

Supplemental Approvals

Generic Name (Trade Name—Company)

May 14, 2018

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

(Plenvu—Valeant/Salix)

Lower-volume bowel cleansing prep for colonoscopies receives FDA approval

Uses/Notes

[Salix Pharmaceuticals announced](#) 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 Plenvu.

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.

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<http://www.aphanet.org/supplemental-approvals/lower-volume-bowel-cleansing-prep-colonoscopies-receives-fda-approval>

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