Atazanavir (ATV, Reyataz)

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Formulations

Powder Packet: 50 mg/packet

Capsules: 200 mg, 300 mg

Generic Formulations

- 150-mg, 200-mg, and 300-mg capsules

Fixed-Dose Combination Tablets

- [Evotaz] Atazanavir 300 mg/cobicistat 150 mg

Capsules and powder packets are not interchangeable.

For additional information, see Drugs@FDA: FDA-Approved Drugs or DailyMed.

Dosing Recommendations

Neonate Dose

- Atazanavir (ATV) is not approved for use in neonates and infants aged <3 months. ATV **should not be administered** to neonates because of risks associated with hyperbilirubinemia (e.g., bilirubin-induced neurologic dysfunction).

Infant and Child Dose

Powder Formulation of ATV[a]

- The powder formulation of ATV must be administered with ritonavir (RTV).
- The powder formulation is not approved for use in infants aged <3 months or weighing <5 kg.

ATV Powder Dosing Table for Infants and Children Aged ≥3 Months and Weighing ≥15 kg[a]

Weight	Once-Daily Dose
15 kg to <25 kg[b]	ATV 250 mg (five packets) plus RTV 100 mg (powder or tablet) with food

Capsule Formulation of ATV[a]

- ATV capsules are not approved for use in children aged <6 years or weighing <15 kg.

Selected Adverse Events

- Indirect hyperbilirubinemia
- Prolonged electrocardiogram PR interval, first-degree symptomatic atrioventricular block in some patients
- Nephrolithiasis
- Increased serum transaminases
- Hyperlipidemia (occurs primarily with RTV boosting)

Special Instructions

- Administer ATV with food to enhance absorption.
- Capsules and powder packets **are not interchangeable.**
- Do not open capsules.
- Because ATV can prolong the PR interval of the electrocardiogram, use ATV with caution in patients with preexisting cardiac conduction system disease or with other drugs that are known to prolong the PR interval (e.g., calcium channel blockers, beta-blockers, digoxin, verapamil).

Atazanavir/Ritonavir (ATV/r) Capsule Dosing Table for Children and Adolescents Aged ≥6 Years and Weighing ≥15 kg

Weight	Once-Daily Dose
<15 kg	Capsules not recommended
15 kg to <35 kg	ATV/r 200 mg/100 mg, both with food
≥35 kg	ATV/r 300 mg/100 mg, both with food

ART-Naive Patients Who Are Unable to Tolerate RTV

Child and Adolescent (Aged ≥13 Years and Weighing ≥40 kg) and Adult Dose

- ATV 400 mg (capsule formulation only) once daily with food
- ATV powder is not an option because it must be administered with RTV.
- For the capsule formulation, the U.S. Food and Drug Administration (FDA) and the Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV (the Panel) **do not recommend** the use of unboosted ATV in children aged <13 years.
- Although the FDA does allow for unboosted ATV in adolescents aged ≥13 years and weighing ≥40 kg if they are not concurrently taking tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF), the Panel **does not recommend** the use of unboosted ATV in this population. Unboosted ATV **is not recommended** because adolescents may require doses of ATV that are higher than those recommended for use in adults to achieve target drug concentrations (see Pediatric Use below).

ART-Naive and ART-Experienced Patients

Child and Adolescent (Weighing ≥35 kg) and Adult Dose

- ATV/r 300 mg/100 mg once daily with food[c]
- Atazanavir/cobicistat (ATV/c) 300 mg/150 mg once daily with food, administered as single agents simultaneously or as the coformulated drug Evotaz[d]
- Both ATV/r and ATV/c must be used in combination with other antiretroviral drugs.

[Evotaz] ATV/c

Child and Adolescent (Weighing ≥35 kg) and Adult Dose

- One tablet once daily with food
- ATV absorption is dependent on low gastric pH; therefore, when ATV is administered with medications that increase gastric pH, dosing adjustments may be indicated (see the Drug Interactions section in the ATV package insert).
- The plasma concentration and, therefore, the therapeutic effect of ATV can be expected to decrease substantially when ATV is coadministered with proton-pump inhibitors (PPIs). Antiretroviral therapy (ART)–naive patients who are receiving any PPI should receive a dose of that PPI that is equivalent to no more than a 20-mg dose of omeprazole. PPIs should be taken approximately 12 hours before taking boosted ATV. Coadministration of ATV with PPIs **is not recommended** in ART-experienced patients.
- Patients with hepatitis B or C virus infections and patients who have marked elevations in transaminase levels before treatment may have an increased risk of further elevations in transaminase levels or hepatic decompensation.

