

LET ME  
BE  
PSORIASIS



CLEAR  
WILL NOT STOP ME

SWITCH TO  
**SILIQ**  
(brodalumab) injection  
210 mg/1.5 mL

Actual Siliq patient.

## Are your patients not clearing on their current biologic?

Learn more about how Siliq could make a difference for them.<sup>1</sup>

### INDICATION

Siliq<sup>®</sup> injection is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

### IMPORTANT SAFETY INFORMATION

#### WARNING: SUICIDAL IDEATION AND BEHAVIOR

Suicidal ideation and behavior, including completed suicides, have occurred in patients treated with Siliq. Prior to prescribing Siliq, weigh the potential risks and benefits in patients with a history of depression and/or suicidal ideation or behavior. Patients with new or worsening suicidal ideation and behavior should be referred to a mental health professional, as appropriate. Advise patients and caregivers to seek medical attention for manifestations of suicidal ideation or behavior, new onset or worsening depression, anxiety, or other mood changes [see Warnings and Precautions (5.1) in the full Prescribing Information].

Because of the observed suicidal behavior in subjects treated with Siliq, Siliq is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Siliq REMS Program [see Warnings and Precautions (5.2) in the full Prescribing Information].

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning for suicidal ideation and behavior, in pocket.

## GIVE THEM EVERY CHANCE OF SUCCESS\*

### Summary of key SILIQ endpoints in pivotal trials at week 12, % of patients

Study Endpoint <sup>a</sup> at week 12	Phase 3 Studies								
	AMAGINE-1 <sup>2</sup>		AMAGINE-2 <sup>3</sup>			AMAGINE-3 <sup>3</sup>			
	SILIQ n=222	Placebo n=220	SILIQ n=612	Stelara <sup>b</sup> n=300	Placebo n=309	SILIQ n=625	Stelara <sup>b</sup> n=313	Placebo n=315	
PASI 75	83	3	86	70	8	85	69	6	
PASI 100	42	<1	44	22	0.6	37	19	0.3	
sPGA 0/1	76	1	79	61	4	80	57	4	

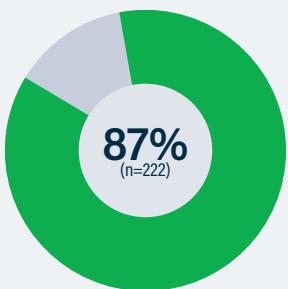
**Study design:** The efficacy and safety of SILIQ were assessed in 3 pivotal clinical trials, AMAGINE-1, AMAGINE-2, and AMAGINE-3. These multicenter, randomized, double-blind, controlled trials included a total of 4373 patients 18 years of age and older with at least a 6-month history of moderate to severe plaque psoriasis. All 3 trials assessed the change from baseline to week 12 compared to placebo for 2 co-primary endpoints: sPGA 0/1 and PASI 75. In AMAGINE-2 and AMAGINE-3, comparisons were also made to ustekinumab for the co-primary endpoint of the proportion of patients who achieved PASI 100 at week 12.<sup>2,3</sup>

<sup>a</sup>Primary endpoints are indicated in **bold**. PASI 100 was a primary endpoint in both AMAGINE-2 and -3 only in comparison with Stelara.

<sup>b</sup>Any other product/brand names and/or logos are trademarks of their respective owners.

### Post hoc analysis of AMAGINE-1: PASI 50 at Week 4<sup>4</sup>

NRI analysis



Almost 9/10 patients had half their psoriasis clear with 4 weeks of treatment while less than 1/10 patients experienced the same results on placebo.<sup>4</sup>

Results were from a post hoc analysis and therefore should be interpreted with caution.

**Study design:** Post-hoc analysis of results from the phase 3 AMAGINE-1 study in patients who received SILIQ and achieved PASI 50 by week 4.

NRI, nonresponder imputation; PASI, Psoriasis Area and Severity Index; sPGA, Static Physician's Global Assessment.

