

Japan approves Chugai Pharma's osteoporosis drug

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Japanese firms Chugai Pharmaceutical and Towa Pharmaceutical have announced that Chugai has obtained regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) for osteoporosis treatment- Edirol Tablets 0.5 µg/0.75 µg (generic name: eldecalcitol, hereafter, Edirol Tablet).

Edirol is an active vitamin D3 derivative created based on Chugai's long-standing vitamin D research. The drug was launched in 2011 in a soft capsule formulation as Edirol Capsule, and has been used as a base drug for the treatment of osteoporosis.

Due to the characteristics of the formulation, Edirol Capsule rolls easily and is hard to grasp with fingers. In addition, patients using Edirol often take other drugs, too. Considering these points, Chugai developed an alternative tablet formulation for Edirol that is easier to handle and identify. The regulatory approval for Edirol Tablet is based on the results of a bioequivalence study comparing the soft capsule and the tablet in 49 healthy adult volunteers.

While Chugai takes responsibilities as a holder of the approval, Towa will be solely responsible for marketing and providing information on appropriate use of Edirol Tablet. Chugai will manufacture Edirol Tablet and supply to Towa. Chugai continues to market and provide information on Edirol Capsule. Towa markets an authorized generic (AG) version of Edirol Capsule.