

November 28, 2008

Translation

Approval of a New Indication for Oxarol[®] Ointment/Lotion
(nonproprietary name: maxacalcitol), Psoriasis Vulgaris Treatment
Topical Products Containing Active Vitamin D₃,
for Extended Treatment of Palmoplantar Pustulosis

Maruho Co., Ltd.
Chugai Pharmaceutical Co., Ltd.

Maruho Co., Ltd. [Head Office, Kita-ku, Osaka; President, Koichi Takagi] (hereafter, “Maruho”) and Chugai Pharmaceutical Co., Ltd. [Head Office, Chuo-ku, Tokyo; President, Osamu Nagayama] (hereafter, “Chugai”) are pleased to announce that the Ministry of Health, Labour and Welfare approved a new indication for Oxarol[®] Ointment 25 µg/g (hereafter, “Ointment”) and Oxarol[®] Lotion 25 µg/g (hereafter, “Lotion”), treatment drugs for keratosis including psoriasis vulgaris, for extended treatment of palmoplantar pustulosis as of November 25, 2008. Chugai has the marketing approval and Maruho distributes for the products.

Maxacalcitol, an active ingredient of the drugs, is an active vitamin D₃ derivative developed by Chugai. It inhibits proliferation and induces differentiation of epidermal keratinocytes. Since market launch of “Ointment” in October 2001, it has been widely used in patients with keratosis including psoriasis vulgaris, remarkably improving the symptoms. “Lotion” was launched in June 2007. It has been improved so that patients can easily apply the product to hairy areas such as head, a common site of psoriasis vulgaris.

The efficacy and safety of the drugs for palmoplantar pustulosis were demonstrated in the clinical trials conducted in applying for approval for extended indication.

Currently, steroids are mainly used for topical treatment of palmoplantar pustulosis. However, since low-concentration tacalcitol is the only active vitamin D₃ derivative that is indicated for palmoplantar pustulosis, the additional indication of topical treatment Oxarol[®] for palmoplantar pustulosis is expected to provide more treatment choices to patients with palmoplantar pustulosis.

[Contact Information]

Public Relations, Maruho Co., Ltd. TEL 06-6371-8831

PR/IR, Chugai Pharmaceutical Co., Ltd. TEL 03-3273-0881

[Reference]

<Product Summary>

Product Name	Oxarol [®] Ointment Oxarol [®] Lotion
Nonproprietary Name	Maxacalcitol
Composition	One gram of Oxarol [®] product contains 25 µg of maxacalcitol
Indications	Psoriasis vulgaris, ichthyosis, palmoplantar keratosis, palmoplantar pustulosis
Dosage and Administration	Appropriate amount of Oxarol [®] product should be applied to the affected area twice daily. Depending on the symptom, application frequency should be decreased as necessary.
Precaution concerning Dosage and Administration	The maximum recommended daily dose of maxacalcitol is 250 µg, or 10 g of topical maxacalcitol.
Package	Ointment: tube 10 g × 1, 10 g × 10 Lotion: bottle 10 g × 1, 10 g × 10
Marketing authorization holder	Chugai Pharmaceutical Co., Ltd.
Drug Price	138.40 yen per 1 g

<Palmoplantar Pustulosis>

Palmoplantar pustulosis is a chronic skin disease characterized mainly by symmetrical distribution of sterile pustules on the palms and soles, and the cause of the pathogenesis is currently not understood. It has been reported that the onset reaches a peak in the age of 40 to 49 years both in men and women and the ratio of women to men tends to increase in the ages of 50 years and older.