

This material is an English translation of the press release announced on June 20, 2022 in Japanese, and the Japanese release is given priority about the content and the interpretation.

June 20, 2022

Notification of approval for manufacturing and marketing approval of the additional indications of “low back pain, humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis” for ZICTHORU[®] Tapes (Transdermal, pain treatment NSAID patch, development code: HP-3150) in Japan

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 been approved for the additional indications of “low back pain, humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis” for ZICTHORU[®] Tapes, transdermal, pain treatment NSAID patch (Development code: HP-3150, generic name: diclofenac sodium, hereinafter referred to as “the product”) in Japan as of today. The product was approved for manufacturing and marketing approval for “analgesia in various cancer” in March, 2021.

This approval is based on the data of Phase III clinical studies that evaluated the efficacy and safety of the product in patients with low back pain, humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis. Hisamitsu has confirmed the efficacy and safety of the product in the clinical studies. With this approval of the additional indications, Hisamitsu expects the product to be a new option for the treatment of low back pain, humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis.

The product is a systemic transdermal system containing non-steroidal anti-inflammatory drugs (NSAIDs) developed using Hisamitsu’s TDDS (Transdermal Drug Delivery System) technology. By transdermal administration of the product once daily, the drug is absorbed directly into the blood of the whole body without going through the gastrointestinal tract, and it is expected to provide sustained pain relief by means of maintaining a stable blood concentration for 24 hours. Also, because the product is a systemic transdermal system that exerts effect via systemic circulation of blood, it does not need to be continuously applied to the site of pain. Therefore, it can be applied not only to the site of pain, but also to any site where the patient can apply it himself, which is expected to reduce the skin damage. In addition, because the product is a systemic transdermal system 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 (to prevent forgetting to apply or overdosing) and there are no restrictions on timing of administration due to dietary influences, which is expected to improve medication adherence.

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	<ul style="list-style-type: none"> • Analgesia in various cancers • Analgesia and anti-inflammation in low back pain, humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis
Dosage and Administration	<p><u>Analgesia in various cancers</u> 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.</p> <p><u>Analgesia and anti-inflammation in low back pain, humeroscapular peri-arthritis, cervico-omo-brachial syndrome and tenosynovitis</u> Usually, for adults, apply 1 patch (75 mg of diclofenac sodium) or 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).</p>
Size of formulation	70 cm ² (7cm x 10cm)
Packaging	70 patches (1 patch/1 pouch×70 pouches) 140 patches (1patch/1 pouch×140 pouches) 70 patches (7 patches/1 pouch×10 pouches)※

※Estimated time of shipment: Early July, 2022