

NEWS RELEASE

December 10, 2021

Nippon Shinyaku Co., Ltd.
Sioe Pharmaceutical Co., Ltd.

Coverage in NHI Drug Price Listing and Launch Date of TADALAFIL Tablets 2.5 mg/5 mg ZA "SIOE"

Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters: Kyoto; President: Toru Nakai) and its consolidated subsidiary Sioe Pharmaceutical Co., Ltd. (Sioe Pharmaceutical; Headquarters: Amagasaki, Hyogo; President: Noboru Nishikawa) announced that TADALAFIL Tablets 2.5 mg/5 mg ZA "SIOE" (hereinafter, these drugs), which are authorized generics (AG) of ZALUTIA[®] Tablets (ZALUTIA) and serve as treatment for urinary disorders caused by benign prostatic hyperplasia, have been listed on the National Health Insurance (NHI) price listing and have been launched today.

These drugs are AG, and the active pharmaceutical ingredients, additives, manufacturing method, and manufacturing factory are the same as those of the brand name drug "ZALUTIA." Marketing authorization will be held by Sioe Pharmaceutical, and sales will be conducted by Nippon Shinyaku.

Nippon Shinyaku has long been engaged in the sales of TADALAFIL preparations in Japan, and has accumulated sufficient information for their appropriate use. Sioe Pharmaceutical will provide AG as the marketing authorization holder, and Nippon Shinyaku will conduct information provision and collection activities as it has performed for ZALUTIA, thereby contributing to the treatment of patients with benign prostatic hyperplasia.

Drug Information

Product name: TADALAFIL Tablets 2.5 mg ZA "SIOE"

TADALAFIL Tablets 5 mg ZA "SIOE"

Drug price: TADALAFIL Tablets 2.5 mg ZA "SIOE" JPY36.30/Tablet

TADALAFIL Tablets 5 mg ZA "SIOE" JPY73.80/Tablet

Marketing authorization approval date: August 16, 2021

NHI price listing coverage date: December 10, 2021

Launch Date: December 10, 2021

Marketing authorization holder: Sioe Pharmaceutical Co., Ltd.

Seller: Nippon Shinyaku Co., Ltd.

Contact Information

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