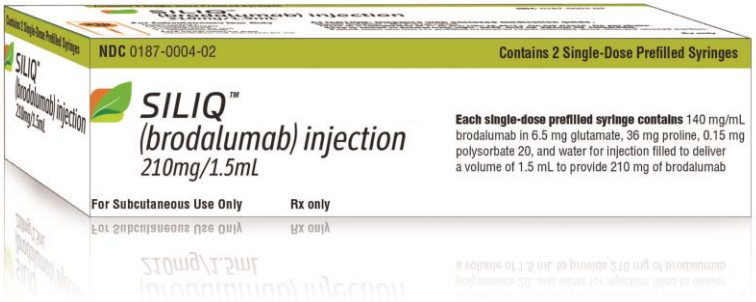
Siliq (brodalumab)



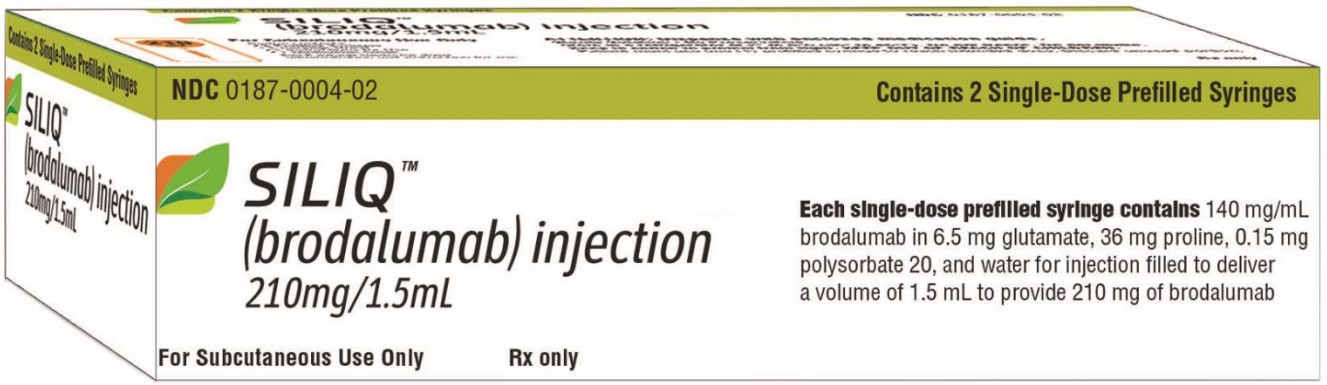
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Siliq
- **Generic name:** Brodalumab
- **Pharmacological class:** Interleukin-17A antagonist
- **Strength and Formulation:** 210mg/1.5mL; soln for SC inj; preservative-free
- **Manufacturer:** Valeant Pharmaceuticals
- **How supplied:** Single-dose prefilled syringes—2
- **Legal Classification:** Rx

SILIQ


NDC 0187-0004-02
Contains 2 Single-Dose Prefilled Syringes
SILIQ™
(brodalumab) injection
210mg/1.5mL
Each single-dose prefilled syringe contains 140 mg/mL brodalumab in 6.5 mg glutamate, 36 mg proline, 0.15 mg polysorbate 20, and water for injection filled to deliver a volume of 1.5 mL to provide 210 mg of brodalumab
For Subcutaneous Use Only
Rx only

Indications

- Moderate-to-severe **plaque psoriasis** in adults who are candidates for systemic therapy or phototherapy and unresponsive to other systemic therapies

Dosage & Administration

- Give by SC inj into thigh, abdomen (except for area around navel), outer area of upper arm; rotate inj sites
- 210mg at Weeks 0, 1, and 2 followed by 210mg every 2 weeks
- If adequate response not achieved after 12–16 weeks, **consider discontinuing**

Considerations for Special Populations

- **Pregnancy:** No human data to inform drug-associated risk
- **Nursing mothers:** Consider benefits and adverse effects
- **Pediatric:** Not established
- **Elderly:** No differences in safety or efficacy

