

NEWS RELEASE



March 18, 2026

Nippon Shinyaku start co-promotion activities of OPSUMIT® Pediatric Dispersible Tablets 1mg and 2.5mg for the Treatment of Pulmonary Arterial Hypertension

Kyoto, Japan, March 18, 2026 - Nippon Shinyaku Co., Ltd. (Headquarters: Kyoto; President: Toru Nakai) announced it has started co-promotion activities with Johnson & Johnson for Opsumit® Pediatric Dispersible Tablets 1mg and 2.5mg (age \geq 3 Months), an endothelin receptor antagonist, for pediatric pulmonary arterial hypertension (PAH).

PAH is a disease with a poor prognosis characterized by an abnormally elevated blood pressure in the pulmonary arteries, which carry blood from the heart to the lungs. It is categorized into idiopathic PAH of unknown cause, hereditary PAH, and PAH associated with various diseases (such as connective tissue disorders and congenital heart disease). The pathophysiology of PAH in adults and children is similar; however, the drugs available for pediatric PAH within Japan are limited, necessitating the development of new therapeutic agents.

Japan's Ministry of Health, Labor and Welfare (MHLW) for Opsumit® Pediatric Dispersible Tablets in 1 mg and 2.5 mg on December 22, 2025.

Nippon Shinyaku is focusing on the field of intractable, rare disorders, and PAH is one of them. Currently, for adult PAH, we offer a portfolio of products including Upravi® (selexipag), Opsumit® (macitentan), Adcirca® (tadalafil), and Yuvanshi® Combination Tablets (macitentan/tadalafil). For pediatric PAH, in addition to Upravi®, we believe that the additional indication for Opsumit® will further contribute to the treatment of PAH.

Summary of Approval

Brand names	Opsumit® 1mg dispersible tablets for pediatric Opsumit® 2.5mg dispersible tablets for pediatric		
Generic name	Macitentan		
Date of approval	December 22, 2025		
Date of NHI reimbursement price listing	March 18, 2026		
Date of launch	March 18, 2026		
Approval numbers	Opsumit® 1mg dispersible tablets for pediatric : 30700AMX00275000 Opsumit® 2.5mg dispersible tablets for pediatric : 30700AMX00271000		
Dosage Forms and Strength	Opsumit® 1mg dispersible tablets for pediatric : An elliptical dispersible tablet containing 1.0mg of macitentan per tablet Opsumit® 2.5mg dispersible tablets for pediatric : A round dispersible tablet containing 2.5mg of macitentan per tablet		
Indication	Pulmonary arterial hypertension		
Dosage and Administration	For children aged 3 months and above, the following dosage of macitentan is administered orally once daily, dispersed in a small amount of water when taken.		
	Age	Body weight	dosage
	≥ 3months to < 6months	-	1.0mg
	≥ 6months to < 2years	-	2.5mg
	≥ 2 years	<15kg	3.5mg
		≥15kg to <25kg	5.0mg
≥25kg to <50kg		7.5mg	
≥50kg		10mg	
NHI reimbursement price	Opsumit® 1mg dispersible tablets for pediatric : JPY 1,496,90/tablet Opsumit® 2.5mg dispersible tablets for pediatric : JPY 3,712,20/tablet		
Packaging unit	Opsumit® 1mg dispersible tablets for pediatric : 30 tablets [10 tablets(Blister)×3] Opsumit® 2.5mg dispersible tablets for pediatric : 30 tablets [10 tablets(Blister)×3]		

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