Powder Administration

- ATV oral powder contains phenylalanine, which can be harmful to patients with phenylketonuria. Each packet of oral powder contains 35 mg of phenylalanine.
- Mix ATV oral powder with at least 1 tablespoon of soft food (e.g., applesauce, yogurt). Oral powder mixed with a beverage (at least 30 mL of milk or water) may be used for older infants who can drink from a cup. For young infants (aged <6 months) who cannot eat solid food or drink from a cup, oral powder should be mixed with at least 10 mL of infant formula and administered using an oral dosing syringe.
- Administer RTV immediately following powder administration.
- Administer the entire dose of oral powder within 1 hour of preparation.

Metabolism/Elimination

- ATV is a substrate and inhibitor of cytochrome P450 (CYP) 3A4 and an inhibitor of CYP1A2, CYP2C9, and uridine diphosphate glucuronosyl transferase 1A1.

ATV Dosing in Patients With Hepatic Impairment

- ATV should be used with caution in patients with mild or moderate hepatic impairment. Consult the manufacturer's prescribing information for the dose adjustment in patients with moderate impairment.

	• ATV is **not recommended** in patients with severe hepatic impairment. • ATV/r is **not recommended** in people with any degree of hepatic impairment. **ATV Dosing in Patients With Renal Impairment** • No dose adjustment is required for patients with renal impairment. • ATV should not be given to ART-experienced patients with end-stage renal disease who are on hemodialysis.

[a] mg/kg dosing is higher for the ATV powder packets than for the capsules. In P1020A, children of similar age and size who were taking ATV powder had lower exposures than those who were taking ATV capsules.

[b] Children weighing ≥25 kg who cannot swallow ATV capsules may receive ATV 300-mg oral powder (six packets) plus RTV 100-mg oral solution, both administered once daily with food.

[c] Adult patients who cannot swallow capsules may take ATV oral powder once daily with food using the adult dose for the capsules. ATV oral powder should be administered with RTV.

[d] See the Cobicistat section for important information about toxicity, drug interactions, and monitoring of patients who receive cobicistat (COBI) and the combination of COBI and TDF.

Drug Interactions

Additional information about drug interactions is available in the Adult and Adolescent Antiretroviral Guidelines and the HIV Drug Interaction Checker.

- *Metabolism:* Atazanavir (ATV) is both a substrate and an inhibitor of the cytochrome P450 (CYP) 3A4 enzyme system and has significant interactions with drugs that are highly dependent on CYP3A4 for metabolism. ATV also competitively inhibits CYP1A2 and CYP2C9. ATV is a weak inhibitor of CYP2C8. ATV inhibits the glucuronidation enzyme uridine diphosphate glucuronosyl transferase (UGT1A1). Because of the potential for multiple drug interactions with ATV, a patient's medication profile should be carefully reviewed for potential drug interactions before administering ATV.
- *Nucleoside reverse transcriptase inhibitors (NRTIs):* Tenofovir disoproxil fumarate (TDF) decreases ATV plasma concentrations, and the effect of tenofovir alafenamide (TAF) on unboosted ATV is unknown. Thus, only atazanavir/ritonavir (ATV/r) or atazanavir/cobicistat (ATV/c) should be used in combination with TDF or TAF.
- *Non-nucleoside reverse transcriptase inhibitors:* Efavirenz (EFV), etravirine (ETR), and nevirapine (NVP) decrease ATV plasma concentrations significantly. NVP and ETR **should not be administered** to patients who are receiving ATV (with or without a booster). Although the combination of EFV and ATV/r is not commonly used in clinical practice, EFV 600 mg once daily may be used in combination with ritonavir (RTV)-boosted ATV 400 mg once daily in antiretroviral therapy (ART)–naive patients. ATV/r should be taken with food, and EFV should be taken on an empty stomach, preferably at bedtime. Coadministering ATV/r and EFV in ART-experienced patients **is not recommended** because this combination is expected to result in suboptimal ATV exposure in these patients.
- *Integrase strand transfer inhibitors:* ATV is an inhibitor of UGT1A1 and may increase plasma concentrations of raltegravir (RAL). This interaction may not be clinically significant.
- *Absorption:* ATV absorption is dependent on low gastric pH. The dose for ATV should be adjusted when it is administered with medications that increase gastric pH. Guidelines for the appropriate doses of ATV to use with antacids, H2 receptor antagonists, and proton-pump

inhibitors in adults are complex and can be found in the package insert for ATV. No information is available on the appropriate doses of ATV to use in children when the drug is coadministered with medications that increase gastric pH.

