

## Otezla® (apremilast) - New warning

- On June 29, 2017, the FDA approved an update to the *Warnings and Precautions* section of the Otezla (apremilast) drug label regarding the risk of diarrhea, nausea and vomiting.
- Otezla is approved to treat adult patients with active psoriatic arthritis, and patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- There have been postmarketing reports of severe diarrhea, nausea, and vomiting 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.
  - Patients who are more susceptible to complications of diarrhea or vomiting should be monitored.
  - Patients who reduced dosage or discontinued Otezla generally improved quickly.
  - If patients develop severe diarrhea, nausea, or vomiting, then consider Otezla dose reduction or suspension.



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