### IMPORTANT SAFETY INFORMATION (cont'd)

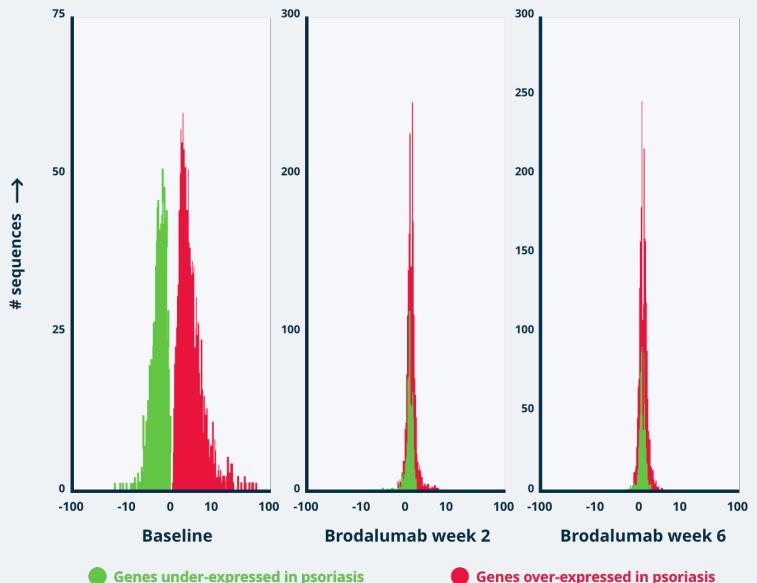
**Contraindications** Do not use SILIQ in patients with Crohn's disease because SILIQ may cause worsening of disease; or in patients with clinically significant hypersensitivity to brodalumab or to any of the excipients in SILIQ or components of the container.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning for suicidal ideation and behavior, in pocket.

## SILIQ NORMALIZES PSORIASIS TRANSCRIPTOME

### Gene Expression Study (Phase 1)<sup>5</sup>

Transcriptome Normalization



The clinical significance of these findings is not known.

Core PsO Microarray: 5000 aberrantly expressed genes in psoriasis

**Study design:** Twenty-five patients with moderate to severe plaque psoriasis were treated with a single dose of brodalumab (n=20) or placebo (n=5). Patients treated with brodalumab received a single dose of 140 mg sc (n=4), 350 mg sc (n=8), and 700 mg iv (n=8). To investigate the molecular and cellular changes in skin following brodalumab treatment, biopsies were obtained from nonlesional skin at baseline and from 3 locations in lesional skin at baseline, week 2, and week 6. The Core PsO Microarray was used to visualize gene expression patterns of 5000 genes known to have altered expression specific to psoriasis.<sup>5</sup>

Thousands of genes are abnormally expressed in psoriatic skin.

### IMPORTANT SAFETY INFORMATION (cont'd)

**SILIQ Risk Evaluation and Mitigation Strategy (REMS) Program** SILIQ is available only through a restricted program called the SILIQ REMS because of observed suicidal ideation and behavior in patients treated with SILIQ. Before prescribing SILIQ, prescribers must be certified with the program, have each patient sign a Patient-Prescriber Agreement Form, and provide the patient a Wallet Card describing symptoms requiring immediate medical evaluation. Pharmacies must be certified and only dispense to patients authorized to receive SILIQ. More information is available at SILIQREMS.com or by calling the SILIQ REMS Program Call Center at 855-511-6135.

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## PRIOR BIOLOGICAL FAILURE

### Stratified Results After 26 Weeks of SiliQ Treatment in Patients With Prior Biologic Failure (n=202)<sup>4</sup>

As observed analysis | Additional secondary endpoint



Results are from an open-label study that used descriptive statistics (as observed analysis) and should be interpreted with caution.

**Study design:** Phase 4, open-label, Canadian study with 251 patients who had an inadequate response to ≥1 prior biologic, including anti-IL-17, anti-IL-23, anti-IL-12/23, or anti-TNF-α. An inadequate response was defined as a lack of adequate therapeutic response, as judged clinically by an investigator, despite being on a stable biologic therapy for ≥12 weeks. Mean PASI score at baseline: 10.2. Patients received SiliQ at weeks 0, 1, 2, and every 2 weeks thereafter until week 26. The primary endpoint was the proportion of patients achieving PASI 100 at week 26. Secondary endpoints included the proportion of patients achieving PASI 75 and PASI 90 at weeks 1, 2, 4, 16, and 26 and PASI 100 at weeks 1, 2, 4, and 16. Additional secondary endpoints included the proportion of patients achieving PASI 75, PASI 90, and PASI 100 at weeks 1, 2, 4, 16, and 26 stratified by the last biologic treatment received. Analysis of data included 216 patients at week 16 and 202 patients at week 26. The analysis was conducted on observed cases, without imputation of missing observations.<sup>4</sup>

BSA, body surface area; IL-12, interleukin 12; IL-17, interleukin 17; IL-23, interleukin 23; PASI, Psoriasis Area and Severity Index; TNF-α, tumor necrosis factor alpha.

