For Immediate Release

June 18, 2019
Sawai Pharmaceutical Co., Ltd.

MHLW Approves Additional Indications for METHOTREXATE Capsules

Osaka, Japan – June 18, 2019 – Sawai Pharmaceutical Co., Ltd. (Head office: Osaka, Japan, President: Mitsuo Sawai) today received approval of partial change application by the Ministry of Health, Labour and Welfare (MHLW) for METHOTREXATE Capsules 2 mg [SAWAI]*.
This approval expands the indications of METHOTREXATE products to include the same uses as their brand equivalents.

* Brand products: RHEUMATREX® (Methotrexate) Capsules 2 mg

"Indications and Usage" and "Dosage and Administration" after approval are described below (New approval is underlined);

Indications and Usage

1. Rheumatoid arthritis
2. Psoriasis vulgaris, which is not adequately responsive to topical therapies
3. Psoriasis arthropathica, pustular psoriasis, or erythrodermic psoriasis
4. Juvenile idiopathic arthritis associated with joint symptoms

Dosage and Administration

1. Rheumatoid arthritis, 2. Psoriasis vulgaris, which is not adequately responsive to topical therapies,
3. Psoriasis arthropathica, pustular psoriasis, or erythrodermic psoriasis
   The usual dose of Methotrexate is 6 mg per week and orally administered once or as a divided dose two or three times. When given in a divided dose, administer every 12 hours from the first day to the second day. In the case of one or two divided doses, discontinue for the remaining 6 days, and in the case of three divided doses, discontinue for the remaining 5 days. This is repeated every week.
   It is necessary to adjust the dosage appropriately depending patient's age, symptoms, tolerability, response to this drug. The dosage should not exceed 16 mg per week.
4. Juvenile idiopathic arthritis associated with joint symptoms
   The usual dose of Methotrexate is 4 to 10 mg/m^2 per week and orally administered once or as a divided dose two or three times. When given in a divided dose, administer every 12 hours from the first day to the second day. In the case of one or two divided doses, discontinue for the remaining 6 days, and in the case of three divided doses, discontinue for the remaining 5 days. This is repeated every week.
   It is necessary to adjust the dosage appropriately depending patient's age, symptoms, tolerability, and response to this drug.

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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