

Launch of Dovobet[®] Ointment Topical Combination Drug for Psoriasis Vulgaris

Tokyo, Japan, September 11, 2014 -- Kyowa Hakko Kirin Co., Ltd. (headquarters: Chiyoda-ku, Tokyo; President and CEO: Nobuo Hanai; “Kyowa Hakko Kirin”) announced today that Dovobet[®] Ointment will be launched in Japan on September 12, 2014 as a topical combination drug for psoriasis vulgaris.

Dovobet[®] Ointment was developed by LEO Pharma A/S (headquarters: Ballerup, Denmark; President & CEO: Gitte P. Aabo). Since the drug was launched in Denmark in 2001 as a topical treatment for psoriasis vulgaris, and it is now approved and marketed in 97 countries worldwide, including the US, and is widely used as one of the first-line treatment for psoriasis vulgaris.

The drug is the first product that has been developed and marketed by LEO Pharma K.K. (Headquarters: Chiyoda-ku, Tokyo; General Manager and Japan Representative Director: Stefan Sakurai) in Japan. LEO Pharma K.K. is responsible for supplying the drug, and Kyowa Hakko Kirin is responsible for distribution and Medical Representatives (MRs) promotion of the drug. Both companies will jointly conduct marketing activities.

Psoriasis is a chronic and intractable skin disease. In Japan, there are reportedly approximately 430,000 sufferers. Although various treatments are available for psoriasis vulgaris, most patients are receiving topical treatment with agents such as active Vitamin D₃ and the corticosteroid. Treatment has involved mono-therapy, combination therapy of the two products. Patients may have these two drugs mixed into a compound at pharmacies or use the individual drugs separately or concurrently. Therefore, improved efficacy and increased patient convenience have been expected of topical products used for the treatment of psoriasis.

“Dovobet[®] Ointment” is a Vitamin D₃ (calcipotrol[®] hydrate) and steroid (betamethasone dipropionate) combination for topical psoriasis treatment. By realizing the chemically stable combination and complementary action of the ingredients, “Dovobet[®] Ointment” rapidly improves the skin symptoms of psoriasis and provides convenient once-daily application, which contributes to increased patient adherence.

Kyowa Hakko Kirin and LEO Pharma K.K. intend to play a significant part in the improvement of the quality of life of patients suffering from psoriasis vulgaris through the distribution and promotion of this drug.

Dovobet® Ointment Product overview

Product name	Dovobet® Ointment
Nonproprietary name	Calcipotriol hydrate/betamethasone dipropionate
Composition	1g contains 52.2µg calcipotriol hydrate (as 50.0µg calcipotriol), 0.643mg betamethasone dipropionate
Indication	Psoriasis vulgaris
Dose and administration	Usually applied once daily in the required amount to the affected site
Precautions related to the dosage and administration	Do not use more than 90g in 1 week
Packaging	Tube: 15g x 1, 15g x 10, 30g x 1
Approval date	July 4, 2014
NHI price listing date	September 2, 2014
Distributed by	Kyowa Hakko Kirin Co., Ltd.
Marketing authorization holder	LEO Pharma K.K.

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