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CHUGAI
Roche Group

Translation

Prophylaxis of Influenza in Infants and Children Approved as an Additional Indication of Anti-influenza Drug Tamiflu®

December 18, 2009 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President: Osamu Nagayama (hereafter, "Chugai")] announced today that on December 18, 2009, the Ministry of Health, Labour and Welfare granted approval for the anti-influenza drug oseltamivir phosphate [product name: Tamiflu®] in an additional indication of "prophylaxis of influenza in adults, infants and children" in the formulation as Tamiflu® Dry Syrup, and it granted approval for a change in the dosage and administration for Tamiflu® Capsules in the pediatric prophylaxis indication. Chugai markets Tamiflu® in Japan.

A newly added indication will enable the prophylaxis administration of Tamiflu® to infants and children under the age of 13. In addition, it has become possible to administer not only Tamiflu® Dry Syrup but also Tamiflu® Capsules to children with a body weight of 37.5 kg or more, which is the same as in the current indication for treatment of influenza. Precise indication and administration methods of Tamiflu® for prophylaxis usage are described in detail in the package insert. It is Chugai's intent to provide information on appropriate usage so that Tamiflu® is administered in a proper fashion.
When used for the purpose of "prophylaxis of A or B-type influenza," Tamiflu® will not be reimbursed by the national health insurance.

Chugai believes that, with the addition of the approved indication of "prophylaxis use in infants and children under the age of 13," Tamiflu® can contribute further to the fight against influenza infection.

[Reference]

* The underlined descriptions are newly added or changed.

Product name: Tamiflu® Capsule 75
Tamiflu® Dry Syrup 3%

Generic name: oseltamivir phosphate

Indications, and Dosage and administration:

	Tamiflu® Dry Syrup 3%	Tamiflu® Capsule 75
Indications	Treatment and prophylaxis of A or B-type influenza	Treatment and prophylaxis of A or B-type influenza
Dosage and Administration	1. Treatment of influenza (1) Adults The usual oral dosage is 75 mg as oseltamivir twice a day for 5 days. Tamiflu Dry Syrup is prepared into suspension at the time of use. (2) Infants and children The usual oral dosage is 2 mg/kg as oseltamivir (66.7 mg/kg as Dry Syrup) twice a day for 5 days. Tamiflu Dry Syrup is prepared into suspension at the time of use. However, the maximum dose a time is 75 mg as oseltamivir. 2. Prophylaxis of influenza (1) Adults The usual oral dosage is 75 mg as oseltamivir once a day for 7 to 10 days. Tamiflu Dry Syrup is prepared into suspension at the time of use. (2) Infants and children The usual oral dosage is 2 mg/kg as oseltamivir (66.7 mg/kg as Dry Syrup) once a day for 10 days. Tamiflu Dry Syrup is prepared into suspension at the time of use. However, the maximum dose a time is 75 mg as oseltamivir.	1. Treatment of influenza The usual oral dosage for adults and children weighing 37.5 kg or more is 75 mg as oseltamivir twice a day for 5 days. 2. Prophylaxis of influenza (1) Adults The usual oral dosage is 75 mg as oseltamivir once a day for 7 to 10 days. (2) Children weighing 37.5 kg or more The usual oral dosage is 75 mg as oseltamivir once a day for 10 days.

Drug prices: Tamiflu® Capsule 75 JPY 309.1/capsule
Tamiflu® Dry Syrup 3% JPY 237.2/gram