**\*Many patients who failed other systemic and biologic treatments have found results with SiliQ.<sup>6-8</sup>**

## IMPORTANT SAFETY INFORMATION (cont'd)

**Hypersensitivity Reactions** Serious hypersensitivity reactions, including anaphylaxis requiring hospitalization, have been reported. If a serious hypersensitivity reaction occurs, immediately discontinue SiliQ and initiate appropriate therapy.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning for suicidal ideation and behavior, in pocket.

### Male | 44 years | SiliQ Q2W

Patient was previously on Humira®, Cosentyx®, and Skyrizi®, respectively.



Actual patient. Individual results may vary.

### Female | 58 years | SiliQ Q2W

Patient was previously on Stelara®, Humira® and Talz®, respectively.



Actual patient. Individual results may vary.

## IMPORTANT SAFETY INFORMATION (cont'd)

**Infections** SiliQ may increase the risk of infections. Serious infections and fungal infections were observed at a higher rate in patients treated with SiliQ than placebo-treated patients in clinical trials, including one case of cryptococcal meningitis that led to discontinuation of therapy.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning for suicidal ideation and behavior, in pocket.

## THE SILIQ SAFETY PROFILE WAS ESTABLISHED IN OVER 4500 PATIENTS<sup>1</sup>

Adverse reactions occurring in  $\geq 1\%$  of patients receiving Siliq and more frequently than placebo in phase 3 trials

Adverse Reactions Through Week 12	Siliq 210 mg Q2W <sup>c</sup> (N=1496) n (%)	Stelara <sup>d</sup> (N=613) n (%)	Placebo (N=879) n (%)
Arthralgia	71 (4.7)	15 (2.4)	29 (3.3)
Headache	64 (4.3)	23 (3.8)	31 (3.5)
Fatigue	39 (2.6)	16 (2.6)	10 (1.1)
Diarrhea	33 (2.2)	5 (0.8)	10 (1.1)
Oropharyngeal pain	31 (2.1)	8 (1.3)	10 (1.1)
Nausea	28 (1.9)	6 (1.0)	10 (1.1)
Myalgia	26 (1.7)	4 (0.7)	3 (0.3)
Injection site reactions (pain, erythema, bruising, hemorrhage, pruritus)	23 (1.5)	12 (2.0)	11 (1.3)
Influenza	19 (1.3)	7 (1.1)	4 (0.5)
Neutropenia	15 (1.0)	5 (0.8)	4 (0.5)
Tinea infections (tinea pedis, versicolor, cruris)	15 (1.0)	3 (0.5)	2 (0.2)

<sup>c</sup>Subjects receiving 210 mg of Siliq at weeks 0, 1, and 2, followed by treatment every 2 weeks during the 12-week period. Safety was also evaluated in an additional dosing group, Siliq 140 mg, which was not included in this table as it is not currently marketed.

<sup>d</sup>Trials 2 and 3 included the active comparator, Stelara (ustekinumab).

## IMPORTANT SAFETY INFORMATION (cont'd)

### Infections (cont'd)

Consider risks and benefits prior to prescribing Siliq in patients with a chronic infection or history of recurrent infection.

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**Siliq**  
(brodalumab) injection  
210 mg/1.5 mL

## OBESE VS NON-OBESE DATA

### Post hoc analysis of AMAGINE-2 and AMAGINE 3: PASI 100 at week 12<sup>9</sup>

NRI analysis



Results were from a post hoc analysis and therefore should be interpreted with caution.

### Post hoc analysis of AMAGINE-2 and AMAGINE 3: PASI 100 at week 52<sup>9</sup>

NRI analysis



Results were from a post hoc analysis and therefore should be interpreted with caution.

