



Sawai Pharmaceutical Receives Approvals for Eight Molecules in 19 Presentations of Generic Drugs

Osaka, Japan – February 15, 2018 – Sawai Pharmaceutical Co., Ltd. (Sawai, Head office: Osaka, Japan, President: Mitsuo Sawai) today received approvals by the Ministry of Health, Labour and Welfare for eight molecules in 19 presentations of generic drugs. Among the eight molecules, six molecules, Irbesartan/Amlodipine, Minodronic Acid Hydrate, Lamotrigine, Nalfurafine Hydrochloride, Lanthanum Carbonate and Oseltamivir Phosphate, are approved for the first time as generics.

* ILUAMIX[®] Combination Tablets LD/HD are Irbesartan and Amlodipine Besilate, and are counted as one molecule.

The products that received approval are listed below.

Therapeutic Category	Product Name	Name of Originator drug
Long-acting ARB / Long-acting Ca antagonists	ILUAMIX [®] Combination Tablets LD [SAWAI] ILUAMIX [®] Combination Tablets HD [SAWAI]	AIMIX [®]
Selective histamine H ₁ -receptor antagonists / Allergic disease treatment	BEPOTASTINE BESILATE OD Tablets 5mg [SAWAI] BEPOTASTINE BESILATE OD Tablets 10mg [SAWAI] BEPOTASTINE BESILATE Tablets 5mg [SAWAI] BEPOTASTINE BESILATE Tablets 10mg [SAWAI]	TALION [®] OD Tablets 5mg TALION [®] OD Tablets 10mg TALION [®] Tablets 5mg TALION [®] Tablets 10mg
Osteoporosis treatment agents	MINODRONIC ACID Tablets 1mg [SAWAI] MINODRONIC ACID Tablets 50mg [SAWAI]	Bonoteo [®] Tablets 1mg Bonoteo [®] Tablets 50mg RECALBON [®] Tablets 1mg RECALBON [®] Tablets 50mg

Antiepileptic therapeutic agents / Bipolar disorder treatment	LAMOTRIGINE Tablets 25mg [SAWAI] LAMOTRIGINE Tablets 100mg [SAWAI]	Lamictal® Tablets 25mg Lamictal® Tablets 100mg
Antiepileptic therapeutic agents	LAMOTRIGINE Tablets 2mg for Pediatric [SAWAI] LAMOTRIGINE Tablets 5mg for Pediatric [SAWAI]	Lamictal® Tablets 2mg Lamictal® Tablets 5mg
Oral antipruritus agents	NALFURAFINE HYDROCHLORIDE OD Tablets 2.5µg [SAWAI]	REMITCH® OD TABLETS 2.5µg REMITCH® capsules 2.5µg NOPICOR® capsules 2.5µg
Hyperphosphatemia treatment agents	LANTHANUM CARBONATE Granules 250mg [SAWAI] LANTHANUM CARBONATE Granules 500mg [SAWAI]	Fosrenol® Granules 250mg Fosrenol® Granules 500mg
Anti-influenza virus agents	OSELTAMIVIR Capsules 75mg [SAWAI] OSELTAMIVIR DS 3% [SAWAI]	TAMIFLU® Capsule 75 TAMIFLU® Dry Syrup 3%
New quinolone antibacterial agent for infusion	LEVOFLOXACIN IV Drip Infusion Bag 500mg/100mL [SAWAI] LEVOFLOXACIN IV Drip Infusion 500mg/20mL [SAWAI]	CRAVIT® INTRAVENOUS DRIP INFUSION BAG 500mg/100mL CRAVIT® INTRAVENOUS DRIP INFUSION 500mg/20ml

About Sawai

Founded in 1929, Sawai Pharmaceutical Co., Ltd. has grown into one of the leading generics companies in Japan. Guided by its corporate philosophy, "Patients First," Sawai markets more than 700 high-quality generic products and reliably delivers them to patients throughout Japan. In 2017, Sawai acquired US-based Upsher-Smith Laboratories, LLC marking its first step in overseas expansion to become a globally recognized generic pharmaceutical company. For more information, visit: <https://www.sawai.co.jp/en/>.

For further information please contact:

PR/IR group, pr@sawai.co.jp