KANUMA® ▼(sebelipase alfa)
2 mg/mL concentrate for solution for infusion

A GUIDE FOR HEALTHCARE PROFESSIONALS

Important Safety Information:

Please read this guide carefully and use it when prescribing KANUMA® as it contains essential safety and efficacy information.

The guide was created as part of the KANUMA® Risk Management Plan and includes risk-minimising measures for the safe and effective use of this medicinal product.

The guide is a mandatory part of the approval process for KANUMA®, to help ensure that healthcare professionals take into account the special safety requirements of prescribing this medicinal product.

Read the Summary of Product Characteristics (SmPC) carefully before you prescribe or administer KANUMA®.

This Educational Material was approved by the SFDA.

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INTRODUCTION

KANUMA® is indicated for long-term enzyme replacement therapy (ERT) in patients of all ages with lysosomal acid lipase (LAL) deficiency.

Please read the Summary of Product Characteristics (SmPC) carefully before prescribing or administering KANUMA®.

LAL DEFICIENCY REGISTRY

To provide additional data on long-term safety of KANUMA® administration, healthcare professionals are strongly encouraged to participate in and enrol all patients diagnosed with LAL deficiency in the LAL deficiency registry. Please note that the registry is a general disease registry not restricted to patients treated with KANUMA® and aims to generate information on disease progression and treatment effects not restricted to exposure to KANUMA®. For information on how to participate, see page 6.

HYPERSENSITIVITY REACTIONS, INCLUDING ANAPHYLAXIS

In clinical studies of patients being treated with KANUMA®, hypersensitivity reactions occurred in 21 of 106 patients (20%) and anaphylactic reactions in 3 of 106 patients (3%). The frequency of the reactions decreased with an increased treatment period, but they were also observed one year after the start of treatment.

The signs and symptoms of the hypersensitivity/anaphylactic reactions included the following:

- chest discomfort, dyspnea, tachypnea, severe respiratory distress
- generalized and itchy rash, urticaria
- laryngeal edema and edema of the eyelid
- tachycardia, hypertension
- paleness, weakness
- abdominal pain, nausea, diarrhea, vomiting
- restlessness, chills
- pyrexia / increased body temperature

The majority of these reactions occurred during or within 4 hours of the end of infusion.

PREVENTION AND TREATMENT OF HYPERSENSITIVITY REACTIONS, INCLUDING ANAPHYLAXIS

1. Ensure that **appropriate medical support,** including any required medicine, is readily available when KANUMA® is administered.

2. **Observe patients for 1 hour** in order to monitor for any signs or symptoms of anaphylaxis or a severe hypersensitivity reaction following the first KANUMA® infusion, including the first infusion after a dose escalation.

3. If, during administration of KANUMA®, signs of hypersensitivity occur, the infusion can be slowed or discontinued at the discretion of the healthcare professional.

4. **In case of anaphylaxis, the infusion must be stopped immediately!** Leave the cannula in place for the potential administration of drugs.

5. Initiate the **standard appropriate medical treatment** for the management of hypersensitivity reactions, this may include treatment with:

    - Antihistamines
    - Antipyretics
    - Corticosteroids

6. For patients who have experienced allergic reactions during infusion, **caution should be exercised upon re-administration.** Start with a lower infusion rate and increase until the tolerance limit of the patient is reached.

7. **After severe reactions the risks and benefits** of a further KANUMA® administration should be considered.

8. **Consider pre-treatment** with antipyretics and/or antihistamines to prevent subsequent reactions in those cases where symptomatic treatment was required.

Contact information for adverse event reporting is provided on page 6.

IMMUNOGENICITY

In pivotal clinical studies, anti-drug antibodies (ADA), have been observed in 21% (9/42) of patients receiving KANUMA®. Of these, a total of 4 patients have developed neutralizing antibodies. Based on the limited data currently available the development of ADA seems to occur more frequently in infants. Most patients who developed ADA did so within the first 3 months of exposure.

- Collection of information on anti-drug antibodies (ADA) to KANUMA® is important to evaluate the impact of development of ADA on a potential loss of effect or development of potential hypersensitivity, including anaphylaxis, and to support identification of ADA development related risk factors.

- Therefore patients should be tested for antidrug antibodies to KANUMA® in the event of severe infusion reactions and in cases of lack or loss of effect.

- For patients who are positive for ADA, testing should be repeated every 6 months.

Anti-drug Antibody Testing

Information on ADA testing is provided in section 4.4 of the SmPC as follows:

- It is recommended that healthcare professionals test their patients for ADA to KANUMA® in the event of severe infusion reactions and in cases of lack or loss of effect

As there are no marketed tests for ADA to KANUMA®, the Marketing Authorisation Holder will provide testing free of charge through a central laboratory.

- An ADA testing kit and accompanying instruction manual will be provided by Alexion. Please contact the regional Medical Director to order ADA testing for your patient at MedicalAffairs.MEA@alexion.com. The instruction manual contains information on how to collect, process, and ship ADA samples.

- Two 1 mL serum samples are required for ADA testing.

- Please be aware that a centrifuge, and a freezer that freezes to -20°C (or colder), are required. If you do not have access to this equipment, please contact the Medical Information team at MedicalAffairs.MEA@alexion.com.

- Anonymised ADA testing results will be shared with the Medical Information team at Alexion, and reported back to physicians by the Medical Director using regular mail. No patient identifying information will be shared throughout the process.

- In the event of a positive ADA testing result, testing should be repeated every 6 months.

CONTACT INFORMATION

Anti-drug Antibody (ADA) Testing and LAL Deficiency Registry

For information on ADA testing or on the LAL deficiency registry and how to participate, please contact the Medical Information team at Alexion at MedicalAffairs.MEA@alexion.com.

Adverse Event Reporting

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

To report any side effects:
The National Pharmacovigilance Centre (NPC), SFDA:

- SFDA Call Center: 19999
- E-mail: npc.drug@sfda.gov.sa
- Fax: +966-11-205-7662
- Website: https://ade.sfda.gov.sa

Adverse events should also be reported to Pharmacovigilance-KSA@blgx.net.

LOCAL REPRESENTATIVE OF THE MARKETING AUTHORISATION HOLDER IN KSA

For more information on Kanuma®, please contact the local representative of the Marketing Authorisation Holder:

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