**Study design:** Post-hoc analysis of the AMAGINE-2 and AMAGINE-3 trials, in which patients were randomized to receive Siliq every 2 weeks, Stelara, or placebo for a 12-week induction phase. Patients were categorized by BMI (<30 kg/m<sup>2</sup> or ≥30 kg/m<sup>2</sup>). At 12 weeks, patients receiving Siliq were re-randomized and patients receiving Stelara continued their treatment, while patients receiving placebo were switched to Siliq. Efficacy endpoints included the proportion of patients who achieved PASI 75, PASI 90, and PASI 100 and the proportion of patients with an sPGA score of 0 or 1. Efficacy was evaluated throughout the 52-week study period.<sup>9</sup>

BMI, Body Mass Index; NRI, nonresponder imputation; PASI, Psoriasis Area and Severity Index.

## IMPORTANT SAFETY INFORMATION (cont'd)

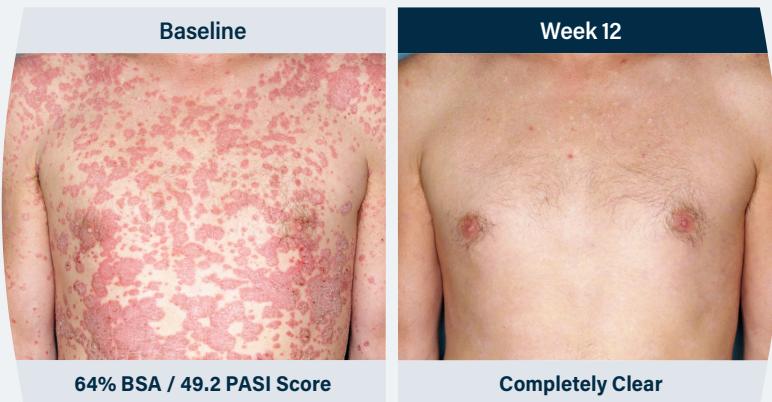
### Infections (cont'd)

Instruct patients to seek treatment if signs or symptoms of a chronic or acute infection occur.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning for suicidal ideation and behavior, in pocket.

## WEEK 12 RESULTS<sup>4</sup>

Male | 40 years | SILIQ Q2W



Male | 40 years | SILIQ Q2W



## WEEK 12 RESULTS<sup>4</sup>

Male | 27 years | SILIQ Q2W



Male | 34 years | SILIQ Q2W



Week 12 Results

These photos are of actual patients treated with SILIQ® in clinical trials. Photos have not been retouched. Individual results may vary.

BSA, body surface area; PASI, Psoriasis Area and Severity Index; Q2W, at two weeks.

## IMPORTANT SAFETY INFORMATION (cont'd)

### Risk for Latent Tuberculosis (TB) Reactivation (cont'd)

Initiate treatment for latent TB prior to starting SILIQ and consider anti-TB therapy prior to initiation in patients with history of latent TB if adequate treatment cannot be confirmed. Monitor closely for symptoms of active TB during and after treatment.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning for suicidal ideation and behavior, in pocket.

## IMPORTANT SAFETY INFORMATION (cont'd)

**Risk for Latent Tuberculosis (TB) Reactivation** Evaluate patients for TB prior to initiating treatment with SILIQ and do not treat patients with active TB.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning for suicidal ideation and behavior, in pocket.

## REAL PATIENT EXPERIENCE WITH SILIQ<sup>4</sup>

Male | 51 years | SILIQ Q2W



Male | 51 years | SILIQ Q2W



## TOTAL CLEARANCE AT WEEK 52<sup>4</sup>

Male | 39 years | SILIQ Q2W



Female | 36 years | SILIQ Q2W



## IMPORTANT SAFETY INFORMATION (cont'd)

**Eczematous Eruptions** Postmarketing cases of severe eczematous eruptions, including atopic dermatitis-like eruptions, have been reported. The onset of eczematous eruptions was variable, ranging from days to months after the first dose of SILIQ.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning for suicidal ideation and behavior, in pocket.

These photos are of actual patients treated with SILIQ® in clinical trials. Photos have not been retouched. Individual results may vary.

BSA, body surface area; PASI, Psoriasis Area and Severity Index; Q2W, at two weeks.

