

FDA Approves Dermira's Qbrexza Cloth to Treat Primary Axillary Hyperhidrosis

The FDA has approved Qbrexza (glycopyrronium) cloth, an anticholinergic indicated for the topical treatment of primary axillary hyperhidrosis in adult and pediatric patients nine years of age and older. Qbrexza is applied directly to the skin and is designed to block sweat production by inhibiting sweat gland activation.

Approval is based on results from two Phase 3 clinical trials, ATMOS-1 and ATMOS-2, which evaluated the efficacy and safety of Qbrexza in patients with primary axillary hyperhidrosis. Both trials assessed the absolute change from baseline in sweat production (the weight or amount of sweat a patient produced) following treatment with Qbrexza and the proportion of patients who achieved at least a four-point improvement from baseline in their sweating severity, as measured by the Axillary Sweating Daily Diary (ASDD), Dermira's proprietary patient-reported outcome (PRO) instrument. The PRO was developed in consultation with the FDA and in accordance with the agency's 2009 guidance on PRO instruments.

"Primary axillary hyperhidrosis is a condition that has negatively impacted many of my patients for most of their lives," says Dee Anna Glaser, MD, professor and interim chair, Department of Dermatology at Saint Louis University School of Medicine and a renowned hyperhidrosis expert. "I look forward to Qbrexza's potential to be a meaningful treatment option that will not only reduce a person's sweat, but will reduce the overall impact this condition has on their daily life."

The most common side effects observed following topical application of Qbrexza to the underarms were dry mouth, dilated pupil (mydriasis), sore throat (oropharyngeal pain), headache, urinary hesitation, blurred vision, dry nose, dry throat, dry eye, dry skin and constipation. The most common local skin reactions were erythema, burning/stinging, and pruritus.

Qbrexza is expected to be available nationwide in pharmacies beginning in October 2018.