INDICATIONS AND USAGE

KANUMA® is a hydrolytic lysosomal cholesteryl ester and triacylglycerol-specific enzyme indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency. (1)

DOSEAGE AND ADMINISTRATION

Infants with Rapidly Progressive LAL Deficiency Presenting within the First 6 Months of Life:

- The recommended starting dosage is 1 mg/kg as an intravenous infusion once weekly. (2.1)
- For patients with a suboptimal clinical response, increase the dosage to 3 mg/kg once weekly. (2.1)
- For patients with continued suboptimal clinical response, further increase the dosage to 5 mg/kg once weekly. (2.1)

Pediatric and Adult Patients with LAL Deficiency:

- The recommended dosage is 1 mg/kg as an intravenous infusion once every other week. (2.1)
- For patients with a suboptimal clinical response, increase the dosage to 3 mg/kg once every other week. (2.1)

See Full Prescribing Information for complete Doseage and Administration Information.

Administration Instructions

- Infuse over at least 2 hours. (2.3)
- Consider further prolonging the infusion time for patients receiving dosages greater than 1 mg/kg or for those who have experienced a hypersensitivity reaction. (2.3)
- Consider a 1-hour infusion for the 1 mg/kg dose in patients who tolerate the infusion. (2.3)

DOSAGE FORMS AND STRENGTHS

Injection: 20 mg/10 mL (2 mg/mL) solution in single-dose vials. (3)

CONTRAINdications

- None. (4)

WARNINGS AND PRECAUTIONS

- Hypersensitivity Reactions including Anaphylaxis: Observe patients during and after the infusion. Consider interrupting the infusion or lowering the infusion rate, based on the severity of the reaction. If a severe hypersensitivity reaction occurs, immediately stop the infusion and initiate appropriate treatment. Pre-treatment with antipyretics and/or antihistamines may prevent subsequent reactions in those cases where symptomatic treatment is required. (5.1)
- Hypersensitivity to Eggs or Egg Products: Consider the risks and benefits of treatment in patients with known systemic hypersensitivity reactions to eggs or egg products. (5.2)

ADVERSE REACTIONS

The most common adverse reactions are:

- Infants with Rapidly Progressive LAL Deficiency Presenting within the First 6 Months of Life (≥30%): diarrhea, vomiting, fever, rinitis, anemia, cough, nasopharyngitis, and urticaria. (6.1)
- Pediatric and Adult Patients with LAL Deficiency (≥8%): headache, fever, oropharyngeal pain, nasopharyngitis, asthenia, constipation, and nausea. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Alexion at 1-844-259-6783 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 11/2021

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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use KANUMA safely and effectively. See full prescribing information for KANUMA.

KANUMA® (sebelipase alfa) injection, for intravenous use

Initial U.S. Approval: 2015

RECENT MAJOR CHANGES

Doseage and Administration (2.1, 2.2) 11/2021
Warnings and Precautions (5.1) 11/2021

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See Full Prescribing Information for complete Doseage and Administration Information.

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symptoms of hypersensitivity reactions, occurring in two or more patients, included abdominal pain, agitation, fever, chills, diarrhea, eczema, edema, hypertension, irritability, laryngeal edema, nausea, pallor, pruritus, rash, and vomiting. The majority of reactions occurred during or within 4 hours of the completion of the infusion. Patients were not routinely pre-medicated prior to infusion of KANUMA in these clinical trials.

Due to the potential for anaphylaxis, appropriate medical support should be readily available when KANUMA is administered. If anaphylaxis occurs, immediately discontinue the infusion and initiate appropriate medical treatment. Observe patients closely during and after the infusion. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should signs and symptoms occur.

The management of hypersensitivity reactions should be based on the severity of the reaction and may include temporarily interrupting the infusion, lowering the infusion rate, and/or treatment with antihistamines, antipyretics, and/or corticosteroids. If interrupted, the infusion may be resumed at a slower rate with increases as tolerated. Pre-treatment with antihypertics and/or antistaminics may prevent subsequent reactions in those cases where symptomatic treatment was required. If a severe hypersensitivity reaction occurs, immediately discontinue the infusion and initiate appropriate medical treatment.

Consider the risks and benefits of re-administering KANUMA following a severe reaction. Monitor patients, with appropriate resuscitation measures available, if the decision is made to re-administer the product.