## IMPORTANT SAFETY INFORMATION (cont'd)

### Eczematous Eruptions (cont'd)

Some cases of severe eczematous eruptions resulted in hospitalization. Treatment may need to be discontinued to resolve the eczematous eruption. Some patients with limited psoriasis treatment options were successfully treated for eczema while continuing SILIQ.

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## SILIQ IS THE FIRST AND ONLY IL-17 RECEPTOR A BLOCKER<sup>1,10,11</sup>

IL-17 cytokines are key players in the development of psoriasis.

SILIQ, a human monoclonal IgG2 antibody, blocks all these IL-17 cytokines by blocking a receptor key to all of them (IL-17RA).

## IL-17 CYTOKINES IN PSORIASIS<sup>12-16</sup>

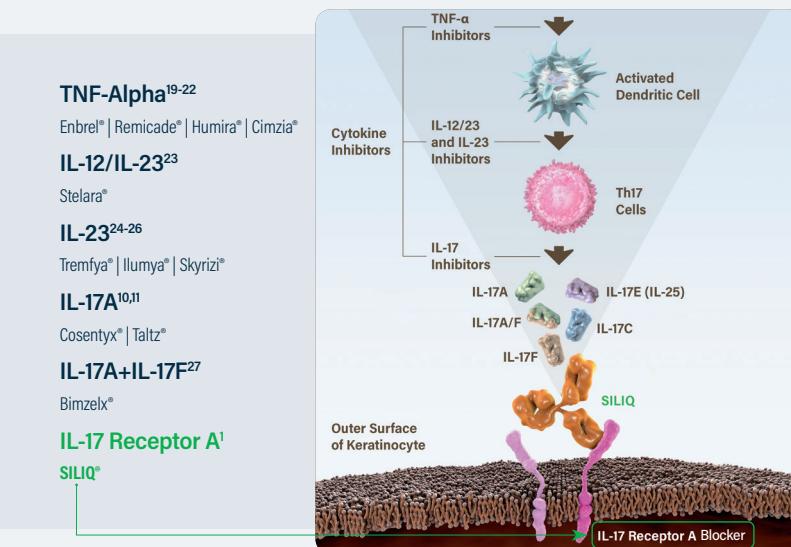
IL-17A <sup>12,14,15,17</sup>	IL-17F <sup>12,14,15</sup>	IL-17C <sup>12,14-16</sup>	IL-17E <sup>12,13</sup>
Pro-inflammatory	Pro-inflammatory	Pro-inflammatory	Pro-inflammatory
Produced by activated T cells	Produced by activated T cells	Produced by activated T cells, epithelial cells, eosinophils, and keratinocytes	Produced by activated T cells, eosinophils, and keratinocytes
Regulates NF- $\kappa$ B and mitogen-activated protein (MAP) kinases	Stimulates IL-6, IL-8, and CSF2/GM-CSF	Stimulates IL-6, IL-8, and CSF2/GM-CSF	Activates NF- $\kappa$ B
Stimulates IL-6 and cyclooxygenase-2 (PTGS2/COX-2)	Inhibits angiogenesis of endothelial cells	Inhibits angiogenesis of endothelial cells	Stimulates IL-8
Enhances nitric oxide (NO)	Induces IL-2, TGF $\beta$ 1/TGF $\beta$ , and monocyte chemoattractant protein-1	Elevated 30x in plaque psoriasis (most abundant protein in lesional skin) <sup>14</sup>	Elevated in plaque psoriasis <sup>13</sup>
Associated with several chronic inflammatory diseases, including rheumatoid arthritis, psoriasis, and multiple sclerosis	Elevated 33x in plaque psoriasis <sup>14</sup>		
Elevated 28x in plaque psoriasis <sup>14</sup>			

links to: <https://www.siliq.com/hcp/how-siliq-works/#moa-sec>



## WHY SILIQ MAY PROVIDE DIFFERENT RESULTS FOR YOUR PATIENTS<sup>8,10,11,15</sup>

Several biologic treatments target different parts of the inflammatory pathway<sup>17,18</sup>



Only Siliq blocks the IL-17 receptor A protein expressed on the cell surface at the site of inflammation<sup>1</sup>

Clinical significance is unknown.

