

## Qbrexza™ (glycopyrronium) – New drug approval

- On June 29, 2018, [Dermira announced](#) the FDA approval of [Qbrexza \(glycopyrronium\)](#) for topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.
- Primary axillary hyperhidrosis, also known as excessive underarm sweating, is a chronic medical skin condition that results in sweating beyond what is physiologically required for normal thermal regulation
  - The exact cause is unknown, but it affects nearly 10 million people in the U.S., with both men and women having similar prevalence.
- Qbrexza contains glycopyrronium is a competitive inhibitor of acetylcholine receptors that are located on certain peripheral tissues, including sweat glands. In hyperhidrosis, glycopyrronium inhibits the action of acetylcholine on sweat glands, reducing sweating.
- The approval of Qbrexza was demonstrated in two randomized vehicle-controlled trials involving 697 subjects ≥ 9 years old with primary axillary hyperhidrosis. The co-primary endpoints were the absolute change from baseline in sweat production and the proportion of subjects having at least a 4-point improvement from baseline in weekly mean Axillary Sweat Daily Diary (ASDD), a patient-report measure of sweating severity.
  - In trial 1, the median change from baseline in sweat production at week 4 was -81 mg/5 minutes for Qbrexza-treated patients vs. -66 mg/5 minutes for vehicle-controlled patients. Moreover, a greater proportion of subjects showed improvements in ASDD with Qbrexza vs. vehicle (53% vs. 28%).
  - In trial 2, the median change from baseline in sweat production at week 4 was -79 mg/5 minutes for Qbrexza-treated patients vs. -58 mg/5 minutes for vehicle-controlled patients. Similarly, a greater proportion of subjects showed improvements in ASDD with Qbrexza vs. vehicle (66% vs. 27%).
- Qbrexza is contraindicated in patients with medical conditions that can be exacerbated by the anticholinergic effect of Qbrexza (eg, glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, Sjogren's syndrome).
- Warnings and precautions of Qbrexza include worsening of urinary retention, control of body temperature, and operating machinery or an automobile.
- The most common adverse reactions (> 2%) with glycopyrronium use include dry mouth, mydriasis, oropharyngeal pain, headache, urinary hesitation, blurred vision, nasal dryness, dry throat, dry eye, dry skin, and constipation. Local skin reactions, including erythema, burning/stinging and pruritus were also common (> 5%).
- The recommended dose of Qbrexza is a single-use pre-moistened cloth applied to clean, dry skin on the underarm areas only. Qbrexza should not be used more frequently than once every 24 hours.
  - Avoid transfer of Qbrexza to the periocular area and do not apply Qbrexza to broken skin.
  - Avoid using Qbrexza with occlusive dressings.

- Dermira plans to launch Qbrexza in October 2018. Qbrexza will be available in individual pouches as a single-use, pre-moistened cloth containing 2.4% glycopyrronium sodium.



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