

For Immediate Release

November 21, 2018
Sawai Pharmaceutical Co., Ltd.

MHLW Approves New Indication for LEVOFOLINATE I.V. Infusion

Osaka, Japan –November 21, 2018 – Sawai Pharmaceutical Co., Ltd. (Sawai, Head office: Osaka, Japan, President: Mitsuo Sawai) today received approval of partial change applications by the Ministry of Health, Labour and Welfare (MHLW) for LEVOFOLINATE I.V. Infusion 25 mg [SAWAI] and 100 mg [SAWAI]*.

This approval expands the indication of LEVOFOLINATE I.V. Infusion 25 mg [SAWAI] and 100 mg [SAWAI] to include the same uses as their brand equivalents.

* Brand products: ISOVORIN® I.V. Infusion 25 mg and 100 mg

“Indications and Usage” and “Dosage and Administration” after approvals are listed below;

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| <p>Indications and Usage (New approval is underlined)</p> | <p>1. Levofolinate and 5-Fluorouracil therapy Enhancing the effect of 5-fluorouracil for the treatment of gastric cancer (which is inoperable or recurrent) and colorectal cancer</p> <p>2. Levofolinate and 5-Fluorouracil continuous intravenous combination therapy Enhancing the effect of 5-fluorouracil for the treatment of colorectal cancer, <u>small intestine cancer</u> and pancreatic cancer not amenable to curative resection</p> |
| <p>Dosage and Administration (New approval is underlined)</p> | <p>1. Levofolinate and 5-Fluorouracil therapy In general, for adults, 250 mg/m² (body surface) as levofolinate is administered by intravenous drip infusion at one time over a period of 2 hours. 600 mg/m² (body surface) as 5-fluorouracil is administered by bolus intravenous injection at one time within 3 minutes, 1 hour after beginning the levofolinate infusion. Repeat 6 times during 1 week, followed by a 2 week break. This is 1 cycle.</p> <p>2. Levofolinate and 5-Fluorouracil continuous intravenous combination therapy for colorectal cancer (1) In general, for adults, 100 mg/m² (body surface) as levofolinate is administered by intravenous drip infusion at one time over a period of 2 hours. Immediately followed by 400 mg/m² (body surface) as 5-fluorouracil is administered by intravenous injection at one time and 600 mg/m² (body surface) as 5-fluorouracil is administered by continuous</p> |

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| | <p>intravenous injection at one time over a period of 22 hours. This is continued for 2 days and repeated every 2 weeks.</p> <p>(2) In general, for adults, 250 mg/m² (body surface) as levofolinate is administered by intravenous drip infusion at one time over a period of 2 hours. Immediately followed by 2600 mg/m² (body surface) as 5-fluorouracil is administered by continuous intravenous injection at one time over a period of 24 hours. Repeat 6 times during 1 week, followed by a 2 week break. This is 1 cycle.</p> <p>(3) In general, for adults, 200 mg/m² (body surface) as levofolinate is administered by intravenous drip infusion at one time over a period of 2 hours. Immediately followed by 400 mg/m² (body surface) as 5-fluorouracil is administered by intravenous injection at one time and 2400 to 3000 mg/m² (body surface) as 5-fluorouracil is administered by continuous intravenous injection at one time over a period of 46 hours. This is continued every 2 weeks.</p> <p>3. Levofolinate and 5-Fluorouracil continuous intravenous combination therapy for <u>small intestine cancer and pancreatic cancer not amenable to curative resection</u></p> <p>In general, for adults, 200 mg/m² (body surface) as levofolinate is administered by intravenous drip infusion at one time over a period of 2 hours. Immediately followed by 400 mg/m² (body surface) as 5-fluorouracil is administered by intravenous injection at one time and 2400 mg/m² (body surface) as 5-fluorouracil is administered by continuous intravenous injection at one time over a period of 46 hours. This is continued every 2 weeks.</p> |
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