AstraZeneca K.K.
Daiichi Sankyo Co., Ltd.

AstraZeneca and Daiichi Sankyo Launch Proton Pump Inhibitor Nexium® 10 mg and 20 mg Granules for Suspension, Sachet, in Japan

Osaka and Tokyo, Japan, April 18, 2018 -- AstraZeneca K.K. (based in Kita-ku, Osaka, Japan; Stefan Woxström, President; hereinafter, AstraZeneca) and Daiichi Sankyo Company Limited (based in Chuo-ku, Tokyo, Japan; Sunao Manabe, President; hereinafter, Daiichi Sankyo) today announced the launch of proton pump inhibitor Nexium® 10 mg and 20 mg Granules for Suspension, Sachet, (generic name: esomeprazole magnesium hydrate).

Nexium® 10 mg and 20 mg Granules for Suspension, Sachet, are a new formulation of Nexium® 10 mg and 20 mg Capsules indicated for gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis, nonerosive reflux disease*, Zollinger-Ellison syndrome, inhibition of recurrence of gastric or duodenal ulcer during nonsteroidal anti-inflammatory drug administration, inhibition of recurrence of gastric or duodenal ulcer during low-dose aspirin administration, and support for eradication of Helicobacter pylori. The granules are suspended in water for oral use, which allows administration to pediatric patients** at a young age. This formulation is also expected to improve drug adherence in patients with difficulty swallowing, such as elderly patients.

In Japan, AstraZeneca is in charge of manufacturing and Daiichi Sankyo is in charge of distribution and sales, resulting in a co-promotion by the two companies.

By providing two dosage forms of Nexium, Nexium® 10 mg and 20 mg Capsules and Nexium® 10 mg and 20 mg Granules for Suspension, Sachet, AstraZeneca and Daiichi Sankyo will increase their contribution to the treatment of a wide range of acid-related diseases in patients ranging from children aged 1 year and older to the elderly with difficulty swallowing.

* Only the 10 mg form is indicated for nonerosive reflux disease
** Pediatric patients at a young age are infants and children aged one year or older. The indications for inhibition of recurrence of gastric or duodenal ulcer during nonsteroidal anti-inflammatory drug administration, inhibition of recurrence of gastric or duodenal ulcer during low-dose aspirin administration, and support for eradication of Helicobacter pylori are limited to adults.

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Product Outline

【Launch date: April 18, 2018】

Brand name	Nexium® 10 mg Granules for Suspension, Sachet Nexium® 20 mg Granules for Suspension, Sachet
Generic name	Esomeprazole magnesium hydrate
Drug price	Nexium® 10 mg Granules for Suspension, Sachet: 80.60 yen Nexium® 20 mg Granules for Suspension, Sachet: 140.30 yen
Dosage and administration	＜Nexium® 10 mg Granules for Suspension, Sachet＞ • Gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis, nonerosive reflux disease, and Zollinger-Ellison syndrome, inhibition of recurrence of gastric or duodenal ulcer during nonsteroidal anti-inflammatory drug administration, and inhibition of recurrence of gastric or duodenal ulcer during low-dose aspirin administration. • Support for eradication of Helicobacter pylori under the following conditions: Gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, stomach after endoscopic treatment for early gastric cancer, Helicobacter pylori-infected gastritis < Nexium® 20 mg Granules for Suspension, Sachet > • Gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis, and Zollinger-Ellison syndrome, inhibition of recurrence of gastric or duodenal ulcer during nonsteroidal anti-inflammatory drug administration, and inhibition of recurrence of gastric or duodenal ulcer during low-dose aspirin administration • Support for eradication of Helicobacter pylori under the following conditions: Gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, stomach after endoscopic treatment for early gastric cancer, Helicobacter pylori-infected gastritis
Dosage and Administration	< Nexium® Granules for Suspension, Sachets: 10 mg> • Gastric ulcer, duodenal ulcer, anastomotic ulcer, Zollinger-Ellison syndrome [Adults] The usual adult dose is 20 mg of esomeprazole made into a suspension in water at the time of use, taken orally once daily. The usual duration of administration is up to 8 weeks for gastric ulcer and anastomotic ulcer and up to 6 weeks for duodenal ulcer. [Children] The usual doses for children aged 1 year and older are 10 mg of esomeprazole for a bodyweight of less than 20 kg and 10 to 20 mg of esomeprazole for a bodyweight of 20 kg or over, depending on symptoms, made into a suspension in water at the time of use, taken orally once daily. The usual duration of administration is up to 8 weeks for gastric ulcer and anastomotic ulcer and up to 6 weeks for duodenal ulcer. • Reflux esophagitis [Adults] The usual adult dose is 20 mg of esomeprazole made into a suspension in water at the time of use, taken orally once daily. The usual duration of administration is up to 8 weeks. As maintenance therapy for continually recurring/relapsing reflux esophagitis, 10 to 20 mg of esomeprazole is made into a suspension in water at the time of use and taken orally once daily. [Children] The usual doses for children aged 1 year and older are 10 mg of esomeprazole for a bodyweight of less than 20 kg and 10 to 20 mg of esomeprazole for a bodyweight of 20 kg or over, depending on symptoms, made into a suspension in water at the time of use, taken orally once daily. The usual duration of administration is up to 8 weeks.