5.2 Hypersensitivity to Eggs or Egg Products

KANUMA is produced in the egg whites of genetically engineered chickens. Patients with a known history of egg allergies were excluded from the clinical trials. Consider the risks and benefits of treatment with KANUMA in patients with known systemic hypersensitivity reactions to eggs or egg products.

6 ADVERSE REACTIONS

6.1 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 clinical practice.

In clinical trials, a total of 106 patients received treatment with KANUMA. The data described below reflect exposure to KANUMA in 75 patients who received KANUMA at dosages up to 3 mg/kg once weekly and 31 patients who received KANUMA at higher dosages. Nineteen patients received KANUMA at escalating doses ranging between 0.35 mg/kg and 5 mg/kg once weekly (see Clinical Studies (14.1)).

- Nine patients (5 males, 4 females) who had growth failure or other evidence of rapidly progressive LAL deficiency presenting within the first 6 months of life received KANUMA for up to 165 weeks (median 60 weeks) at escalating doses of 1.0 mg/kg to 5 mg/kg once weekly.
- 66 pediatric and adult patients with LAL deficiency aged 4 to 58 years (33 males, 33 females) received KANUMA 1 mg/kg every other week for up to 36 weeks.

Table 2 summarizes the most common adverse reactions occurring in >30% of patients with rapidly progressive LAL deficiency presenting within the first 6 months of life receiving KANUMA in Study 1.

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>KANUMA</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>6 (67)</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>6 (67)</td>
<td></td>
</tr>
<tr>
<td>Fever</td>
<td>5 (56)</td>
<td></td>
</tr>
<tr>
<td>Rhinitis</td>
<td>5 (56)</td>
<td></td>
</tr>
<tr>
<td>Anemia</td>
<td>4 (44)</td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>3 (33)</td>
<td></td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>3 (33)</td>
<td></td>
</tr>
<tr>
<td>Urticaria</td>
<td>3 (33)</td>
<td></td>
</tr>
</tbody>
</table>

Other less common adverse reactions reported in patients with rapidly progressive disease presenting within the first 6 months of life who received KANUMA included hypotonia, decreased oxygen saturation, retching, sneezing, and tachycardia.

For infant patients within Study 1 and Study 3 (n = 19), the following additional adverse reactions were reported in ≥30% of infants who received KANUMA since the time of marketing authorization, including patients who received an escalated dose to 3 mg/kg qw: hypersensitivity, diarrhea, abdominal pain, and dizziness.

Increases in circulating LDL-cholesterol (LDL-c) and triglycerides above pre-treatment values were reported in 29 of 36 (81%) and 21 of 36 (58%) patients, respectively, at 2 and 4 weeks following initiation of KANUMA (see Clinical Pharmacology (12.2)). The maximum mean percentage increase was 18% for LDL-c at Week 2 and 5% for triglycerides at Week 4.

6.2 Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay and 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 in the studies described above with the incidence of antibodies in other studies or to other sebelipase alfa products may be misleading.

Approximately 8% (9/106) of pediatric and adult patients with LAL deficiency developed antibodies to sebelipase alfa (anti-drug antibodies or ADA) following treatment with KANUMA across all clinical studies. Among the 9 patients who developed ADA were positive for neutralizing antibodies (NAb).

Five of 35 (14%) KANUMA-treated pediatric and adult patients who completed the 20-week double-blind period of study treatment developed ADA. All patients were receiving 1 mg/kg once every other week. All 5 ADA-positive patients first developed measurable ADA titers within the first 3 months of exposure. Two of the 5 ADA-positive patients had a measurable ADA titer at only one time point. In the 3 patients with measurable ADA titers at multiple time points, ADA titers decreased to undetectable levels during continued treatment. Two patients developed in vitro neutralizing antibodies during the open-label extension phase after 20 weeks and 52 weeks of treatment with KANUMA, respectively. There is no clear association between the development of ADA and decreased efficacy in pediatric and adult patients treated with KANUMA.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data with KANUMA use in pregnant women are insufficient to identify a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Animal reproductive studies conducted with sebelipase alfa showed no evidence of embryolethality, fetotoxicity, teratogenicity, or abnormal early embryonic development at dosages up to 164 and 526 times the human dosage of 1 mg/kg every other week (based on AUC) in rats and rabbits, respectively.