Warnings/Precautions

- Must enroll patients in the **Siliq REMS program**; advise patients of the risk of suicidal ideation and behavior
- History of **depression or suicidality**

Warnings/Precautions

- May increase risk of infections
- Chronic or history of recurrent infection: consider the risks/benefits
- If a **serious infection** develops or is not responding to standard therapy, monitor closely and discontinue until resolves

Warnings/Precautions

- **Evaluate** for TB infection prior to initiating; monitor for active TB during and after therapy
- Patients with active TB infection: **do not initiate**
- History of latent or active TB: consider anti-TB therapy prior to initiation
- **Discontinue** if Crohn’s disease develops

Interactions

- **Avoid** concomitant live vaccines
- Concomitant **CYP450 substrates** with a narrow therapeutic index (eg, warfarin, cyclosporine); monitor and consider adjusting dose

Adverse Reactions

- Arthralgia
- Headache
- Fatigue
- Diarrhea
- Oropharyngeal pain
- Nausea
- Myalgia
- Inj site reactions
- Influenza
- Neutropenia
- Tinea infections

Mechanism of Action

- **Brodalumab** is an interleukin-17A (IL-17A) antagonist that inhibits IL-17 cytokine-induced responses by binding to IL-17RA
- Blocking IL-17RA inhibits IL-17 cytokine-induced responses including the release of pro-inflammatory cytokines and chemokines

Clinical Studies

- Siliq was studied in 3 multicenter, randomized, double-blind, controlled trials **(Trials 1, 2, and 3)**
- Enrolled patients (≥18 years old) had at least a 6-month history of moderate to severe plaque psoriasis

Clinical Studies

- In all trials, patients were randomized to Siliq 210mg or placebo
- In Trials 2 and 3, patients randomized to ustekinumab received a 45mg dose (if weight ≤100kg) or 90mg dose (if weight >100kg)

Clinical Studies

- The two **co-primary endpoints** were:
  - Proportion of patients who achieved a PASI 75 score at Week 12
  - Proportion of subjects with an sPGA of 0 (clear) or 1 (almost clear) and at least a 2-point improvement from baseline

Clinical Studies

- In **Trial 1**, the Siliq arm was superior at achieving PASI 75 response (83% vs. 3%) and sPGA success (76% vs. 1%) vs. placebo at Week 12
- PASI100 response was achieved in 42% of patients in the Siliq arm vs. <1% in the placebo arm

Clinical Studies

- In **Trial 2,** the Siliq arm was superior at achieving PASI 75 response (86% vs. 70% vs. 8%) and sPGA success (79% vs. 61% vs. 4%) vs. ustekinumab and placebo at Week 12, respectively
- PASI100 response was achieved in 44% of patients in the Siliq arm vs. 22% in the ustekinumab arm and 1% in the placebo arm

Clinical Studies

- In **Trial 3,** the Siliq arm was superior at achieving PASI 75 response (85% vs. 69% vs. 6%) and sPGA success (80% vs. 57% vs. 4%) vs. ustekinumab and placebo at Week 12, respectively
- PASI100 response was achieved in 37% of patients in the Siliq arm vs. 19% in the ustekinumab arm and <1% in the placebo arm

Clinical Studies

- In **Trial 1**, responders at Week 12 were re-randomized to receive either placebo or Siliq
- Continued treatment with Siliq was superior in maintaining sPGA and PASI 75 at Week 52 (83% and 87%, respectively) vs. placebo (0%)

Clinical Studies

- In both **Trial 2 and 3**, the original Siliq group was re-randomized to 1 of 4 Siliq regimens and the original placebo group was crossed over to Siliq
- The ustekinumab group continued treatment until they crossed over at Week 52 to Siliq

Clinical Studies

- At Week 52, 79% of sPGA responders and 72% of PASI 100 responders maintained their response with Siliq

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/siliq/drug/34702/