# (http://blog.pharmacist.com)

Home > Lower-volume bowel cleansing prep for colonoscopies receives FDA approval

#### **Generic Name:**

Polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and potassium chloride for oral solution

### **Trade Name:**

Plenvu

# Company:

Valeant/Salix

Notes:

<u>Salix Pharmaceuticals announced</u> FDA approval of polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride, and potassium chloride for oral solution, a lower-volume (1L) polyethylene glycol based (PEG) bowel preparation, under the trade name Plenyu.

Plenvu is the lowest, total-volume preparation bowel cleanser available in the United States, according to Salix.

Approval was based on multiple Phase III clinical trials, including the NOCT study, which compared Plenvu versus a trisulfate bowel cleansing solution (Suprep) using a two-day split-dosing regimen in adults. Both primary endpoints were met, achieving noninferior overall bowel cleansing success and "excellent plus good" cleansing of the ascending colon.

Plenvu is also the only FDA-approved bowel cleanser to offer split dosing on the same day as the colonoscopy procedure.

# **Medication Monitor Categories:**

Supplemental Approvals

**Source URL:** <a href="http://blog.pharmacist.com/supplemental-approvals/lower-volume-bowel-cleansing-prep-colonoscopies-receives-fda-approval">http://blog.pharmacist.com/supplemental-approvals/lower-volume-bowel-cleansing-prep-colonoscopies-receives-fda-approval</a>