



Shionogi Launches XOFLUZA® Granules 2% – New Formulation for Influenza Treatment and Prophylaxis

OSAKA, Japan, Nov. 12, 2025 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; hereafter "Shionogi") is pleased to announce the launch today of a new formulation of the anti-influenza virus drug XOFLUZA® (generic name: baloxavir marboxil; hereafter "XOFLUZA") – XOFLUZA® Granules 2%.

XOFLUZA is a first-in-class, single-dose oral medicine for both treatment and prophylaxis of influenza with an innovative mechanism of action designed to block viral replication by inhibiting the cap-dependent endonuclease protein, potentially reducing the duration of infectiousness and disease.^{1, 2} Furthermore, it has been shown to reduce transmission of influenza from an infected person to household members.³ XOFLUZA is approved in more than 75 countries, including Japan and the United States, for the treatment of uncomplicated influenza types A and B. In Japan, XOFLUZA is indicated for the treatment and prophylaxis of influenza types A and B in adults and children.

Until now, XOFLUZA has only been available in tablet form, but there has been a need for a formulation suitable for patients who have difficulty taking tablets, such as younger children. The newly launched granule formulation is easier to take and allows for appropriate dosing based on age and body weight. Furthermore, with its availability for pediatric patients weighing less than 10 kg, it is expected to serve as a new treatment option for pediatric influenza, contributing to the care of a broader range of patients.

Shionogi is committed to "Protect people worldwide from the threat of infectious diseases" as one of our key focus and is working on the realization of total care for infectious diseases. Shionogi will continue to promote activities so that we can quickly deliver the anti-infective drugs necessary to protect people's health to patients around the world.

Product Information				
Product name	XOFLUZA® Granules 2%			
Generic Name	Baloxavir Marboxil			
Indication	Treatment and prophylaxis of influenza A or B virus infection			
Dosage regimen	XOFLUZA should be usually administered in a single oral dose according to the following dosage. The section underlined indicates the content included in this launch.			
	Indications	Age	Body weight	Dose
	Treatment	Adults and children aged 12 years or older	≥80 kg	Four 20-mg tablets or <u>eight packages of granules (80 mg of baloxavir marboxil)</u>
			<80 kg	Two 20-mg tablets or <u>four packages of granules (40 mg of baloxavir marboxil)</u>

		Children aged less than 12 years	≥40 kg	Two 20-mg tablets or <u>four packages of granules (40 mg of baloxavir marboxil)</u>
			≥20 kg to <40 kg	One 20-mg tablet or <u>two packages of granules (20 mg of baloxavir marboxil)</u>
			≥10 kg to <20 kg	One 10-mg tablet or <u>one package of granules (10 mg of baloxavir marboxil)</u>
			<10 kg	<u>Granules 50 mg/kg (1 mg/kg of baloxavir marboxil)</u>
	Prophylaxis	Adults and children aged 12 years or older	≥80 kg	Four 20-mg tablets or <u>eight packages of granules (80 mg of baloxavir marboxil)</u>
			<80 kg	Two 20-mg tablets or <u>four packages of granules (40 mg of baloxavir marboxil)</u>
		Children aged less than 12 years	≥40 kg	Two 20-mg tablets or <u>four packages of granules (40 mg of baloxavir marboxil)</u>
			≥20 kg to <40 kg	One 20-mg tablet or <u>two packages of granules (20 mg of baloxavir marboxil)</u>
Date of NHI price listing	12 November 2025			
Date of launch	12 November 2025			
Drug price	XOFLUZA® Granules 2% : ¥1,666.20 per packet			
Marketing Authorization Holder	Shionogi & Co., Ltd.			

About XOFLUZA

XOFLUZA is a first-in-class, single-dose oral medicine with an innovative mechanism of action designed to block viral replication by inhibiting the cap-dependent endonuclease protein, potentially reducing the duration of infectiousness and disease.^{1, 2} XOFLUZA's mechanism of action has demonstrated efficacy in a wide range of influenza viruses, including in vitro activity against oseltamivir-resistant strains and avian strains (H7N9, H5N1) in non-clinical studies.^{4, 5} Furthermore, it has been shown to reduce transmission of influenza from an infected person to household members.+ Development and commercialization of this product are conducted under a partnership with the Roche Group, with Shionogi responsible for sales in Japan and Taiwan, and Roche handling sales in other countries. XOFLUZA is approved in more than 75 countries, including Japan and the United States, for the treatment of uncomplicated influenza types A and B.¹⁰ In Japan, XOFLUZA is indicated for the treatment and prophylaxis of influenza types A and B in adults and children.

Forward-Looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related

forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

For Further Information, Contact:

SHIONOGI Website Inquiry Form: <https://www.shionogi.com/global/en/contact.html>

References

1. Hayden FG, et al. *N Engl J Med.* 2018;379:913–923.
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3. Monto, AS. et al. *N Engl J Med.* 2025; 392:1582-1593.
4. Noshi T, et al. *Antiviral Res.* 2018;160:109-117.
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