

November 19, 2019

Launch of Coralan[®] Tablet, an HCN Channel Blocker in Japan

Ono Pharmaceutical Co., Ltd. (Osaka, Japan, President and Representative Director: Gyo Sagara; “ONO”) announced today that it has launched Coralan[®] (generic name: ivabradine hydrochloride) Tablet 2.5mg, 5mg and 7.5mg (“Coralan”), a HCN (hyperpolarization-activated cyclic nucleotide-gated) channel blocker, for the treatment of patients with chronic heart failure with sinus rhythm and baseline resting heart rate ≥ 75 beats per minute (limited to patients receiving standard treatment of chronic heart failure, including β -blocker) in Japan.

Heart failure is defined as a clinical syndrome in which dyspnea, fatigue and edema appear as a result of failure of compensatory function of the cardiac pump due to cardiac dysfunction, resulting in a decrease in exercise tolerance. Chronic heart failure (CHF) is the condition where the situation of heart failure chronically continues, and the number of patients with CHF in Japan is estimated to reach 1.2 million in 2020*1. The drugs used for the treatment of CHF include angiotensin-converting enzyme inhibitors, angiotensin receptor antagonists, β -blockers, anti-aldosterone drugs, diuretics, etc. for the purpose of controlling symptoms of patients, preventing hospitalization, and avoiding death in patients with CHF.

In patients with CHF, the heart rate tends to increase to compensate for the inability of the heart to exert sufficient blood volume leading to put more strain on the heart. In addition, it has been shown that higher heart rates have a negative impact on the prognosis in patients with CHF.

Coralan, discovered and developed by Servier, is an innovative orally-active drug which suppresses hyperpolarization-activated cationic current (I_f), cardiac pacemaker current, by inhibiting the HCN channel expressed in the cardiac sinus node. It has the effect of decreasing only heart rate without affecting the cardiac conductivity, contractility, repolarization and blood pressure. Coralan provides a new treatment options for patients with high heart rate even if they take existing drugs for the treatment of CHF.

Ivabradine has been approved in 124 countries or regions, among which it has been approved in 116 countries for both indications of CHF and chronic stable angina pectoris.

In accordance with the license agreement entered in September 2011 with Servier, an independent international pharmaceutical company headquartered in France, ONO has exclusive rights to develop and commercialize Ivabradine in Japan and has been committed to developing the product for the treatment of CHF.

*1 : Guidelines for Diagnosis and Treatment of Acute and Chronic Heart Failure. (JCS 2017/JHFS 2017)

Overview of Coralan® Tablet 2.5 mg, 5mg and 7.5mg

Product Name	Coralan® Tablet 2.5 mg, 5mg and 7.5mg
Generic name (JAN)	Ivabradine hydrochloride
Indication	Chronic heart failure with sinus rhythm and baseline resting heart rate ≥ 75 beats per minute (limited to patients receiving standard treatment of chronic heart failure, including β -blocker)
Dosage and administration	Usually, for adults, start the administration at 2.5 mg of ivabradine orally after meal twice a day. Thereafter, adjust dose in more than 2-weeks interval as needed in a stepwise manner, to achieve and maintain a target resting heart rate while assessing the tolerability. One-dose should be settled either 2.5, 5 or 7.5 mg. In either dose, administer ivabradine orally after meal twice a day. The dose should be decreased based on patients' condition.
Approval date	September 20, 2019
NHI price listing date	November 19, 2019
NHI drug price	Coralan® Tablet 2.5 mg: ¥ 82.90 /tablet Coralan® Tablet 5 mg: ¥ 145.40 /tablet Coralan® Tablet 7.5 mg: ¥ 201.90 /tablet
Package	Coralan® Tablet 2.5 mg: PTP 100 tablets, Bottle 100 tablets, 500 tablets Coralan® Tablet 5 mg: PTP 100 tablets, Bottle 100 tablets, 500 tablets Coralan® Tablet 7.5 mg: PTP 100 tablets, Bottle 100 tablets, 500 tablets
Manufacturer/distributor	Ono Pharmaceutical Co., Ltd.

Product photograph



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