contraindications (4) and Warnings and Precautions (5.1)*].

6.1 Clinical Trials Experience

Because clinical trials are conducted under 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.

The safety data described below reflect exposure to KALBITOR in 255 patients with HAE treated with either intravenous or subcutaneous KALBITOR. Of the 255 patients, 66% of patients were female and 86% were Caucasian. Patients treated with KALBITOR were between the ages of 10 and 78 years.

Overall, the most common adverse reactions in 255 patients with HAE were headache (16.1%), nausea (12.9%), fatigue (11.8%), diarrhea (10.6%), upper respiratory tract infection (8.2%), injection site reactions (7.4%), nasopharyngitis (5.9%), vomiting (5.5%), pruritus (5.1%), upper abdominal pain (5.1%), and pyrexia (4.7%). Anaphylaxis was reported in 3.9% of patients with HAE. Injection site reactions were characterized by local pruritus, erythema, pain, irritation, urticaria, and/or bruising.

The incidence of adverse reactions below is based upon 2 placebo-controlled, clinical trials (EDEMA3® and EDEMA4®) in a total of 143 unique patients with HAE. Patients were treated with KALBITOR 30 mg subcutaneous or placebo. Patients were permitted to participate sequentially in both placebo-controlled trials; safety data collected during exposure to KALBITOR was attributed to treatment with KALBITOR, and safety data collected during exposure to placebo was attributed to treatment with placebo. Table 1 shows adverse reactions occurring in ≥3% of KALBITOR-treated patients that also occurred at a higher rate than in the placebo-treated patients in the two controlled trials (EDEMA3 and EDEMA4) of the 30 mg subcutaneous dose.

Table 1: Adverse Reactions Occurring at ≥3% and Higher than Placebo in 2 Placebo Controlled Clinical Trials in Patients with HAE Treated with KALBITOR

	KALIBITOR N=100	**Placebo N=81**
Adverse Reactions	n (%)[a]	n (%)[a]
Headache	8 (8%)	6 (7%)
Nausea	5 (5%)	1 (1%)
Diarrhea	4 (4%)	3 (4%)
Pyrexia	4 (4%)	0
Injection site reactions	3 (3%)	1 (1%)
Nasopharyngitis	3 (3%)	0

[a] Patients experiencing more than 1 event with the same preferred term are counted only once for that preferred term.

Some patients in EDEMA3 and EDEMA4 received a second, open-label 30 mg subcutaneous dose of KALBITOR within 24 hours following the initial dose. Adverse reactions reported by these patients who received the additional 30 mg subcutaneous dose of KALBITOR were consistent with those reported in the patients receiving a single dose.

6.2 Immunogenicity

In the KALBITOR HAE program, patients developed antibodies to KALBITOR. Rates of seroconversion increased with exposure to KALBITOR over time. Overall, 7.4% of patients seroconverted to anti-ecallantide antibodies. Neutralizing antibodies to ecallantide were determined *in vitro* to be present in 4.7% of patients.

Anti-ecallantide and anti-*P. pastoris* IgE antibodies were also detected. Patients who seroconvert may be at a higher risk of a hypersensitivity reaction. The long-term effects of antibodies to KALBITOR are not known.

The test results for the ecallantide program were determined using one of two assay formats: ELISA and bridging electrochemiluminescence (ECL). As with all therapeutic proteins, there is a potential for immunogenicity with the use of KALBITOR. The incidence of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to KALBITOR with the incidence of antibodies to other products may be misleading.

7 DRUG INTERACTIONS

No formal drug interactions studies were performed. No *in vitro* metabolism studies were performed.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

There are no adequate and well-controlled trials of KALBITOR in pregnant women. KALBITOR has been shown to cause developmental toxicity in rats, but not rabbits. Because animal reproductive studies are not always predictive of human response, KALBITOR should be used during pregnancy only if clearly needed.
In rats, intravenous KALBITOR at an intravenous dose approximately 13 times the maximum recommended human dose (MRHD) on a mg/kg basis caused increased numbers of early resorptions and percentages of resorbed conceptuses per litter in the presence of mild maternal toxicity. No development toxicity was observed in rats that received an intravenous dose approximately 8 times the MRHD on a mg/kg basis. There were no adverse effects of KALBITOR on embryofetal development in rats that received subcutaneous doses up to approximately 2.4 times the MRHD on an AUC basis, and in rabbits that received intravenous doses up to approximately 6 times the MRHD on an AUC basis.