## IMPORTANT SAFETY INFORMATION (cont'd)

**Crohn's Disease** In clinical trials, which excluded Crohn's patients, one Siliq patient was withdrawn after developing Crohn's disease. Discontinue Siliq if a patient develops Crohn's disease.

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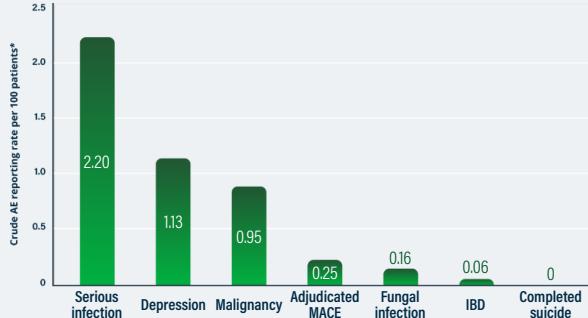
## IMPORTANT SAFETY INFORMATION (cont'd)

**Immunizations** Avoid use of live vaccines in patients treated with Siliq.

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## 6-YEAR POSTMARKETING SAFETY DATA: CLINICAL EVENTS OF SPECIAL INTEREST<sup>2,4,28</sup>

Within the 6-year period, data were collected from 5138 patients in the United States who were administered Siliq, of which 2553 (50%) reported  $\geq 1$  AE.

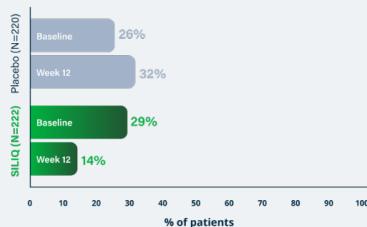


Crude AE reporting rate per 100 patients was calculated as the number of clinical events of special interest divided by 5138 Siliq patients multiplied by 100 patients.

AE, adverse event; IBD, inflammatory bowel disease; MACE, major adverse cardiovascular event.

### Depression Is Often a Comorbidity of Severe Psoriasis<sup>2,4</sup>

Phase 3 Study (AMAGINE-1): Prevalence of Depression at Week 12  
HADS score  $\geq 8$  | Other endpoint



Many patients who have moderate to severe plaque psoriasis also have depression. In clinical studies for Siliq, patients could participate even if they had depression or a history of depression.<sup>2,3</sup>

Siliq users with a history of suicidality or depression had an increased incidence of suicidal ideation and behavior as compared to users without such a history. Patients with new or worsening symptoms of depression or suicidality should be referred to a mental health professional, as appropriate.<sup>1</sup>

HADS, Hospital Anxiety and Depression Scale.

### IMPORTANT SAFETY INFORMATION (cont'd)

**Adverse Reactions** The most commonly reported adverse reactions in clinical trials were arthralgia, headache, fatigue, diarrhea, oropharyngeal pain, nausea, myalgia, injection site reactions, influenza, neutropenia, and tinea infections.

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PI Pocket



### SIMPLIFYING PATIENT ACCESS

Efficient and easy to use, Siliq Solutions™ helps your patients get the most from their treatment.



#### Instant Savings Program

No matter what your insurance covers, pay as little as **\$0 per month** with commercial insurance coverage<sup>†,‡</sup>



#### Specialty Pharmacy

Ensure prescriptions get filled with a seamless connection to Siliq-certified specialty pharmacies

<sup>†</sup>Subject to a \$15,000 maximum benefit for 24 months from the patient's first eligible date of program participation.

<sup>‡</sup>If a patient's commercial insurance does not cover Siliq, or coverage is delayed or denied, the patient may pay \$50 per month until coverage is approved or up to 24 months from program initiation.

**CALL 1-855-460-7928**

Monday-Friday, 8 AM-5 PM ET

To report SUSPECTED ADVERSE REACTIONS, contact Customer Service at 1-800-321-4576 or the FDA at 1-800-FDA-1088, or visit [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch).

