

Dymista filed in Europe

The marketing authorization application for Dymista (a novel formulation of azelastine hydrochloride and fluticasone propionate) has been filed in Europe. The application uses a decentralized procedure and the reference member state is Germany.

Dymista is a nasal spray formulation for patients with symptomatic treatment of moderate to severe allergic rhinitis and rhinoconjuctivitis. The efficacy and safety of Dymista has been documented in several studies involving over 4,000 patients, including a long-term safety study with more than 600 patients.

"The regulatory filing for Dymista in Europe is important for our azelastine franchise. Earlier this year, Dymista was filed in the US and we will continue now with filings in other key markets", said Anders Lönner, CEO of Meda AB.

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