NEW

Monitor & Optimize

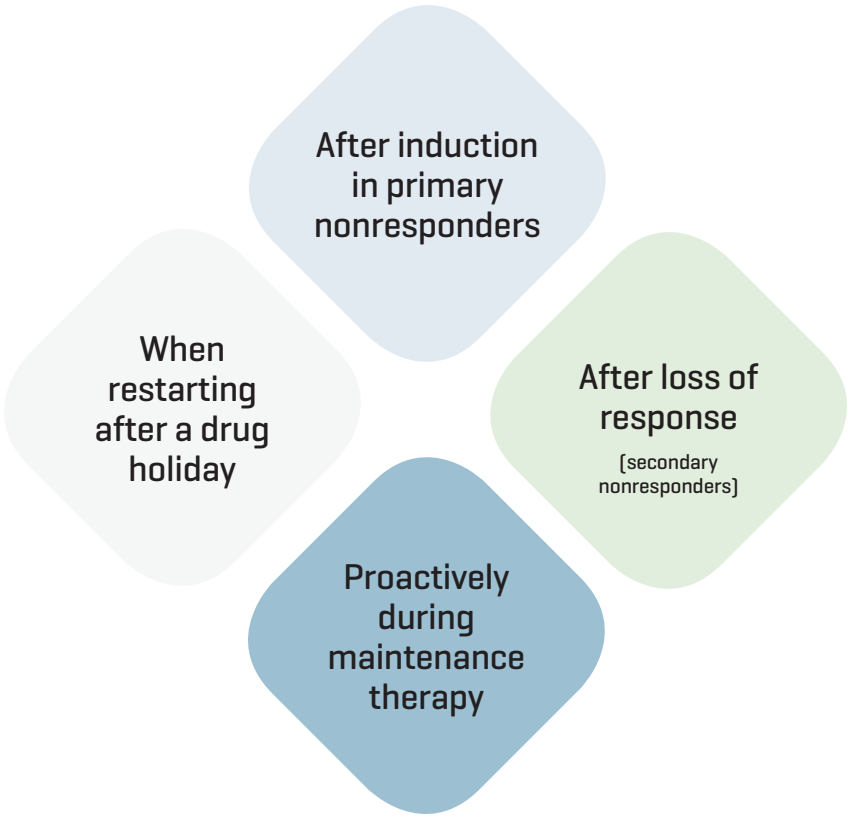
PROMETHEUS®
Anser® VDZ

Monitoring provides valuable information that may help you optimize inflammatory bowel disease clinical response to vedolizumab (VDZ)

- Quantifies if patients have sufficient VDZ concentrations and/or have developed antibodies to vedolizumab (ATV), helping you maximize duration of VDZ therapy
- Drug-tolerant assay overcomes limitations of assays that cannot measure both serum drug and antidrug antibody levels in the presence of VDZ
  - No reported interference[1]

Uniquely provides both serum VDZ and ATV levels any time during treatment

Using the RAND/UCLA Appropriateness Method, an expert panel recommended testing for drug and antibody concentrations in the following scenarios[2]:



The incidence and impact of ATV on clinical response is unknown

- Immunogenicity could not be reliably assessed in early VDZ clinical trials due to drug interference with the ELISA assay[3,4]
- The FDA mandated reanalyzing serum VDZ samples and ATV reporting by March 2017[5]
  - Current ATV rate during treatment phase of UC and CD clinical trials (4%) may be underestimated[3,6]

NEW

Critical data that may help you:

Optimize Dosing

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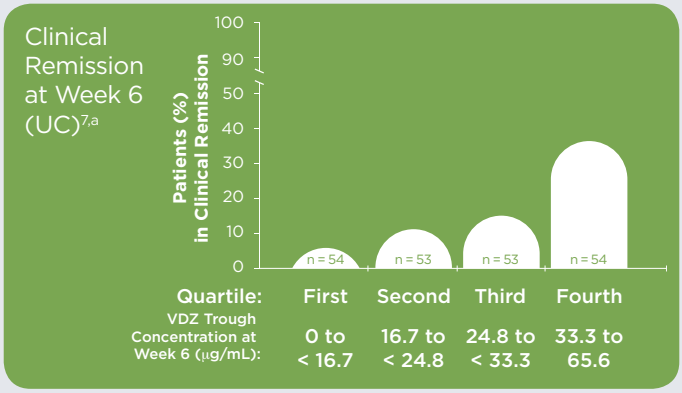
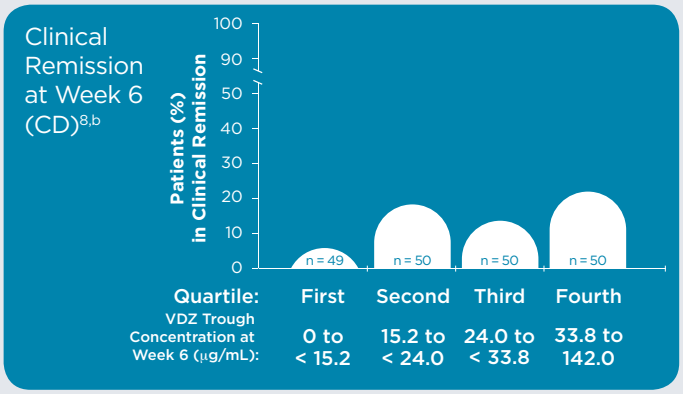
Observed clinical associations between vedolizumab trough level and response during induction from the GEMINI I and II pivotal trials[7,8,*,†]





