

August 16, 2018  
Sawai Pharmaceutical Co., Ltd.

**Sawai Pharmaceutical Receives Approvals for  
Six Compounds with 13 Strengths of Generic Drugs**

Osaka, Japan – August 15, 2018 – Sawai Pharmaceutical Co., Ltd. (Sawai, Head office: Osaka, Japan, President: Mitsuo Sawai) received approvals by the Ministry of Health, Labour and Welfare for six compounds with 13 strengths of generic drugs. Among the six compounds, four compounds, Mirtazapine, Atomoxetine Hydrochloride, Tramadol Hydrochloride / Acetaminophen and Capecitabine, are approved for the first time as generics.

\* TOARASET® Combination Tablets are Tramadol Hydrochloride and Acetaminophen, and are counted as one compound.

\* FREWELL® Combination Tablets are Norethisterone and Ethinylestradiol, and are counted as one compound.

**The list of approved products:**

1. MIRTAZAPINE OD Tablets 15 mg [SAWAI] / 30 mg [SAWAI],  
MIRTAZAPINE Tablets 15 mg [SAWAI] / 30 mg [SAWAI]
  - Generic name: Mirtazapine
  - Indications: Depression / depressive state
  - Brand products: REFLEX® TABLETS 15 mg / 30 mg, REMERON® Tablets 15 mg / 30 mg
2. ATOMOXETINE Capsules 5 mg [SAWAI] / 10 mg [SAWAI] / 25 mg [SAWAI] / 40 mg [SAWAI]
  - Generic name: Atomoxetine Hydrochloride
  - Indications: Attention-deficit / hyperactivity disorder (ADHD)
  - Brand products: Strattera® Capsules 5mg / 10 mg / 25 mg / 40 mg
3. TOARASET® Combination Tablets [SAWAI]
  - Generic name: Tramadol Hydrochloride / Acetaminophen
  - Indications: Non-cancerous chronic pain and pain after tooth extraction that cannot be managed by treatments with non-opioid analgesics
  - Brand products: TRAMCET® Combination Tablets
4. ROPINIROLE Extended-release Tablets 2 mg [SAWAI] / 8 mg [SAWAI],
  - Generic name: Ropinirole Hydrochloride
  - Indications: Parkinson's disease
  - Brand products: ReQuip® CR Tablets 2 mg / 8 mg
5. FREWELL® Combination Tablets ULD [SAWAI]
  - Generic name: Norethisterone / Ethinylestradiol
  - Indications: Dysmenorrhea
  - Brand products: LUNABELL® Tablets ULD
6. CAPECITABINE Tablets 300 mg [SAWAI]
  - Generic name: Capecitabine
  - Indications: Inoperable or recurrent breast cancer, colorectal cancer, gastric cancer
  - Brand products: XELODA® Tablets 300

The products announced in this press release are not approved by the Food & Drug Administration for sale and distribution in the United States.

◆ Contact Information ◆

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