Reyataz® (atazanavir) – Expanded Indication

- The FDA approved Bristol-Myers Squibb’s Reyataz (atazanavir) oral powder, a protease inhibitor, for use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection for patients ≥ 3 months of age weighing at least 5 kg.

  - Previously, Reyataz oral powder was only approved for the treatment of HIV-1 infection in patients ≥ 3 months of age weighing at least 10 kg.
  - Reyataz is also available as 150 mg, 200 mg, and 300 mg capsules.

- The expanded indication for Reyataz oral powder was based on data from 134 patients weighing 5 kg to < 35 kg treated in two multicenter clinical trials, PRINCE I and PRINCE II. In these studies, patients were given Reyataz oral powder plus ritonavir, in combination with two nucleoside reverse transcriptase inhibitors.

  - Based on a modified intention-to-treat analysis, the overall proportions of patients who achieved HIV RNA < 400 copies/mL at week 48 were 79% and 62%, among antiretroviral-naïve and antiretroviral-experienced patients, respectively.
  - The median increase from baseline in absolute CD4 count was 215 cells/mm³ (6%) in antiretroviral-naïve patients and 133 cells/mm³ (4%) in antiretroviral-experienced patients who received Reyataz with ritonavir.

- In pediatric patients ≥ 3 months of age and weighing 5 kg to < 15 kg, the recommended daily dose of Reyataz oral powder is 200 mg (4 packets). In pediatric patients 15 kg to < 25 kg, the daily dose of Reyataz oral powder is 250 mg (5 packets).

  - Reyataz oral powder must be mixed with food (applesauce or yogurt), milk, liquid infant formula, or water for administration, and ritonavir must be given immediately afterwards.

- In pediatric patients weighing less than 15 kg, Reyataz capsules are not recommended. The dose of Reyataz capsules in patients 6 to < 18 years of age is based on body weight, not to exceed the adult dose.

- In adults, the recommended oral daily dose of Reyataz is 300 mg with ritonavir 100 mg. In treatment-naïve adults who are unable to tolerate ritonavir, the recommended dose of Reyataz is 400 mg once daily.