ONGOING TREATMENT

SUPPORTING
your patients
ON OTEZLA

Helping empower patients during ongoing treatment

INDICATIONS

Otezla® (apremilast) is indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Otezla is indicated for the treatment of adult patients with active psoriatic arthritis.

Otezla is indicated for the treatment of adult patients with oral ulcers associated with Behçet's Disease.

IMPORTANT SAFETY INFORMATION

Contraindications

- Otezla® (apremilast) is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation

Please see Important Safety Information presented throughout, and Full Prescribing Information here.

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Ongoing compliance is driven by many factors[1]

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Noncompliance can be both intentional and unintentional[1]

- Unintentional noncompliance includes a patient's lack of understanding of instructions or forgetting to take medication
- Intentional noncompliance is when a patient actively decides to discontinue their medication

Discussing compliance can help support patient outcomes[1,2]

There are many possible causes of noncompliance, including[1,3-5]:

- Discontinuation of therapy at resolution of symptoms
- Concerns about treatment, including safety
- Unrealistic treatment expectations
- Continuation of coverage

It is important that patients understand that they should not stop or alter their treatment routine without first consulting with their healthcare provider[6]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

- Diarrhea, Nausea, and Vomiting: Cases of severe diarrhea, nausea, and vomiting were associated with the use of Otezla. Most events occurred within the first few weeks of treatment. In some cases patients were hospitalized. Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting; advise patients to contact their healthcare provider. Consider Otezla dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting

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Staying on treatment with Otezla

Discussing compliance, ongoing treatment expectations, and potential concerns during follow-up visits can help patients stay on track with their treatment goals.[1,6]

Topics for discussion during follow-up visits

Chronic nature of disease[1,3,7]	Remind patients about the chronic nature of their condition—an improvement in symptoms doesn't mean their condition is cured. Therefore, they must continue treatment as prescribed.
Ongoing treatment[1,3,7]	• Remind patients that improvement in symptoms may be best observed with continued dosing • Encourage patients to track their progress over time • Reinforce the importance of taking Otezla® (apremilast) as prescribed to help achieve results
Patient support	Otezla offers a $0 co-pay card* for eligible patients. You can call **1-844-4OTEZLA** or visit **otezla.com** to fill out a form or learn more.
Other	Additional information and resources are available at **otezla.com**.

Remind patients to consult with a healthcare provider before stopping Otezla.[7]

For additional guidance, please refer to the Patient Counseling section of the PI.

*Certain restrictions apply; eligibility not based on income, must be 18 years or older. This offer is not valid for persons eligible for reimbursement of this product, in whole or in part under Medicaid, Medicare, or similar state or federal programs. Offer not valid for cash-paying patients. People who are not eligible can call **1-844-4OTEZLA** to discuss other financial assistance opportunities.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

- Depression: Carefully weigh the risks and benefits of treatment with Otezla for patients with a history of depression and/or suicidal thoughts/behavior, or in patients who develop such symptoms while on Otezla. Patients, caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and they should contact their healthcare provider if such changes occur

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Additional resources are available for patients at **otezla.com.**
For more information about patient support,
call Otezla SupportPlus™ **at 1-844-4OTEZLA** (1-844-468-3952)

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  - Psoriasis: Treatment with Otezla is associated with an increase in depression. During clinical trials, 1.3% (12/920) of patients reported depression compared to 0.4% (2/506) on placebo. Depression was reported as serious in 0.1% (1/1308) of patients exposed to Otezla, compared to none in placebo-treated patients (0/506). Suicidal behavior was observed in 0.1% (1/1308) of patients on Otezla, compared to 0.2% (1/506) on placebo. One patient treated with Otezla attempted suicide; one patient on placebo committed suicide
  - Psoriatic Arthritis: Treatment with Otezla is associated with an increase in depression. During clinical trials, 1.0% (10/998) reported depression or depressed mood compared to 0.8% (4/495) treated with placebo. Suicidal ideation and behavior was observed in 0.2% (3/1441) of patients on Otezla, compared to none in placebo-treated patients. Depression was reported as serious in 0.2% (3/1441) of patients exposed to Otezla, compared to none in placebo-treated patients (0/495). Two patients who received placebo committed suicide compared to none on Otezla
  - Behçet's Disease: Treatment with Otezla is associated with an increase in depression. During the clinical trial, 1% (1/104) reported depression or depressed mood compared to 1% (1/103) treated with placebo. No instances of suicidal ideation or behavior were reported in patients treated with Otezla or treated with placebo

