

Wilate (von Willebrand factor/coagulation factor VIII complex [human]) – Expanded indication

- On December 1, 2023, the [FDA approved](#) Octapharma’s [Wilate \(von Willebrand factor/coagulation factor VIII complex \[human\]\)](#), in children and adults with von Willebrand disease for routine prophylaxis to reduce the frequency of bleeding episodes.
 - Wilate was previously approved in children and adults with von Willebrand disease for on-demand treatment and control of bleeding episodes and perioperative management of bleeding.
- Wilate is also approved in adolescents and adults with hemophilia A for routine prophylaxis to reduce the frequency of bleeding episodes and on-demand treatment and control of bleeding episodes.
- The approval of Wilate for the expanded indication was based on a prospective, non-controlled study in 33 evaluable patients with von Willebrand disease. The total annualized bleeding rates (ABRs) under prophylactic treatment in this study was compared to the ABRs recorded for the same patients during a previous, non-interventional, on-demand treatment study. ABRs for all bleeding episodes, treated and untreated, for the on-demand treatment and the prophylaxis treatment are summarized in the table below.
 - There were 10 (30.3%) patients with 0 bleeding episodes and 15 (45.5%) patients with 0 spontaneous bleeding episodes.

	On-demand treatment	Prophylaxis treatment	Ratio of ABRs (95% CI)
ABR (± SD) per patient for all types of bleeds (excluding menstrual bleeds)	33.38 ± 23.61 (median 24, range 11-114.5)	5.24 ± 7.75 (median 2, range 0-35.8)	0.16 (0.1; 0.27)
ABR (± SD) per subject – spontaneous bleeds	24.42 ± 20.05 (median 19, range 4.9-92.8)	3.23 ± 5.92 (median 1, range 0-24.6)	0.14 (0.08; 0.25)
ABR (± SD) per subject – joint bleeds	7.56 ± 11.51 (median 3.43, range 0-39.1)	0.53 ± 1.48 (median 0, range 0-6.9)	0.08 (0.03; 0.18)

- The recommended dose of Wilate for routine prophylaxis treatment of von Willebrand disease is 20 to 40 IU/kg, two or three times per week, via intravenous infusion.
 - Refer to the Wilate drug label for dosing for all its other uses.