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Announcement of Approval of Additional Indications for Onoact® 50 for Injection, Short-Acting Selective β_1 Blocker

Ono Pharmaceutical Co., Ltd. announced that an additional indication of Onoact® 50 for Injection, emergency treatment of post-operative tachyarrhythmia (atrial fibrillation and flutter, and sinus tachycardia) with monitoring of circulatory dynamics was approved on October 20, 2006. The drug is the first short-acting selective β_1 blocker in Japan that is discovered and developed by the company, and has been sold and marketed for emergency treatment of intra-operative tachyarrhythmia (atrial fibrillation and flutter, and sinus tachycardia) since September 2002.

It is reported that during surgical operation, various stimulative actions on a living body, such as endotracheal intubation, extubation, skin incision and other surgical procedures, facilitate the excessive release of catecholamine such as adrenaline and noradrenaline mainly from the stimulated sympathetic nerve, often leading to an increase in heart rate as well as tachyarrhythmia.

These physiological reactions not only develop during the operation but also persist after it. It is reported that once patients with ischemic heart disease or hypertension are complicated with tachyarrhythmia, it may give an additional burden on the heart, and induce myocardial infarction due to ischemic state of coronary artery. Therefore, a drug that can be easily titrated for emergency treatment of tachyarrhythmia developing not only during the operation but also after it has long been awaited.

Onoact® 50 for injection, which has been developed to fulfill these medical needs, improves tachyarrhythmia by selectively blocking β_1 receptors located mainly in the heart and by inhibiting the action of catecholamine that raises the heart rate.

Because this fast-acting drug can be easily titrated for its very short half-life in blood (approx. 4 min), It is expected that the drug can be widely used and contribute to the medical practice in emergency treatment of tachyarrhythmia developing not only during the operation but also after it.

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PRODUCT PROFILE

- Onoact® 50 for Injection -

Nonproprietary name	Landiolol hydrochloride
Composition	50 mg of landiolol hydrochloride per vial
Indications	1. Emergency treatment for intra-operative tachyarrhythmia (atrial fibrillation and flutter, and sinus tachycardia) 2. Emergency treatment for post-operative tachyarrhythmia (atrial fibrillation and flutter, and sinus tachycardia) with monitoring of circulatory dynamics
Dosage and administration	1. During operation Landiolol hydrochloride is intravenously administered at 0.125 mg/kg/min for one minute, and at 0.04 mg/kg/min thereafter. The dosage should be appropriately adjusted between 0.01 and 0.04 mg/kg/min based on the heart rate and blood pressure to be measured during the infusion. 2. After operation Landiolol hydrochloride is intravenously administered at 0.06 mg/kg/min for one minute, and at 0.02 mg/kg/min thereafter. In case targeted heart rate lowering effect is not obtained during the first 5 to 10 minutes then it is intravenously administered at 0.125 mg/kg/min for one minute, and at 0.04 mg/kg/min thereafter. The dosage should be appropriately adjusted between 0.01 and 0.04 mg/kg/min based on the heart rate and blood pressure to be measured during the infusion.
NHI Price	Yen 6,800 per vial
Packaging	Onoact® 50 for Injection 5 vials or 10 vials

Manufactured and distributed by Ono Pharmaceutical Co., Ltd.