STARTING TREATMENT

SUPPORTING
your patients
ON OTEZLA

Preparing your patients for the first 2 weeks of therapy

INDICATIONS

Otezla® (apremilast) is indicated for the treatment of adult 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.

Otezla® (apremilast) 30mg tablets

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

Otezla® (apremilast) 30mg tablets

Setting expectations is an important first step[2]

Empower patients to achieve treatment goals

- When patients work together with their healthcare provider, it can help ensure their chronic condition remains manageable[2]

Emphasize that compliance is critical for chronic conditions

- Treating chronic diseases is ongoing, so helping patients develop compliant behavior is essential[1,2]

Encourage patients to take advantage of support services

- For example, savings programs, access to nurse support, etc

The majority of patients reporting nausea and diarrhea did so within the first 2 weeks; the events tended to resolve over time with continued dosing[3]

Postmarketing reports of severe diarrhea, nausea, and vomiting have been associated with the use of Otezla. In some cases, patients were hospitalized. Monitor patients who are more susceptible to complications of diarrhea or vomiting.[3]

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
- 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
  - 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

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Otezla® (apremilast) 30mg tablets

Starting your patients on Otezla

Convenient, oral dosing and no label-required lab monitoring[3]

Starting Otezla

- Review the benefits and risks of Otezla, including efficacy expectations and the most common adverse reactions
- Let your patients know about support services from Otezla SupportPlus™, such as the $0 co-pay program,* the Otezla Bridge Program, and 24/7 access to trained nurses

Dosing and titration[3]

- 5-day initial dose titration is intended to reduce gastrointestinal symptoms associated with the start of therapy
- After titration, the maintenance dosage is 30 mg twice daily with or without food. For additional dose modifications, please see the Full Prescribing Information for Otezla†

The Otezla half-life[3]

- Otezla has an elimination half-life of approximately 6-9 hours
- Patient dosing adherence is important to maintain therapeutic serum concentrations

Making compliance a habit

- Connect taking Otezla to something they do each day, such as eating breakfast and dinner or brushing their teeth in the morning and evening
- Have patients set a reminder using an alarm, or encourage them to download the GOtezla® app to track symptoms and other treatment information

Explaining the specialty pharmacy

- Let patients know that they will receive a phone call from an unfamiliar number to set up delivery of Otezla from the specialty pharmacy directly to their door
- Coach patients to follow up in 1 week if they have not been contacted by the specialty pharmacy. They can call Otezla SupportPlus™ at **1-844-4OTEZLA** (1-844-468-3952)

*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.

†Otezla dosage should be reduced to 30 mg once daily in patients with severe renal impairment (creatinine clearance less than 30 mL/min).

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

- Depression: (cont'd)
  - 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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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)

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® (apremilast)
  - 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. Lebwohl MG, Kavanaugh A, Armstrong AW, Van Voorhees AS. *Am J Clin Dermatol.* 2016;17(1):87-97. **2.** Yélamos O, Ros S, Puig L. *Psoriasis (Auckl).* 2015;5:109-115. **3.** Otezla [package insert]. Thousand Oaks, CA: Amgen Inc.

Please see full Prescribing Information here.

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