- Coadministering cobicistat (COBI)—a CYP3A4 inhibitor—and medications that are metabolized by CYP3A4 may increase the plasma concentrations of these medications. This may increase the risk of clinically significant adverse reactions (including life-threatening or fatal reactions) that are associated with the concomitant medications. Coadministration of COBI, ATV, and CYP3A4 inducers may lead to lower exposures of COBI and ATV, a loss of efficacy of ATV, and possible development of resistance.[1,2] Coadministering COBI and ATV with some antiretroviral (ARV) agents (i.e., with ETR, with EFV in ART-experienced patients, or with another ARV drug that requires pharmacokinetic [PK] enhancement, such as another protease inhibitor [PI] or elvitegravir) may result in decreased plasma concentrations of that agent, leading to loss of therapeutic effect and the development of resistance.

Major Toxicities

- *More common:* Indirect hyperbilirubinemia that can result in jaundice or icterus but is not a marker of hepatic toxicity. Headache, fever, arthralgia, depression, insomnia, dizziness, nausea, vomiting, diarrhea, and paresthesia.
- *Less common:* Prolongation of the electrocardiogram PR interval. Abnormalities in atrioventricular (AV) conduction are generally limited to first-degree AV block, but second-degree AV block has been reported. Rash is generally mild or moderate, but in rare cases includes life-threatening Stevens-Johnson syndrome. Fat maldistribution and lipid abnormalities may be less common than with other PIs. The use of ATV/r is associated with lipid abnormalities, but to a lesser extent than with other boosted PIs.
- *Rare:* New-onset diabetes mellitus, hyperglycemia, ketoacidosis, exacerbation of preexisting diabetes mellitus, spontaneous bleeding in hemophiliacs, and elevation in serum transaminases. Chronic kidney disease, including biopsy-proven cases of granulomatous interstitial nephritis that were associated with the deposition of ATV drug crystals in the renal parenchyma, has occurred. Nephrolithiasis and cholelithiasis have been reported. Hepatotoxicity (patients with hepatitis B virus or hepatitis C virus infections are at increased risk of hepatotoxicity).

Resistance

The International Antiviral Society–USA maintains a list of updated resistance mutations, and the Stanford University HIV Drug Resistance Database offers a discussion of each mutation.

Pediatric Use

Approval

ATV is approved by the U.S. Food and Drug Administration (FDA) for use in infants (aged ≥3 months and weighing ≥5 kg), children, and adolescents. Because RTV oral solution is no longer commercially available, use of ATV/r is limited to children weighing ≥15 kg who can use the RTV 100-mg powder packet or 100-mg tablet. ATV coformulated with COBI (as Evotaz) has been approved by the FDA for use in pediatric patients weighing ≥35 kg.

Efficacy

Studies in ART-naive adults have shown that ATV/r is as effective as EFV and lopinavir/ritonavir (LPV/r) when administered with two NRTIs.[3-6] In AIDS Clinical Trials

Group (ACTG) A5257, ATV/r was compared to darunavir/ritonavir (DRV/r) or RAL, each administered with a TDF/emtricitabine backbone. Although all three regimens had equal virologic efficacy, the regimen that contained ATV/r was discontinued more frequently than the other regimens because of toxicity, but most often because of hyperbilirubinemia or gastrointestinal complaints.[7]

International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT)/Pediatric AIDS Clinical Trials Group (PACTG) P1020 enrolled 195 ART-naive and ART-experienced patients with HIV aged 3 months to 21 years. Capsule and powder formulations of ATV given with and without RTV boosting were investigated in this open-label study; area under the curve (AUC) targeting was used to direct dose finding. Of the 195 patients enrolled, 142 patients received ATV-based treatment at the final recommended dose. Among these patients, 58% were ART-naive. At Week 48, 69.5% of the ART-naive patients and 43.3% of the ART-experienced patients had HIV viral loads ≤400 copies/mL.[8,9]

Two open-label clinical trials in infants and children, PRINCE-1 and PRINCE-2, studied a powder formulation of ATV that was administered once daily and boosted with liquid RTV.[10-12] In total, 134 infants and children aged ≥3 months and weighing between 5 and 35 kg were evaluated. Using a modified intent-to-treat analysis, 28 of 52 ARV-naive patients (54%) and 41 of 82 ART-experienced patients (50%) had HIV RNA <50 copies/mL at Week 48. The median increase from baseline in absolute CD4 T lymphocyte cell count at 48 weeks of therapy was 215 cells/mm^3 (a 6% increase) in ARV-naive patients and 133 cells/mm^3 (a 4% increase) in ARV-experienced patients.