The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Animal Data

Sebelipase alfa administered during the period of organogenesis to rats (on gestation days 6, 9, 12, 15, and 17) and rabbits (on gestation days 7, 10, 13, 16 and 19) at intravenous doses up to 60 and 50 mg/kg, respectively, (approximately 164 and 526 times the human AUC of 1387 ng.h/mL at 1 mg/kg dose administered once every other week, respectively) did not cause any adverse effects on embryofetal development. A pre- and post-natal development study in rats showed no adverse effects on pre- and postnatal development at intravenous doses (administered on gestation days 6, 9, 12, 15, 18, and 20 and days 4, 7, 10, 14, and 17 postpartum) of sebelipase alfa up to 60 mg/kg/day (approximately 164 times the human AUC of 1387 ng.h/mL at 1 mg/kg dose administered once every other week).

8.2 Lactation

Risk Summary

There are no data on the presence of sebelipase alfa in human milk, the effects on the breastfed infant, or the effects on milk production. It is not known if sebelipase alfa is present in animal milk. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for KANUMA and any potential adverse effects on the breastfed infant from sebelipase alfa or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness of KANUMA have been established in pediatric patients aged 1 month and older. Clinical trials with KANUMA were conducted in 56 pediatric patients (range 1 month to <18 years old, see Clinical Studies (14.1)).

8.5 Geriatric Use

Clinical trials of KANUMA did not include any patients aged 65 years old and older. It is not known whether they respond differently than younger patients.

11 DESCRIPTION

Sebelipase alfa is a recombinant human lysosomal acid lipase (rhLAL) that is a lysosomal glycoprotein enzyme produced by recombinant DNA technology in the egg white of genetically engineered chickens. Purified sebelipase alfa is a monomeric glycoprotein enzyme produced by recombinant DNA technology in the egg white of genetically engineered chickens, containing 6 N-linked glycosylation sites and has a molecular mass of approximately 55 kDa. The specific activity of sebelipase alfa is 195 to 345 units/mg. One unit is the amount of enzyme activity that catalyzes the hydrolysis of 1 micromole of the synthetic substrate 4-methylumbelliferyl oleate per minute at 37°C under specified assay conditions.
12.2 Pharmacodynamics

In clinical trials, after initiation of dosing with KANUMA, breakdown of accumulated lysosomal lipids and initiation of increases in LDL-c and triglycerides within the first 2 to 4 weeks of treatment. In general, following increases in LDL-c and triglycerides, these parameters decreased to below pre-treatment values within 8 weeks of treatment with KANUMA.

In all patients with elevated alanine aminotransferase (ALT) values at baseline (82 of 84 patients in clinical trials), reductions in ALT values were observed, generally within 2 weeks after initiation of treatment with KANUMA. Treatment interruption resulted in increases in LDL-c and ALT values and decreases in HDL-c.

12.3 Pharmacokinetics

The pharmacokinetic profile of sebelipase alfa was nonlinear with a greater than dose-proportional increase in exposure between 1 and 3 mg/kg based on non-compartmental analysis of data from 26 adults. No accumulation was observed following once weekly or once every other week dosing. Using a population pharmacokinetic model, sebelipase alfa pharmacokinetic parameters were estimated for 65 pediatric and adult patients who received intravenous infusions of KANUMA at 1 mg/kg once weekly for 8 weeks (10 patients) or 12 weeks (23 patients) in Study 2, and 12 to 24 months of age, and 18 were adults. The pharmacokinetic profiles of sebelipase alfa were similar between adolescents and adults. The T₁/₂ and Tmax were similar across all age groups.

### Table 4: Mean (SD) Pharmacokinetics Parameters at Week 22 in Pediatric and Adult Patients Receiving 1 mg/kg Once Every Other Week

<table>
<thead>
<tr>
<th>Parameter</th>
<th>4-11 years old</th>
<th>12-17 years old</th>
<th>≥18 years old</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>24</td>
<td>23</td>
<td>18</td>
</tr>
<tr>
<td>AUC (ng·hr/mL)</td>
<td>942 (388)</td>
<td>1454 (699)</td>
<td>1861 (599)</td>
</tr>
<tr>
<td>Cₘₐₓ (ng/mL)</td>
<td>490 (205)</td>
<td>784 (480)</td>
<td>957 (303)</td>
</tr>
<tr>
<td>Tmax (hr)</td>
<td>1.3 (0.6)</td>
<td>1.1 (0.3)</td>
<td>1.3 (0.6)</td>
</tr>
<tr>
<td>CL (L/hr)</td>
<td>31.1 (7.1)</td>
<td>37.4 (12.4)</td>
<td>38.2 (12.5)</td>
</tr>
<tr>
<td>Vₜ (L)</td>
<td>3.6 (3.0)</td>
<td>5.4 (2.4)</td>
<td>5.3 (1.6)</td>
</tr>
<tr>
<td>T₁/₂ (min)</td>
<td>5.4 (3.3)</td>
<td>6.6 (3.7)</td>
<td>6.6 (3.7)</td>
</tr>
</tbody>
</table>

