Help your patients with tips and information

Patients may have questions about what to expect on Otezla® (apremilast). It may help to discuss the following before they begin treatment:

- Explain that the first 5 days are called the “titration” period, which means patients will gradually increase their dose over 5 days until they reach the recommended dose of 30 mg BID.
- The titration is intended to reduce gastrointestinal side effects associated with initial therapy.
- The most common side effects while taking Otezla are diarrhea, nausea, and headache; and were generally reported as mild or moderate in severity.
- Diarrhea, nausea, and headache occurred within the first 2 weeks after starting Otezla and tended to resolve over time with continued dosing.
- 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.
- After the titration period, remind your patients to:
  - Take one 30-mg pill in the morning and one 30-mg pill at night.
  - Keep the Otezla bottle where they can see it so that they remember to take it every day.
  - Connect their taking their medication to something they do each day, such as brushing their teeth.

If patients have any questions, specially trained nurses are available 24/7 to assist them at 1-844-4OTEZLA (1-844-468-3952).

INDICATIONS

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

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.

# 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.

# IMPORTANT SAFETY INFORMATION

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.

- 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% (1/1108) of patients treated with Otezla, compared to none in placebo-treated patients. 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) with placebo. Suicidal ideation and behavior was observed in 0.2% (3/1444) of patients on Otezla, compared to none in placebo treated patients. Depression was reported as serious in 0.0% (0/1444) 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.

- Weight Decrease: Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla.