

This material is an English translation of the press release announced on Jul. 13, 2020 in Japanese, and the Japanese release is given priority about the content and the interpretation.

---

Jul. 13, 2020

**Notice regarding Application for Approval of Partial Change of Approved Matters of “Mohrus® Paps XR 120 mg and 240 mg”, Transdermal Analgesic Anti-Inflammatory Patches**

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu City, Saga Prefecture; President and CEO: Kazuhide Nakatomi; hereinafter referred to as “Hisamitsu Pharmaceutical”) is pleased to announce that it has submitted application for approval of partial change of the approved matters for a new formulation of transdermal analgesic anti-inflammatory patches “Mohrus® Paps XR 120 mg and 240 mg” (Non-proprietary name: Ketoprofen) on July 8.

Hisamitsu Pharmaceutical has been working on the development of a new formulation that contains new additives and also adjusts the amount of existing additives in order to reduce skin irritation, in consideration of the side effect reports on skin irritation at the site of application of the existing formulations.

It has decided to submit application for partial change to the new formulation, since the bioequivalence of the new formulation to the current formulation has been verified.

Hisamitsu Pharmaceutical hopes that this new formulation will contribute to pain relief treatment for many more patients.

It expects to obtain approval by the end of FY 2020.

■ **Mohrus® Paps XR 120 mg and 240 mg**

“Mohrus® Paps XR 120 mg and 240 mg” containing ketoprofen, non-steroidal anti-inflammatory analgesics, were developed as once-daily patches with nine indications, including lumbago and local joint pain relief in rheumatoid arthritis.

Hisamitsu Pharmaceutical launched Mohrus® Paps XR 120 mg (10 cm x 14 cm) in December 2015 and Mohrus® Paps XR 240 mg (14 cm x 20 cm) in February 2017.

\* Reference information

Product name	Mohrus® Paps XR 120 mg, Mohrus® Paps XR 240 mg
Non-proprietary name	Ketoprofen
Indications	<p>○ Pain relief and anti-inflammation of the following diseases and symptoms Lumbagos (myofascial lumbago, osteoarthritis of the spine, discopathy, lumbar strain), osteoarthritis, periartthritis scapulohumeralis, tenovaginitis, peritendinitis, humeral epicondylitis (tennis elbow, etc.), muscle pain, and swelling and pain after injuries</p> <p>○ Local joint analgesia in rheumatoid arthritis</p>
Dosage and administration	Apply to the affected area once daily.
Size of product	10 cm x 14 cm (Mohrus® Paps XR 120 mg) 14 cm x 20 cm (Mohrus® Paps XR 240 mg)
Start of sales	December 2015 (Mohrus® Paps XR 120 mg) February 2017 (Mohrus® Paps XR 240 mg)