Pharmacokinetics and Dosing

Oral Capsule

The IMPAACT/PACTG 1020A trial in children and adolescents indicated that ATV could only achieve protocol-defined PK targets in the absence of RTV boosting when used at higher doses (on a mg per kg body weight or mg per m^2 of body surface area basis) than the 400 mg dose per day that is currently recommended in adults. Median doses of ATV, both with and without RTV boosting, from IMPAACT/PACTG 1020A are outlined in Table A below.[9,13] In this study, the AUCs for the unboosted arms were similar to those seen in the ATV/r arms, but the maximum plasma concentration (C_{max}) was higher and the minimum plasma concentration (C_{min}) was lower in the unboosted arms. When administering unboosted ATV to pediatric patients, therapeutic drug monitoring is recommended to ensure that adequate ATV plasma concentrations have been achieved. A minimum target trough concentration for ATV is 150 ng/mL,[14] but higher target trough concentrations may be required in PI-experienced patients. IMPAACT P1058, a study of unboosted ATV PK in ART-experienced children, concluded that once-daily ATV 400 mg provided suboptimal exposure and that administering higher, unboosted doses or splitting the daily dose into twice-daily doses warranted investigation in ART-experienced children, adolescents, and young adults.[15]

In contrast to unboosted ATV, PK criteria were satisfied at a dose of at least 205 mg per m^2 of body surface area in pediatric subjects when ATV was administered with RTV.[13] A model-based approach that used ATV concentration–time data from three adult studies and one pediatric study (P1020A),[16] along with refined PK modeling,[17] informed the current FDA-approved product label for children aged ≥6 years to <18 years and weighing ≥15 kg.

Table A. Summary of Atazanavir Dosing Information Obtained From IMPAACT/PACTG 1020A

Age Range	ATV Given With RTV	ATV Median Dose (mg/m^2)[a]	ATV Median Dose (mg)
6–13 years	No	509	475
6–13 years	Yes	206	200
>13 years	No	620	900
>13 years	Yes	195	350

[a] These doses satisfied protocol-defined area under the curve/pharmacokinetic parameters and met all acceptable safety targets. These doses differ from those recommended by the manufacturer. Therapeutic drug monitoring was used to determine patient-specific dosing in this trial.

Source: Kiser JJ, Rutstein RM, Samson P, et al. Atazanavir and atazanavir/ritonavir pharmacokinetics in HIV-infected infants, children, and adolescents. *AIDS*. 2011;25(12):1489-96.

Key: ATV = atazanavir; RTV = ritonavir

Cobicistat as a Pharmacokinetic Enhancer

COBI (as Tybost) is approved by the FDA at the 150-mg dose for use with ATV 300 mg in children and adolescents weighing ≥35 kg. A study of 14 adolescents, aged 12 to 18 years, showed that COBI is a safe and effective PK enhancer when used in combination with ATV and two NRTIs in adolescent patients.[18] PK findings from this study are summarized in Table B below.

Table B. Pharmacokinetic Parameters for Atazanavir Administered With Cobicistat (as Tybost) in Pediatric Patients Aged 12 to 18 Years and Adults

PK Parameters[a]	ATV		COBI	
	Pediatric Patients (n = 12)	Adult Patients (n = 30)	Pediatric Patients (n = 12)	Adult Patients (n = 30)
AUC_{tau} µg·h/mL Geometric mean (CV%)	49.48 (49.1)	39.96 (52.1)	12.11 (44.7)	9.65 (41.8)
C_{max} µg/mL Geometric mean (CV%)	4.32 (49.9)	3.54 (45.8)	1.28 (31.7)	1.28 (35.6)
C_{tau} µg/mL Geometric mean (CV%)	0.91 (96.4)	0.58 (84.7)	0.09 (156.2)	0.04 (112.7)

[a] The information in this table comes from the Tybost package insert.[1]

Key: ATV = atazanavir; AUC_{tau} = area under the concentration-time curve over the dosing interval; C_{max} = maximum serum concentration; C_{tau} = trough serum concentration at the end of the dosing interval; COBI = cobicistat; CV = coefficient of variation; PK = pharmacokinetic