8.2 Labor and Delivery
No information is available on the effects of KALBITOR during labor and delivery.

8.3 Nursing Mothers
It is not known whether ecallantide is excreted in human milk. Caution should be exercised when ecallantide is administered to a nursing woman.

8.4 Pediatric Use
Safety and effectiveness of KALBITOR in patients below 16 years of age have not been established.

8.5 Geriatric Use
Clinical trials of KALBITOR did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

10 OVERDOSAGE
There have been no reports of overdose with KALBITOR. HAE patients have received single doses up to 90 mg intravenously without evidence of dose-related toxicity. No deaths occurred in monkeys that received intravenous or subcutaneous doses up to 25 mg/kg (approximately 22 times the MRHD on an AUC basis).

11 DESCRIPTION
KALBITOR (ecallantide) is a human plasma kallikrein inhibitor for injection for subcutaneous use.
KALBITOR is a clear and colorless, sterile, and nonpyrogenic solution. Each vial contains 10 mg ecallantide as the active ingredient, and the following inactive ingredients: 0.76 mg disodium hydrogen orthophosphate (dihydrate), 0.2 mg monopotassium phosphate, 0.2 mg potassium chloride, and 8 mg sodium chloride in water for injection, USP. KALBITOR is preservative free, with a pH of approximately 7.0. A 30 mg dose is supplied as 3 vials each containing 1 mL of 10 mg/mL KALBITOR. Each vial contains a slight overfill. Vials are intended for single use. Ecallantide is a 60-amino-acid protein produced in *Pichia pastoris* yeast cells by recombinant DNA technology.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
Hereditary angioedema (HAE) is a rare genetic disorder caused by mutations to C1–esterase-inhibitor (C1-INH) located on Chromosome 11q and inherited as an autosomal dominant trait. HAE is characterized by low levels of C1-INH activity and low levels of C4. C1-INH functions to regulate the activation of the complement and intrinsic coagulation (contact system pathway) and is a major endogenous inhibitor of plasma kallikrein. The kallikrein-kinin system is a complex proteolytic cascade involved in the initiation of both inflammatory and coagulation pathways. One critical aspect of this pathway is the conversion of High Molecular Weight (HMW) kininogen to bradykinin by the protease plasma kallikrein. In HAE, normal regulation of plasma kallikrein activity and the classical complement cascade is therefore not present. During attacks, unregulated activity of plasma kallikrein results in excessive bradykinin generation. Bradykinin is a vasodilator which is thought by some to be responsible for the characteristic HAE symptoms of localized swelling, inflammation, and pain.
KALBITOR is a potent (Ki = 25 pM), selective, reversible inhibitor of plasma kallikrein. KALBITOR binds to plasma kallikrein and blocks its binding site, inhibiting the conversion of HMW kininogen to bradykinin. By directly inhibiting plasma kallikrein, KALBITOR reduces the conversion of HMW kininogen to bradykinin and thereby treats symptoms of the disease during acute episodic attacks of HAE.

12.2 Pharmacodynamics
No exposure-response relationships for KALBITOR to components of the complement or kallikrein-kinin pathways have been established.

The effect of KALBITOR on activated partial thromboplastin time (aPTT) was measured because of potential effect on the intrinsic coagulation pathway. Prolongation of aPTT has been observed following intravenous dosing of KALBITOR at doses ≥20 mg/m^2. At 80 mg administered intravenously in healthy subjects, aPTT values were prolonged approximately two-fold over baseline values and returned to normal by 4 hours post-dose.
For patients taking KALBITOR, no significant QT prolongation has been seen. In a randomized, placebo-controlled trial (EDEMA4) studying the 30 mg subcutaneous dose versus placebo, 12-lead ECGs were obtained at baseline, 2 hours and 4 hours post-dose (covering the time of expected C_{max}), and at follow-up (day 7). ECGs were evaluated for PR interval, QRS complex, and QTc interval. KALBITOR had no significant effect on the QTc interval, heart rate, or any other components of the ECG.

