New Drug Approvals

Generic Name (Trade Nameâ€"Company)

July 9, 2018

Glycopyrronium

(Qbrexza—Dermira)

FDA approves first once-daily, topical prescription for excessive underarm sweating

Uses/Notes

Dermira announced FDA approval of glycopyrronium cloth, an anticholinergic indicated for topical treatment of primary axillary hyperhidrosis in adult and pediatric patients aged 9 years and older.

Commonly known as excessive underarm sweating, primary axillary hyperhidrosis is a chronic medical skin condition that results in sweating beyond what is needed for normal body temperature regulation. The exact cause is unknown, but it affects nearly 10 million people in the United States, with both men and women having similar prevalence. Approved under the trade name Qbrexza (pronounced kew brex' zah), it is applied directly to the skin and is designed to block sweat production by inhibiting sweat gland activation.

Approval was based on results from two Phase III 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 most common adverse effects observed following topical application of Qbrexza to the underarms were dry mouth, dilated pupil, sore throat, 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. For more information, visit www.qbrexza.com.

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