

This material is an English translation of the press release announced on Mar 23, 2021 in Japanese, and the Japanese release is given priority about the content and the interpretation.

Mar 23, 2021

**Notification of approval for manufacturing and marketing approval of
ZICTHORU[®] Tapes for “cancer pain” in Japan
(Transdermal, pain treatment NSAID patch, development code: HP-3150)**

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga Prefecture, Japan; President and CEO: Kazuhide Nakatomi, hereinafter referred to as “Hisamitsu”) announces that it has obtained approval for manufacturing and marketing for ZICTHORU[®] Tapes 75 mg, transdermal, pain treatment NSAID patch for “cancer pain” (Development code: HP-3150, generic name: diclofenac sodium, hereinafter referred to as “the product”) in Japan as of today.

The product is a systemic transdermal formulation developed using Hisamitsu’s TDDS (Transdermal Drug Delivery System) technology, and the efficacy and safety of the product have been confirmed in clinical trials in patients with cancer pain.

In Japan, NSAIDs that had the indication of cancer pain are only injections, and the product is the first transdermal preparation for cancer pain containing NSAIDs in Japan.

By transdermal administration of the product once daily, the drug is transferred directly into the blood of the whole body without going through the gastrointestinal tract, and the effect is maintained by means of maintaining a stable blood concentration for 24 hours. It can also be administered to patients who have difficulty swallowing, and the patient's medication status can be visually confirmed by family members and caregivers.

With this approval, Hisamitsu expects the product to be a new option for the treatment of cancer pain as the first transdermal preparation containing NSAIDs that can be used for patients with cancer pain in Japan.

Hisamitsu will contribute to further improving the quality of life of patients with cancer pain by providing proper information of the product.

Reference:

Trade name	ZICTHORU® Tapes 75 mg
Active pharmaceutical ingredient	Diclofenac sodium
Indication	Analgesia in various cancers
Dosage and Administration	Usually, for adults, apply 2 patches (150 mg of diclofenac sodium) to the chest, abdomen, upper arms, back, lumbar region or thigh once a day, and replace them every day (about 24 hours). The dose can be increased up to 3 patches (225 mg of diclofenac sodium) daily depending on the symptoms and condition.
Size of formulation	70 cm ² (7cm x 10cm)