12.3 Pharmacokinetics

Following the administration of a single 30 mg subcutaneous dose of KALBITOR to healthy subjects, a mean (± standard deviation) maximum plasma concentration of 586 ± 106 ng/mL was observed approximately 2 to 3 hours post-dose. The mean area under the concentration-time curve was 3017 ± 402 ng*hr/mL. Following administration, plasma concentration declined with a mean elimination half-life of 2.0 ± 0.5 hours. Plasma clearance was 153 ± 20 mL/min and the volume of distribution was 26.4 ± 7.8 L.
Based on a population pharmacokinetic analysis, body weight, age, and gender were not found to affect KALBITOR exposure significantly. Ecallantide is a small protein (7054 Da) and renal elimination in the urine of treated subjects has been demonstrated. No pharmacokinetic data are available in patients or subjects with hepatic or renal impairment.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

There are no animal or human studies to assess the carcinogenic or mutagenic potential of KALBITOR (ecallantide).
KALBITOR had no effects on fertility and reproductive performance in rats at subcutaneous doses up to 25 mg/kg/day (approximately 21 times the MRHD on a mg/kg basis).

13.2 Animal Toxicology

Reproductive Toxicology Studies
KALBITOR has been shown to cause developmental toxicity in rats, but not rabbits. Treatment of rats with an intravenous dose of 15 mg/kg/day (approximately 13 times the MRHD on a mg/kg basis) caused increased numbers of early resorptions and percentages of resorbed conceptuses per litter in the presence of mild maternal toxicity. However, no development toxicity was observed in rats that received an intravenous dose of 10 mg/kg/day (approximately 8 times the MRHD on a mg/kg basis). KALBITOR was not teratogenic in rats at subcutaneous doses up to 20 mg/kg/day (approximately 2.4 times the MRHD on an AUC basis) and rabbits that received intravenous doses up to 5 mg/kg/day (approximately 6 times the MRHD on an AUC basis).

14 CLINICAL STUDIES

The safety and efficacy of KALBITOR was evaluated in 2 randomized, double-blind, placebo-controlled trials (EDEMA4 and EDEMA3) in 168 patients with HAE. Patients having an attack of hereditary angioedema, at any anatomic location, with at least 1 moderate or severe symptom, were treated with 30 mg subcutaneous KALBITOR or placebo. Because patients could participate in both trials, a total of 143 unique patients participated. Of the 143 patients, 94 were female, 123 were Caucasian, and the mean age was 36 years. There were 64 patients with abdominal attacks, 55 with peripheral attacks, and 24 with laryngeal attacks.
In both trials, the effects of KALBITOR were evaluated using the Mean Symptom Complex Severity (MSCS) score and the Treatment Outcome Score (TOS). These measures evaluated the severity of attack symptoms at all anatomical locations (MSCS score) and response to therapy (TOS).
MSCS score is a point-in-time measure of symptom severity. At baseline, 4 hours, and 24 hours, patients rated the severity on a categorical scale (0 = normal, 1 = mild, 2 = moderate, 3 = severe) for symptoms at each affected anatomical location. Ratings were averaged to obtain the MSCS score. A decrease in MSCS score reflected an improvement in symptoms.
TOS is a measure of symptom response to treatment. At 4 hours and 24 hours, patient assessment of response characterized by their change from baseline in symptom severity and collected by anatomic site of attack involvement, was recorded on a categorical scale (significant improvement [100], improvement [50], same [0], worsening [–50], significant worsening [-100]). The response at each anatomic site was weighted by baseline severity and then the weighted scores across all involved sites were averaged to calculate the TOS. A TOS value >0 reflected an improvement in symptoms from baseline.

