



Facts About GELNIQUE™ (oxybutynin chloride) Gel 10%

Mechanism of Action

GELNIQUE™ (oxybutynin chloride) Gel 10% is the first and only topical gel approved by the FDA for the treatment of overactive bladder (OAB). It is a quick-drying, clear and colorless, fragrance-free hydroalcoholic gel containing oxybutynin chloride, an antispasmodic, anticholinergic agent. GELNIQUE is designed to deliver a consistent dose of oxybutynin through the skin over a 24-hour period and provides strong efficacy without sacrificing tolerability.

GELNIQUE will provide OAB patients with an effective and novel alternative to currently available oral treatment options. The active ingredient in GELNIQUE is delivered transdermally, so it is not metabolized by the liver in the same way as orally administered oxybutynin. This results in a low level of side effects, including dry mouth and constipation.

Indication & Dosing

GELNIQUE is indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency. A one-gram (approx. 1 mL) dose of 100mg/g GELNIQUE, applied once daily to the thigh, abdomen, upper arm or shoulder, delivers about 4mg oxybutynin each day.

Clinical Efficacy

- The approval of GELNIQUE is based on a Phase 3 randomized, double-blind, placebo-controlled, parallel group trial that evaluated a total of 789 patients with signs and symptoms of OAB.
 - One-gram, once-daily dose of GELNIQUE for 12 weeks was superior to placebo at relieving OAB symptoms, including a reduction in incontinence episodes and urinary frequency, and an increase in void volume.
- Additional pharmacology studies showed that showering one hour or later or the application of sunscreen 30 minutes before or after GELNIQUE application did not significantly alter the absorption and

systemic blood levels of oxybutynin. Minimal amounts of oxybutynin were transferred when treated people came into direct skin-to-skin contact with their untreated partner. Clothing over the application site eliminated any drug transference.

Safety

- In a clinical trial, GELNIQUE™ was well tolerated with a low incidence of adverse events and no treatment-related serious adverse events. The most frequently reported treatment-related adverse events (>2% and greater than placebo) were dry mouth (6.9%) and application-site reactions (5.4%).

**Clinical
Development**

GELNIQUE was developed by Watson Pharmaceuticals, Inc., a global leader in the development and distribution of pharmaceuticals with a broad portfolio of generic products and a specialized portfolio of branded pharmaceuticals focused on Urology, Gynecology and Nephrology (Medical).