Oral Powder

The unboosted ATV powder arms in IMPAACT/PACTG P1020A were closed because participants were unable to achieve protocol-defined AUC target exposures of 30,000 to 90,000 ng·hr/mL based on exposures in adults on unboosted ATV. Children aged 3 months to 2 years who were in the boosted ATV powder cohorts and received a daily dose of ATV 310 mg per m^2 of body surface area achieved average ATV exposures that approached, but did not meet, protocol targets. Variability in exposures was high, especially among the very young children of 3 months to 2 years in this study.[9]

Two separate open-label, multicenter clinical trials assessed the PK, safety, tolerability, and virologic response of ATV oral powder for FDA approval. These included PRINCE-1, which enrolled pediatric patients aged 3 months to <6 years,[10] and PRINCE-2, which enrolled pediatric patients aged 3 months to <11 years.[1] All patients in the PRINCE trials were treated with boosted ATV oral powder and two NRTIs. RTV was administered as an oral solution in PRINCE-1 and as either an oral solution, capsule, or tablet in PRINCE-2.

In total, 134 treated patients (weighing 5 to <35 kg) from both studies were evaluated during the FDA approval process. Table C lists the recommended doses for each weight band and the PK parameters that were measured during the PRINCE trials, including mean AUC. In these PK studies, although the PK targets were met in all patients using ATV powder except those in the 5 kg to <10 kg weight band, the coefficients of variation were large, especially among the youngest patients.

Table C. Pharmacokinetic Parameters for Atazanavir Powder in Children (PRINCE-1 and PRINCE-2) Versus Capsules in Young Adults and Adults

PK Parameters	PRINCE Trial[a] ATV/r					Young Adult Study[b]	Adult Study
	Dose: 150 mg/ 80 mg Weighing: 5 kg to <10 kg	Dose: 200 mg/ 80 mg Weighing: 5 kg to <10 kg	Dose: 200 mg/ 80 mg Weighing: 10 kg to <15 kg	Dose: 250 mg/ 80 mg Weighing: 15 kg to <25 kg	Dose: 300 mg/ 100 mg Weighing: ≥25 kg to <35 kg		
AUC ng·h/mL Mean[c] (CV% or 95% CI)	32,503 (61) n = 20	39,519 (54) n = 10	50,305 (67) n = 18	55,687 (45) n = 31	44,329 (63) n = 8	35,971 (30,853–41,898) n = 22	46,073 (66) n = 10
C_{24h} ng/mL Mean[c] (CV% or 95% CI)	336 (76) n = 20	550 (60) n = 10	572 (111) n = 18	686 (68) n = 31	468 (104) n = 8	578 (474–704) n = 22	636 (97) n = 10

[a] This information comes from the Reyataz package insert.[11]

[b] The young adults were also receiving tenofovir disoproxil fumarate.[8]

[c] Means are geometric means.

Note: RTV oral solution is no longer available. Use of ATV/r is now limited to children weighing ≥15 mg who can receive 100 mg RTV using powder or tablets.

Key: ATV/r = atazanavir/ritonavir; AUC = area under the curve; CI = confidence interval; CV = coefficient of variation; PK = pharmacokinetic

Transitioning From Powder to Capsules

For children who reach a weight of ≥25 kg and require the powder formulation, ATV 300-mg powder (six packets) plus RTV 100-mg powder, both administered once daily with food, may be used. ATV capsules and RTV tablets should be used for children who can swallow pills. Bioavailability is higher for the capsules than for the powder; therefore, a lower mg/kg dose is recommended when using capsules. Opened capsules have not been studied and should not be used.

Toxicity

In the IMPAACT/PACTG 1020A trial, 9% of patients enrolled had a total bilirubin ≥5.1 times the upper limit of normal,[13] whereas 9% of patients enrolled in the PRINCE studies had a total bilirubin ≥2.6 times the upper limit of normal.[10,12] The most common laboratory abnormality during the PRINCE trials was elevated amylase levels, which occurred in 33% of patients.[11] Three children (2%) had treatment-related cardiac disorders during the PRINCE trials; one child discontinued therapy because of QT corrected for heart rate (QTc) prolongation, and two experienced first-degree AV block.[10,12] In IMPAACT/PACTG P1020A, three children (3%) had QTc prolongations >470 msec; two of these children came off the study, and all were asymptomatic.

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