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# Discover more about SILIQ® REMS

## **SILIQ®** (brodalumab) injection 210 mg/1.5 mL

**Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning for suicidal ideation and behavior, in pocket.**

**References:** 1. SILIQ. Prescribing Information. Bausch Health Companies, Inc; 2024. 2. Papp KA, Reich K, Paul C, et al. A prospective phase III, randomized, double-blind, placebo-controlled study of brodalumab in patients with moderate-to-severe plaque psoriasis. *Br J Dermatol.* 2016;175(2):273-286. 3. Lebwohl M, Strober B, Menter A, et al. Phase 3 studies comparing brodalumab with ustekinumab in psoriasis. *N Engl J Med.* 2015;373(14):1318-1328. 4. Data on file. Bausch Health US, LLC. Bridgewater, NJ. 5. Russell CB, Rand H, Bigler J, et al. Gene Expression profiles normalized in psoriatic skin by treatment with brodalumab, a human anti-IL-17 receptor monoclonal antibody. *J Immunol.* 2014;192(8):3828-3836. 6. Kimmel G, Chima M, Kim HJ et al. Brodalumab in the treatment of moderate-to-severe psoriasis in patients who have previously failed anti-interleukin 17A therapies. *J Am Acad Dermatol.* 2019;81(3):857-859. 7. Langley RG, et al. Efficacy and safety of brodalumab in patients with psoriasis who had inadequate responses to ustekinumab: subgroup analysis of two randomized phase III trials. *Br J Dermatol.* 2019;180:306-314. 8. Papp KA, Gordon KB, Langley RG, et al. Impact of previous biologic use on efficacy and safety of brodalumab and ustekinumab in patients with moderate-to-severe plaque psoriasis: integrated analysis of AMAGINE-2 and AMAGINE-3. *Br J Dermatol.* 2018;179 (2):320-328. 9. Hsu S, Green LJ, Lebwohl MG, et al. Comparable efficacy and safety of brodalumab in obese and nonobese patients with psoriasis: analysis of two randomized controlled trials. *Br J Dermatol.* 2020;182(4):880-888. 10. COSENTYX. Prescribing Information. Novartis Pharmaceuticals Corporation; 2017. 11. Taltz. Prescribing Information. Eli Lilly and Company; 2017. 12. GeneCards: The Human Gene Database. Weizman Institute of Science; 2023. <https://www.genecards.org/>. Accessed December 12, 2024. 13. Senra L, Stalder R, Alvarez Martinez D, et al. Keratinocyte-derived IL-17E contributes to inflammation in psoriasis. *J Invest Dermatol.* 2016;136(10):1970-1980. 14. Johansen C, Usher PA, Kjellerup RB, et al. Characterization of the interleukin-17 isoforms and receptors in lesional psoriatic skin. *Br J Dermatol.* 2009;160:319-324. 15. Malakouti M, Brown GE, Wang E, et al. The role of IL-17 in psoriasis. *J Dermatol Treat.* 2015;26(1):41-44. 16. Johnston A, Fritz Y, Dawes SM, et al. Keratinocyte overexpression IL-17C promotes psoriasisform skin inflammation. *J Immunol.* 2013;190(5):2252-2262. 17. Biologics. National Psoriasis Foundation: <https://www.psoriasis.org/biologics/>. Accessed December 12, 2024. 18. Current Biologics on the Market. National Psoriasis Foundation: <https://www.psoriasis.org/current-biologics-on-the-market/>. Accessed December 12, 2024. 19. Enbrel. Prescribing Information. Immunex Corporation; 2024. 20. REMICADE. Prescribing Information. Janssen Biotech Inc; 2021. 21. HUMIRA Injection. Package Insert. AbbVie; 2024. 22. CIMZIA. Prescribing Information. Smyrna; 2024. 23. STELARA. Prescribing Information. Janssen Biotech; 2024. 24. TREMFYA. Prescribing Information. Janssen Biotech; 2024. 25. ILUMYA. Package Insert. Sun Pharmaceutical Industries, Inc; 2024. 26. SKYRIZI. Package Insert. AbbVie; 2024. 27. BIMZELX. Prescribing Information. Smyrna; 2024. 28. Lebwohl MG, Koo JY, Armstrong AW, et al. Brodalumab: Six-Year IS Pharmacovigilance Report. *Dermatol Ther (Heidelb).* 2024; <https://doi.org/10.1007/s13555-024-01304-y>; <https://link.springer.com/article/10.1007/s13555-02>. Accessed January 14, 2025.

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