Parameter values were estimated using a population pharmacokinetic model. AUC = Area under the plasma concentration time curve. Cₘₐₓ = Maximum concentration. Tmax = Time to maximum concentration. CL = Clearance. Vₜ = Central volume of distribution. T₁/₂ = Half-life.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to evaluate carcinogenic potential or studies to evaluate mutagenic potential have not been performed with sebelipase alfa. Sebelipase alfa at intravenous doses up to 60 mg/kg administered twice weekly (approximately 164 times the human AUC of 1387 ng·h/mL at 1 mg/kg dose administered once every other week) was found to have no adverse effect on fertility and reproductive performance of male and female rats.

13.2 Animal Toxicology and/or Pharmacology

In a rat disease model of LAL deficiency that exhibits several abnormalities analogous to the human disease, sebelipase alfa administered intravenously at dosages up to 3 mg/kg once weekly showed improvements in survival, body weight gain, organ weight reduction, reduction in serum transaminases (ALT and aspartate aminotransferase [AST]), reduction in serum and hepatic lipids, and improvement in liver histopathology.

14 CLINICAL STUDIES

14.1 Infants with Rapidly Progressive LAL Deficiency Presenting with the First 6 Months of Life

A multicenter, open-label, single-arm clinical study of KANUMA was conducted in 9 infants with LAL deficiency who had growth failure or other evidence of rapidly progressive disease prior to 6 months of age. The age range at entry was 1 to 6 months. Patients received KANUMA at 0.35 mg/kg once weekly for 4 weeks (range: 3 to 27 months) in Study 1 and 15 months in Study 2. After being escalated to 1 mg/kg (n=36) or placebo (n=30) once every other week for 20 weeks in the double-blind period. Of the 9 patients whose KANUMA dose was escalated to 5 mg/kg once weekly, 6 were alive at their last follow up at 3 years, and 2 were alive at their last follow up at 5 years. Of these 9 patients, 6 experienced normalization of ALT and/or AST which had remained abnormal on the lower KANUMA dose.

14.2 Pediatric and Adult Patients with LAL Deficiency

Across Study 1 and another study, Study 3, in infants with rapidly progressive LAL Deficiency, 9 patients received successive dose escalations up to 5 mg/kg once weekly due to suboptimal clinical response (see Recommended Dose (2.1)). The median duration of exposure to 5 mg/kg for 9 patients whose doses were escalated to 5 mg/kg overall was 33 months (range: 27 to 39 months) for patients in Study 1 and 15 months in Study 2. Of the 9 patients whose KANUMA dose was escalated to 5 mg/kg once weekly, 6 were alive at their last follow up at 3 years, and 2 were alive at their last follow up at 5 years. Of these 9 patients, 6 experienced normalization of ALT and/or AST which had remained abnormal on the lower KANUMA dose.

14.3 How Supplied/Storage and Handling

KANUMA (sebelipase alfa) injection is a preservative-free, clear to slightly opalescent, colorless to slightly colored, nonpyrogenic solution supplied as 20 mg/10 mL in single-dose, glass vials. NDC 25682-007-01: 20 mg/10 mL vial

Store KANUMA refrigerated at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not shake or freeze the vials.

17 PATIENT COUNSELING INFORMATION

Hyperosmolarity Reactions, Including Anaphylaxis

Advise patients and caregivers that reactions related to administration and infusion may occur during and after KANUMA treatment, including anaphylactic reactions, life-threatening anaphylaxis and severe hypersensitivity reactions. Inform patients of the signs and symptoms of anaphylactic reactions, anaphylaxis and hypersensitivity reactions, and have them seek immediate medical care should signs and symptoms occur. [See Warnings and Precautions (5.1)].

Hypersensitivity to Eggs or Egg Products

KANUMA is produced in the egg white of genetically engineered chickens. Patients with a known history of egg allergies were excluded from the clinical trials. Consider the risks and benefits of treatment with KANUMA in patients with known systemic hypersensitivity reactions to eggs or egg products. [See Warnings and Precautions (5.2)].

Manufactured by:
Alexion Pharmaceuticals, Inc.
121 Seaport Boulevard,
Boston MA 02210 USA
US License Number 13-188-765-4747 (phone)