EDEMA4

EDEMA4 was a randomized, double-blind, placebo-controlled trial in which 96 patients were randomized 1:1 to receive KALBITOR 30 mg subcutaneous or placebo for acute attacks of HAE. The primary endpoint was the change from baseline in MSCS score at 4 hours, and the TOS at 4 hours was a key secondary endpoint. Patients treated with KALBITOR demonstrated a greater decrease from baseline in the MSCS than placebo and a greater TOS than patients with placebo and the results were statistically significant (Table 2).
At 24 hours, patients treated with KALBITOR also demonstrated a greater decrease from baseline in the MSCS than placebo (-1.5 vs. -1.1; p = 0.04) and a greater TOS (89 vs. 55, p = 0.03).

Table 2: Change in MSCS Score and TOS at 4 Hours

	EDEMA4		EDEMA3	
	KALBITOR (N=48)	Placebo (N=48)	KALBITOR (N=36)	Placebo (N=36)
Change in MSCS Score at 4 Hours				
n	47	42	34	35
Mean	-0.8	-0.4	-1.1	-0.6
95% CI	-1.0, -0.6	-0.6, -0.1	-1.4, -0.8	-0.8, -0.4
P-value	0.010		0.041	
TOS at 4 Hours				
n	47	42	34	35
Mean	53	8	63	36
95% CI	39, 68	-12, 28	49, 76	17, 54
P-value	0.003		0.045	

MSCS: Mean Symptom Complex Severity
TOS: Treatment Outcome Score
CI: confidence interval

More patients in the placebo group (24/48, 50%) required medical intervention to treat unresolved symptoms within 24 hours compared to the KALBITOR-treated group (16/48, 33%).
Some patients reported improvement following a second 30 mg subcutaneous dose of KALBITOR, administered within 24 hours following the initial dose for symptom persistence or relapse, but efficacy was not systematically assessed for the second dose.

EDEMA3

EDEMA3 was a randomized, double-blind, placebo-controlled trial in which 72 patients were randomized 1:1 to receive KALBITOR or placebo for acute attacks of HAE. EDEMA3 was similar in design to EDEMA4 with the exception of the order of the prespecified efficacy endpoints. In EDEMA3, the primary endpoint was the TOS at 4 hours, and the key secondary efficacy endpoint was the change from baseline in MSCS at 4 hours. As in EDEMA4, patients treated with KALBITOR demonstrated a greater decrease from baseline in the MSCS than placebo and a greater TOS than patients treated with placebo and the results were statistically significant (Table 2).
In addition, more patients in the placebo group (13/36, 36%) required medical intervention to treat unresolved symptoms within 24 hours compared to the KALBITOR–treated group (5/36, 14%).

16 HOW SUPPLIED/STORAGE AND HANDLING

KALBITOR (ecallantide) is supplied as three 10 mg/mL single-use vials packaged in a carton. Each vial contains 10 mg of ecallantide. Each vial contains a slight overfill.

- NDC (47783-101-01): 3 single-use vials in 1 carton

KALBITOR should be kept refrigerated (2°C to 8°C/36°F to 46°F). Vials removed from refrigeration should be stored below 86°F/30°C and used within 14 days or returned to refrigeration until use.
Protect vials from light until use.
Do not use beyond the expiration date.

17 PATIENT COUNSELING INFORMATION

See Medication Guide

- Patients should be advised that KALBITOR may cause anaphylaxis and other hypersensitivity reactions. Patients should be advised that KALBITOR should be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema. Patients who have known clinical hypersensitivity to KALBITOR should be instructed not to receive additional doses of KALBITOR. [see *Boxed Warning*, *Contraindications (4), and Warnings and Precautions (5.1)*]

- Patients should be advised to consult the Medication Guide for additional information regarding the risk of anaphylaxis and other hypersensitivity reactions.

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.
55 Network Drive, Burlington, MA 01803

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This Medication Guide has been approved by the U.S. Food and Drug Administration.
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Kalbitor
ecallantide
10 mg/mL
3 Vials
NDC# 47783-101-01

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