

## **EISAI SUBMITS APPLICATION FOR PARTIAL CHANGE TO LABEL OF EGG WHITE LYSOZYME PREPARATION NEUZYM®**

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, “Eisai”) announced today that its pharmaceutical manufacturing and marketing subsidiary Sannova Co., Ltd. (Headquarters: Gunma Prefecture, President & CEO: Toshio Kaneko) submitted an application for partial change to the approved label for egg white lysozyme preparation Neuzym® to Japan’s Ministry of Health, Labour and Welfare (MHLW) on December 21, 2011. The company is seeking approval to remove alveolar pyorrhea and other conditions as approved indications for the product as well as to make changes to dosage and administration.

The application submitted applies to all six products that make up the Neuzym® Series – Neuzym® Tablets (10 mg, 30 mg and 90 mg), Neuzym® Granules (10%), Neuzym® Fine Granules (20%), and Neuzym® Syrup (0.5%). While Sannova is the marketing and manufacturing authorization holder for Neuzym®, Eisai is responsible for marketing the products.

Neuzym® and other egg white lysozyme preparations have been designated by the MHLW Pharmaceutical Affairs and Food Sanitation Council’s Special Committee on Drug Efficacy Reevaluation as drugs for which efficacy must be reevaluated. Given the actual utilization of Neuzym® in the current healthcare environment, Eisai and Sannova are now in the process of developing the protocol for additional clinical studies to reevaluate the efficacy of the preparation. However, the two companies have determined that it would not be feasible to conduct any further studies in the currently approved indications of “alveolar pyorrhea (inflammatory type)” and “hemorrhage during or after minor operations (dentistry and urology),” and have therefore submitted an application to remove these indications and make changes to dosage and administration for Neuzym® accordingly.

While Neuzym® will no longer be able to be used in the treatment of “alveolar pyorrhea (inflammatory type)” and “hemorrhage during or after minor operations (dentistry and urology)” following approval of the partial label change, Eisai and Sannova will work to ensure that information is provided to healthcare professionals in order to avoid confusion either in the medical setting or amongst patients being treated with the preparation.

**[Please refer to the following notes for details of the proposed partial change  
to the Neuzym® label]**

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**[Notes to editors]**

1. Proposed partial change to the Neuzym<sup>®</sup> label (application seeks to remove underlined parts)

1) Neuzym<sup>®</sup> Tablets 10 mg

Current Label	Revised Label (Proposed)
<p><b>【Indications】</b> Remission of swelling in the following diseases: Chronic sinusitis Difficulty of expectoration in the following diseases with hard-to-eliminate sputum and frequent hawking: Bronchitis, bronchial asthma and bronchiectasis <u>Hemorrhage during or after minor operations (dentistry and urology)</u></p>	<p><b>【Indications】</b> Remission of swelling in the following diseases: Chronic sinusitis Difficulty of expectoration in the following diseases with hard-to-eliminate sputum and frequent hawking: Bronchitis, bronchial asthma and bronchiectasis</p>

※No changes will be made to the dosage and administration information contained in the Neuzym<sup>®</sup> Tablets 10 mg package insert.

2) Neuzym<sup>®</sup> Tablets 30 mg, Neuzym<sup>®</sup> Tablets 90 mg, Neuzym<sup>®</sup> Granules 10%, Neuzym<sup>®</sup> Fine Granules 20%

Current Label	Revised Label (Proposed)
<p><b>【Indications】</b> Remission of swelling in the following diseases: Chronic sinusitis <u>and alveolar pyorrhea (inflammatory)</u> Difficulty of expectoration in the following diseases with hard-to-eliminate sputum and frequent hawking: Bronchitis, bronchial asthma and bronchiectasis <u>Hemorrhage during or after minor operations (dentistry and urology)</u></p>	<p><b>【Indications】</b> Remission of swelling in the following diseases: Chronic sinusitis Difficulty of expectoration in the following diseases with hard-to-eliminate sputum and frequent hawking: Bronchitis, bronchial asthma and bronchiectasis</p>
<p><b>【Dosage and Administration】</b> <u>For remission of swelling in chronic sinusitis, difficulty in expectoration in bronchitis, bronchial asthma and bronchiectasis with hard-to-eliminate sputum and frequent hawking, and hemorrhage during or after minor operations (dentistry and urology):</u> The usual adult dosage for oral use is 60-270 mg (potency) of lysozyme hydrochloride daily divided into three doses. <u>For remission of swelling of alveolar pyorrhea (inflammatory type):</u> The usual adult dosage for oral use is 180-270 mg (potency) of lysozyme hydrochloride daily divided into three doses. Depending on the severity of symptoms, local treatment (e.g. removal of dental calculus, mouth rinses or topical application of</p>	<p><b>【Dosage and Administration】</b>  The usual adult dosage for oral use is 60-270 mg (potency) of lysozyme hydrochloride daily divided into three doses.</p>

<p><u>appropriate remedies to the affected area) may be advisable before or during administration.</u></p> <p>Neuzym should not be administered aimlessly, since the mechanism of action of lysozyme has not been completely elucidated nor have dose-effect relationships been clearly established.</p>	<p>Neuzym should not be administered aimlessly, since the mechanism of action of lysozyme has not been completely elucidated nor have dose-effect relationships been clearly established.</p>
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3) Neuzym<sup>®</sup> Syrup 0.5%

Current Label	Revised Label (Proposed)
<p><b>【Indications】</b>            Difficulty of expectoration in the following diseases with hard-to-eliminate sputum and frequent hawking:                Bronchitis, bronchial asthma and bronchiectasis            Remission of swelling in the following diseases:                Chronic sinusitis  <u>Hemorrhage during or after minor operations (dentistry and urology)</u></p>	<p><b>【Indications】</b>            Difficulty of expectoration in the following diseases with hard-to-eliminate sputum and frequent hawking:                Bronchitis, bronchial asthma and bronchiectasis            Remission of swelling in the following diseases:                Chronic sinusitis</p>

※No changes will be made to the dosage and administration information contained in the Neuzym<sup>®</sup> Syrup 0.5% package insert.