	• Non-erosive reflux disease [Adults] The usual adult dose is 10 mg of esomeprazole made into a suspension in water at the time of use, taken orally once daily. The usual duration of administration is up to 4 weeks. [Children] The usual dose for children aged 1 year and older is 10 mg of esomeprazole made into a suspension in water at the time of use, taken orally once daily. The usual duration of administration is up to 4 weeks. • Prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with non-steroidal anti-inflammatory drugs The usual adult dose is 20 mg of esomeprazole made into a suspension in water at the time of use, taken orally once daily. • Prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with low-dose aspirin The usual adult dose is 20 mg of esomeprazole made into a suspension in water at the time of use, taken orally once daily. • Adjuvant therapy for Helicobacter pylori eradication The usual adult dose is 20 mg of esomeprazole made into a suspension in water at the time of use, concomitantly with 750 mg (potency) of amoxicillin hydrate and 200 mg (potency) of clarithromycin, taken orally twice daily for 7 days. The dose of clarithromycin may be increased appropriately as required. However, the limits on dosing are 400 mg (potency) per time and twice daily. If Helicobacter pylori eradication with triple therapy consisting of proton pump inhibitor, amoxicillin hydrate, and clarithromycin fails, the usual dose for adults of 20 mg of esomeprazole is made into a suspension in water at the time of use and taken orally, concomitantly with 750 mg (potency) of amoxicillin hydrate and 250 mg of metronidazole, twice daily for 7 days as alternative therapy. <Nexium® Granules for Suspension, Sachets: 20 mg> • Gastric ulcer, duodenal ulcer, anastomotic ulcer, Zollinger-Ellison syndrome [Adults] The usual adult dose is 20 mg of esomeprazole made into a suspension in water at the time of use, taken orally once daily. The usual duration of administration is up to 8 weeks for gastric ulcer and anastomotic ulcer and up to 6 weeks for duodenal ulcer. [Children] For infants and children with a bodyweight of 20 kg or over, the usual dose is 10 to 20 mg of esomeprazole, depending on symptoms, made into a suspension in water at the time of use, taken orally once daily. The usual duration of administration is up to 8 weeks for gastric ulcer and anastomotic ulcer and up to 6 weeks for duodenal ulcer. • Reflux esophagitis [Adults] The usual adult dose is 20 mg of esomeprazole made into a suspension in water at the time of use, taken orally once daily. The usual duration of administration is up to 8 weeks. As maintenance therapy for continually recurring/relapsing reflux esophagitis, 10 to 20 mg made into a suspension in water at the time of use is taken orally once daily. [Children] For infants and children with a body weight of 20 kg or over, the usual dose is 10 to 20 mg of esomeprazole, depending on symptoms, made into a suspension in water at the time of use, taken orally once daily. The usual duration of administration is up to 8 weeks. • Prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with non-steroidal anti-inflammatory drugs The usual adult dose is 20 mg of esomeprazole made into a suspension in water at the time of use, taken orally once daily.

	• Prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with low-dose aspirin The usual adult dose is 20 mg of esomeprazole made into a suspension in water at the time of use, taken orally once daily. • Adjuvant therapy for Helicobacter pylori eradication The usual adult dose is 20 mg of esomeprazole made into a suspension in water at the time of use, concomitantly with 750 mg (potency) of amoxicillin hydrate and 200 mg (potency) of clarithromycin, taken orally twice daily for 7 days. The dose of clarithromycin may be increased appropriately as required. However, the limits on dosing are 400 mg (potency) per time and twice daily. If Helicobacter pylori eradication with triple therapy consisting of proton pump inhibitor, amoxicillin hydrate, and clarithromycin fails, the usual dose for adults of 20 mg of esomeprazole is made into a suspension in water at the time of use and taken orally, concomitantly with 750 mg (potency) of amoxicillin hydrate and 250 mg of metronidazole, twice daily for 7 days as alternative therapy.
Date of manufacturing and marketing approval	January 19, 2018
Date of listing in National Health Insurance drug price list	April 18, 2018
Release date	April 18, 2018
Manufacturing and marketing	AstraZeneca K.K.
Sales	Daiichi Sankyo Co., Ltd.

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About Nexium® (esomeprazole magnesium hydrate)

Nexium® (esomeprazole magnesium hydrate) selectively inhibits the proton pump that is responsible for the final process of gastric acid secretion to suppress acid secretion and thereby produce excellent clinical effects in acid related disease.

Nexium® has been approved and marketed in more than 125 countries. In Japan, it was approved in July 2011 for the following indications in adults: gastric ulcer, duodenal ulcer, anastomotic ulcer, reflux esophagitis, nonerosive reflux disease, Zollinger-Ellison syndrome, risk reduction of NSAID-related gastric or duodenal ulcer recurrence, and supplemental H. pylori eradication in the stomach after endoscopic therapy for gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, and early gastric cancer. Nexium® has been marketed jointly by AstraZeneca and Daiichi Sankyo since September 15, 2011. Additional indications of “risk reduction of low-dose aspirin-related duodenal or gastric ulcer recurrence” and “supplemental H. pylori eradication in H. pylori enteritis” were approved in June 2012 and February 2013, respectively. Since its first launch, Nexium® has been widely used and demonstrated favourable performance in clinical practice.
Additional indication for children aged 1 year and older for Nexium® was approved in January 2018.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for hypertension and thrombotic disorders, under the Group’s 2025 Vision to become a “Global Pharma Innovator with Competitive Advantage in Oncology,” Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: www.daiichisankyo.com.

About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in main therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit www.astrazeneca.com and follow us on Twitter @AstraZeneca.

In Japan, we focus on three therapy areas, Oncology, Cardiovascular and Metabolic Diseases/Gastrointestinal, and Respiratory, to contribute to patients’ health and healthcare advancements. For more information, please visit: https://www.astrazeneca.co.jp

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