

Impeklo[™] (clobetasol propionate) – New drug approval

- On May 19, 2020, the <u>FDA approved</u> Mylan's <u>Impeklo (clobetasol propionate)</u> 0.05% lotion, for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 18 years of age or older.
 - Impeklo should not be used in the treatment of rosacea or perioral dermatitis. Use in patients under 18 years of age is not recommended due to numerically high rates of hypothalamic-pituitary-adrenal (HPA) axis suppression
- Clobetasol is generically available in various other formulations, including as a lotion (eg, generic Clobex[®] lotion).
 - Clobex lotion is also approved for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.
- Warnings and precautions for Impeklo include effects on the endocrine system; ophthalmic adverse reactions; local adverse reactions with topical corticosteroids; allergic contact dermatitis; and concomitant skin infections.
- The most common adverse reactions (> 1%) with Impeklo use were skin atrophy, telangiectasia, discomfort skin and skin dry.
- Impeklo should be applied topically to the affected skin areas twice daily and rubbed in gently and completely.
 - The total dosage should not exceed 50 grams per week because of the potential for the drug to suppress the HPA axis. More than 10 pump actuations per application twice daily or 20 pump actuations per day for more than 7 days should not be used.
 - The use of Impeklo on the face, axillae, or groin should be avoided and avoid use if there is atrophy at the treatment site.
 - Impeklo lotion contains a topical corticosteroid; therefore treatment should be limited to 2 consecutive weeks for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses and up to 2 additional weeks in localized lesions (less than 10% body surface area) of moderate to severe plaque psoriasis that have not sufficiently improved after the initial 2 weeks of treatment. The use of Impeklo should be discontinued when control is achieved.
- Mylan's launch plans for Impeklo are pending. Impeklo will be available as a 0.05% lotion in a metered-dose pump.



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