

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

- On November 28, 2017, the FDA approved Promius Pharma's Impoyz (clobetasol propionate)
 0.025% cream, for the treatment of moderate to severe plaque psoriasis in patients 18 years of age and older.
- Clobetasol propionate is also available generically as a 0.05% <u>cream</u>, 0.05% <u>emollient cream</u>, 0.05% <u>foam</u>, 0.05% <u>gel</u>, 0.05% <u>liquid spray</u>, 0.05% <u>lotion</u>, 0.05% <u>ointment</u>, 0.05% <u>shampoo</u>, and 0.05% <u>solution</u>.
 - Refer to individual drug labels for indication information.
- The approval of Impoyz was based on two vehicle-controlled studies evaluating 532 patients ≥ 18
 years with moderate to severe plaque psoriasis. The primary endpoint was the proportion of subjects
 who achieved treatment success at day 15.
 - In study 1, 30.2% of Impoyz-treated patients achieved the primary endpoint vs. 9.0% of vehicle-treated patients.
 - In study 2, 30.1% of Impoyz-treated patients achieved the primary endpoint vs. 9.7% of vehicle-treated patients.
- Warnings and precautions of Impoyz include effects on the endocrine system, local adverse reactions, concomitant skin infections, and allergic contact dermatitis.
- The most common adverse reaction (≥ 1%) with Impoyz use was application site discoloration.
- Impoyz should be applied as a thin layer to the affected skin areas twice daily and rubbed in gently and completely.
 - Impoyz may be used for up to two consecutive weeks.
 - The total dosage should not exceed 50 grams/week.
 - Do not use on the face, scalp, axilla, groin, or other intertriginous areas.
- Promius Pharma's launch plans for Impoyz are pending. Impoyz will be available as a 0.025% cream in 60 g and 112 g tubes.



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