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IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

- Weight Decrease: Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla
  - Psoriasis: Body weight loss of 5-10% occurred in 12% (96/784) of patients treated with Otezla and in 5% (19/382) of patients treated with placebo. Body weight loss of ≥10% occurred in 2% (16/784) of patients treated with Otezla compared to 1% (3/382) of patients treated with placebo
  - Psoriatic Arthritis: Body weight loss of 5-10% was reported in 10% (49/497) of patients taking Otezla and in 3.3% (16/495) of patients taking placebo
  - Behçet's Disease: Body weight loss of >5% was reported in 4.9% (5/103) of patients taking Otezla and in 3.9% (4/102) of patients taking placebo
- Drug Interactions: Apremilast exposure was decreased when Otezla was co-administered with rifampin, a strong CYP450 enzyme inducer; loss of Otezla efficacy may occur. Concomitant use of Otezla with CYP450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended

Adverse Reactions

- Psoriasis: Adverse reactions reported in ≥5% of patients were (Otezla%, placebo%): diarrhea (17, 6), nausea (17, 7), upper respiratory tract infection (9, 6), tension headache (8, 4), and headache (6, 4)
- Psoriatic Arthritis: Adverse reactions reported in at least 2% of patients taking Otezla, that occurred at a frequency at least 1% higher than that observed in patients taking placebo, for up to 16 weeks (after the initial 5-day titration), were (Otezla%, placebo%): diarrhea (7.7, 1.6); nausea (8.9, 3.1); headache (5.9, 2.2); upper respiratory tract infection (3.9, 1.8); vomiting (3.2, 0.4); nasopharyngitis (2.6, 1.6); upper abdominal pain (2.0, 0.2)
- Behçet's Disease: Adverse reactions reported in ≥5% of patients taking Otezla, that occurred at a frequency at least 1% higher than that observed in patients taking placebo, for up to 12 weeks, were (Otezla%, placebo%): diarrhea (41.3, 20.4); nausea (19.2, 10.7); headache (14.4, 10.7); upper respiratory tract infection (11.5, 4.9); upper abdominal pain (8.7, 1.9); vomiting (8.7, 1.9); back pain (7.7, 5.8); viral upper respiratory tract infection (6.7, 4.9); arthralgia (5.8, 2.9)

Use in Specific Populations

- Pregnancy: Otezla has not been studied in pregnant women. Advise pregnant women of the potential risk of fetal loss. Consider pregnancy planning and prevention for females of reproductive potential. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Otezla during pregnancy. Information about the registry can be obtained by calling 1-877-311-8972 or visiting https://mothertobaby.org/ongoing-study/otezla/
- Lactation: There are no data on the presence of apremilast or its metabolites in human milk, the effects of apremilast on the breastfed infant, or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Otezla and any potential adverse effects on the breastfed child from Otezla or from the underlying maternal condition
- Renal Impairment: Otezla dosage should be reduced in patients with severe renal impairment (creatinine clearance less than 30 mL/min); for details, see Dosage and Administration, Section 2, in the Full Prescribing Information

References: 1. Yélamos O, Ros S, Puig L. *Psoriasis (Auckl).* 2015;5:109-115. **2.** Brown MT, Bussell JK. *Mayo Clin Proc.* 2011;86(4):304-314. **3.** Lebwohl MG, Kavanaugh A, Armstrong AW, Van Voorhees AS. *Am J Clin Dermatol.* 2016;17(1):87-97. **4.** Hugtenburg JG, Timmers L, Elders PJ, Vervloet M, Van Dijk L. *Patient Prefer Adherence.* 2013;7:675-682. **5.** Thorneloe RJ, Griffiths CEM, Emsley R, et al. *J Invest Dermatol.* 2018;138(4):785-794. **6.** Sabaté E. Adherence to Long-term Therapies: Evidence for Action. Geneva, Switzerland: World Health Organization; 2003. **7.** Otezla [package insert]. Thousand Oaks, CA: Amgen Inc.

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