Ultravate® (halobetasol propionate) – Expanded indication

- On August 27, 2020, the FDA approved Sun Pharmaceuticals' Ultravate (halobetasol propionate) lotion, for the topical treatment of plaque psoriasis in patients twelve (12) years of age and older.

    — Previously, Ultravate was approved for the same indication in patients eighteen (18) years of age and older.

- Halobetasol propionate is also available generically as a cream and ointment.

    — The cream and ointment are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

- Safety and effectiveness of Ultravate lotion for the treatment of moderate to severe plaque psoriasis have been established in patients 12 years of age and older. It is supported by evidence from adequate and well-controlled trials in adults and from one uncontrolled safety trial in 16 adolescents (12 to less than 17 years of age).

- The recommended dose of Ultravate for the treatment of plaque psoriasis is to apply a thin layer to the affected skin twice daily for up to two weeks. Therapy should be discontinued when control is achieved. If no improvement is seen within two weeks, reassessment of diagnosis may be necessary.

    — Treatment beyond two weeks is not recommended and the total dosage should not exceed 50 grams (50 ml) per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal axis.
    — Use should be avoided on the face, scalp, groin, or axillae.
    — Ultravate is not for ophthalmic, oral, or intravaginal use.