

The Reyataz (atazanavir) Capsule label was updated to include the dosing recommendations for pediatric patients 6 to 18 years of age.

REYATAZ should not be administered to pediatric patients below the age of 3 months due to the risk of kernicterus

Section 2.2 Recommended Pediatric Dosage was added to the label.

The recommended dosage of REYATAZ for pediatric patients (6 to less than 18 years of age) is based on body weight and should not exceed the recommended adult dosage. REYATAZ Capsules must be taken with food. The data are insufficient to recommend dosing of REYATAZ for any of the following: (1) patients less than 6 years of age, (2) without ritonavir in patients less than 13 years of age, and (3) treatment-experienced pediatric patients with body weight less than 25 kg.

Therapy-Naive Pediatric Patients

The recommended dosage of REYATAZ with ritonavir in treatment-naive patients at least 6 years of age is shown in Table 1.

For treatment-naive patients at least 13 years of age and at least 39 kg, who are unable to tolerate ritonavir, the recommended dose is REYATAZ 400 mg (without ritonavir) once daily with food.

Table 1: Dosage for Treatment-Naive Pediatric Patients (6 to less than 18 years of age) for REYATAZ Capsules with ritonavir

Body Weight		REYATAZ dose ^{a,b}	ritonavir dose ^b
(kg)	(lbs)	(mg)	(mg)
15 to less than 25	33 to less than 55	150	80 ^c
25 to less than 32	55 to less than 70	200	100 ^d
32 to less than 39	70 to less than 86	250	100 ^d
at least 39	at least 86	300	100 ^d

^a The recommended dosage of REYATAZ can be achieved using a combination of commercially available capsule strengths.

^b The dosage of REYATAZ and ritonavir was calculated as follows:

- 15 kg to less than 20 kg: REYATAZ 8.5 mg/kg with ritonavir 4 mg/kg once daily with food.
- at least 20 kg: REYATAZ 7 mg/kg with ritonavir 4 mg/kg once daily with food not to exceed REYATAZ 300 mg and ritonavir 100 mg.

^c Ritonavir liquid.

^d Ritonavir capsule or liquid.

Therapy-Experienced Pediatric Patients

The recommended dosage of REYATAZ with ritonavir in treatment-experienced patients at least 6 years of age is shown in Table 2.

Table 2: Dosage for Treatment-Experienced Pediatric Patients (6 to less than 18 years of age) for REYATAZ Capsules with ritonavir

Body Weight		REYATAZ dose ^{a,b}	ritonavir dose ^b
(kg)	(lbs)	(mg)	(mg)
25 to less than 32	55 to less than 70	200	100 ^c
32 to less than 39	70 to less than 86	250	100 ^c
at least 39	at least 86	300	100 ^c

^a The recommended dosage of REYATAZ can be achieved using a combination of commercially available capsule strengths.

^b The dosage was calculated as REYATAZ 7 mg/kg with ritonavir 4 mg/kg once daily with food not to exceed REYATAZ 300 mg and ritonavir 100 mg.

^c Ritonavir capsule or liquid.

In section 6 Adverse Reactions subsection 6.2 Clinical Trial Experience in Pediatric Patients was added and includes the following information:

The safety profile of REYATAZ in pediatric patients (6 to less than 18 years of age) was comparable to that observed in clinical studies of REYATAZ in adults. The most common Grade 2–4 adverse events ($\geq 5\%$, regardless of causality) reported in pediatric patients were cough (21%), fever (19%), rash (14%), jaundice/scleral icterus (13%), diarrhea (8%), vomiting (8%), headache (7%), and rhinorrhea (6%). Asymptomatic second-degree atrioventricular block was reported in 2% of patients. The most common Grade 3–4 laboratory abnormality was elevation of total bilirubin (≥ 3.2 mg/dL) which occurred in 49% of pediatric patients. All other Grade 3–4 laboratory abnormalities occurred with a frequency of less than 3%.

In section 14 Clinical Studies, subsection 14.3 Pediatric Patients was added and includes the following:

Assessment of the pharmacokinetics, safety, tolerability, and efficacy of REYATAZ is based on data from the open-label, multicenter clinical trial PACTG 1020A conducted in

patients from 3 months to 21 years of age. In this study, 182 patients (83 antiretroviral-naive and 99 antiretroviral-experienced) received once daily REYATAZ, with or without ritonavir, in combination with two NRTIs.

Ninety-nine patients (6 to less than 18 years of age) treated with the REYATAZ capsule formulation, with or without ritonavir, were evaluated. In this cohort, the overall proportions of antiretroviral-naive and -experienced patients with HIV RNA <400 copies/mL at week 24 were 68% (28/41) and 33% (19/58), respectively. The overall proportions of antiretroviral-naive and -experienced patients with HIV RNA <50 copies/mL at week 24 were 59% (24/41) and 24% (14/58), respectively. The median increase from baseline in absolute CD4 count at 20 weeks of therapy was 171 cells/mm³ in antiretroviral-naive patients and 116 cells/mm³ in antiretroviral-experienced patients.