While there is no well-defined VDZ trough level predictive of positive clinical outcomes, observations from several studies include:

- Higher week 6 VDZ levels were associated with mucosal healing at week 6[9,‡]
- Week 6 VDZ levels were significantly higher in patients in clinical remission at ≥ 28 weeks vs treatment-failure patients ($P < 0.05$)[10,§]
- Higher VDZ trough levels at week 6 correlated with clinical remission at week 14[11,**]
- VDZ levels were significantly higher in patients with clinical response at week 14 vs nonresponders ($P = 0.02$) and higher in steroid-free patients vs steroid-dependent patients[12,††]

[a]Clinical remission defined as a Mayo score of 2 or lower and no subscore > 1.

[b]Clinical remission defined as Crohn's Disease Activity Index of ≤ 150.

*Supplemental data from GEMINI I randomized, double-blind, placebo-controlled trials of VDZ induction and maintenance therapy in patients with active UC where serum VDZ levels were reported based off ELISA.[3]

†Supplemental data from GEMINI II randomized, double-blind, placebo-controlled trials of VDZ induction and maintenance therapy in CD patients where serum VDZ levels were reported based off ELISA.[3]

‡Post hoc analysis of GEMINI I study of UC patients where VDZ levels were reported based off unnamed assay.[9]

§Prospective observational study of 34 patients (65% CD) where VDZ levels were reported based off ELISA.[10]

**Post hoc analysis of GEMINI I study of UC patients where VDZ levels were reported based off ELISA.[11]

††Clinical practice study of 35 IBD patients (16 CD, 19 UC) where VDZ levels were reported based off PROMETHEUS® Anser® VDZ.[12]

References: 1. Salbato J, Westin, S, Reddy R, et al. Validation of a homogenous mobility shift assay (HMSA) for the measurement of vedolizumab (VLM) and anti-VLM antibodies in inflammatory bowel disease (IBD) patient serum. Poster presented at: Digestive Disease Week: May 16-19, 2015; Washington, DC. **2.** Melmed GY, Irving PM, Jones J, et al. Appropriateness of testing for anti-tumor necrosis factor agent and antibody concentrations, and interpretation of results. *Clin Gastroenterol Hepatol.* 2016;14(9):1302-1309. **3.** Bryant RV, Sandborn WJ, Travis SP. Introducing vedolizumab to clinical practice: who, when, and how? *J Crohns Colitis.* 2015;9(4):356-366. **4.** Raine T. Vedolizumab for inflammatory bowel disease: changing the game, or more of the same? *United European Gastroenterol J.* 2014;2(5):333-344. **5.** Approval package for application number 125476Orig1s000. Food and Drug Administration, Center for Drug Evaluation and Research. Reference 3509973. http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/125476Orig1s000ltr.pdf. Accessed July 21, 2016. **6.** ENTYVIO [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; 2014. **7.** Feagan BG, Rutgeerts P, Sands BE, et al; GEMINI 1 Study Group. Vedolizumab as induction and maintenance therapy for ulcerative colitis. *N Engl J Med.* 2013;369(8): 699-710. **8.** Sandborn WJ, Feagan BG, Rutgeerts P, et al; GEMINI 2 Study Group. Vedolizumab as induction and maintenance therapy for Crohn's disease. *N Engl J Med.* 2013;369(8):711-721. **9.** Rosario M, Abhyankar B, Sankoh S, Dirks N, Lasch K, Sandborn W. Relationship between vedolizumab pharmacokinetics and endoscopic outcomes in patients with ulcerative colitis. *J Crohn's Colitis.* 2015;9(suppl 1):DOP040. **10.** Paul S, Williet N, Claudez P, et al. Serum vedolizumab assay at week 6 predicts sustained clinical remission and lack of recourse to optimisation in IBD. [DDW abstract Sa1939]. *Gastroenterology.* 2016;150(suppl 1):S410. **11.** Osterman M, Roblin X, Glover S, et al. Association of vedolizumab drug concentrations at or before week 6 with remission at week 14 in moderately to severely active ulcerative colitis patients from GEMINI 1. [DDW abstract 512]. *Gastroenterology.* 2016;150(suppl 1):S105. **12.** Boland BS, Dulai P, Jain A, et al. Association of vedolizumab concentrations using PROMETHEUS® Anser® VDZ mobility shift assay and clinical response in IBD patients in standard clinical practice. Poster presented at: American College of Gastroenterology Scientific Meeting; October 14-19, 2016; Las Vegas, NV. (P375)

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