

Qbrexza (glycopyrronium)



NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Qbrexza
- **Generic name:** Glycopyrronium
- **Pharmacological class:** Anticholinergic
- **Strength and Formulation:** 2.4% solution; per cloth (pre-moistened)
- **Manufacturer:** Dermira, Inc.
- **How supplied:** Single-use cloth—30
- **Legal Classification:** Rx

Qbrexza



Indication

- Primary axillary hyperhidrosis

Dosage & Administration

- **≥9yrs:** Using a single cloth, apply once daily to both axillae
- Do not occlude

Considerations for Special Populations

- **Pregnancy:** No available data to inform a drug-associated risk
- **Nursing mothers:** Consider mother's clinical need and potential adverse effects on breastfed infant
- **Pediatric:** <9yrs: not established
- **Renal impairment:** Elimination severely impaired in renal failure

Contraindications

- **Conditions that can be exacerbated by anticholinergic effect**
 - Glaucoma, paralytic ileus, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, Sjogren's syndrome

Warnings/Precautions

- History or presence of documented **urinary retention**
- **Monitor** for urinary retention (esp. in prostatic hypertrophy or bladder-neck obstruction); discontinue immediately if develops
- High ambient temperature

Warnings/Precautions

- Advise patients to **avoid** use if generalized lack of sweating develops when exposed to hot/warm temperatures
- Avoid other body areas, broken skin, contact with the eyes, or transfer to the periocular area
- Flammable

Interactions

- Additive anticholinergic effects with other anticholinergic-containing drugs; avoid

Adverse Reactions

- Dry mouth
- Mydriasis
- Oropharyngeal pain
- Headache
- Urinary hesitation
- Vision blurred
- Nasal dryness
- Dry throat/eye/skin
- Constipation
- Local skin reactions (eg, erythema, burning/stinging/pruritus)

Mechanism of Action

- Glycopyrronium is a competitive inhibitor of acetylcholine receptors that are located on certain peripheral tissues, including sweat glands
 - It inhibits the action of acetylcholine on sweat glands, reducing sweating

Clinical Studies

- Qbrexza was evaluated in 2 randomized, vehicle-controlled multicenter trials (**Trial 1 and Trial 2**) in patients with primary axillary hyperhidrosis aged ≥ 9 years (N=697)
- All produced ≥ 50 mg sweat in each axilla over a 5-minute period and rated severity of sweating daily over a week with mean score of ≥ 4 on ASDD item #2

Clinical Studies

- Patients were randomized to Qbrexza or vehicle applied once daily to each axilla
- **Co-primary endpoints:**
 - Proportion of subjects having at least a 4-point improvement from baseline in weekly mean ASDD item #2 score at week 4
 - Mean absolute change from baseline in gravimetrically measured sweat production at week 4

Clinical Studies

- Trial 1:
 - ASDD item #2 response at week 4: **53%** (Qbrexza) vs **28%** (vehicle)
 - Median change from baseline in sweat production at week 4 (mg/5mins): **-81mg** vs **-66mg**

Clinical Studies

- Trial 2:
 - ASDD item #2 response at week 4: **66%** (Qbrexza) vs **27%** (vehicle)
 - Median change from baseline in sweat production at week 4 (mg/5mins): **-79mg** vs **-58mg**

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

<https://www.empr.com/qbrexza/drug/34879/>