HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use REYATAZ safely and effectively. See full prescribing information for REYATAZ.

REYATAZ® (atazanavir) capsules, for oral use

REYATAZ® (atazanavir) oral powder

Initial U.S. Approval: 2003

----------RECENT MAJOR CHANGES----------

Dosage and Administration,	
Testing Prior to Initiation and During Treatment with REYATAZ (2.2)	10/2017
Dosage of REYATAZ Capsules in Pediatric Patients (2.4)	5/2017
Dosage and Administration of REYATAZ Oral Powder in Pediatric Patients (2.5)	5/2017
Contraindications (4)	3/2018
Warnings and Precautions	
Chronic Kidney Disease (5.5)	10/2017

----------INDICATIONS AND USAGE----------

REYATAZ is a protease inhibitor indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 infection for patients 3 months and older weighing at least 5 kg. (1)

----------DOSAGE AND ADMINISTRATION----------

- *Pretreatment testing* Renal laboratory testing should be performed in all patients prior to initiation of REYATAZ and continued during treatment with REYATAZ. Hepatic testing should be performed in patients with underlying liver disease prior to initiation of REYATAZ and continued during treatment with REYATAZ. (2.2)
- *Treatment-naive adults* REYATAZ 300 mg with ritonavir 100 mg once daily with food or REYATAZ 400 mg once daily with food. (2.3)
- *Treatment-experienced adults* REYATAZ 300 mg with ritonavir 100 mg once daily with food. (2.3)
- *Pediatric patients* REYATAZ capsule dosage is based on body weight not to exceed the adult dose and must be taken with food. (2.4)
- *REYATAZ oral powder* Must be taken with ritonavir and food and should not be used in pediatric patients who weigh less than 5 kg. (2.5)
- *Pregnancy* REYATAZ 300 mg with ritonavir 100 mg once daily with food, with dosing modifications for some concomitant medications. (2.6)
- *Dosing modifications* may be required for concomitant therapy (2.3, 2.4, 2.5, 2.6), renal impairment (2.7), and hepatic impairment (2.8).

----------DOSAGE FORMS AND STRENGTHS----------

- Capsules: 150 mg, 200 mg, 300 mg. (3, 16)
- Oral powder: 50 mg packet. (3, 16)

----------CONTRAINDICATIONS----------

- REYATAZ is contraindicated in patients with previously demonstrated hypersensitivity (eg, Stevens-Johnson syndrome, erythema multiforme, or toxic skin eruptions) to any of the components of this product. (4)
- Coadministration with alfuzosin, triazolam, orally administered midazolam, ergot derivatives, rifampin, irinotecan, lurasidone (if REYATAZ is coadministered with ritonavir), lovastatin, simvastatin, indinavir, cisapride, pimozide, St. John's wort, nevirapine, elbasvir/grazoprevir, glecaprevir/pibrentasvir, and sildenafil when dosed as REVATIO®. (4)

----------WARNINGS AND PRECAUTIONS----------

- *Cardiac conduction abnormalities* PR interval prolongation may occur in some patients. ECG monitoring should be considered in patients with preexisting conduction system disease or when administered with other drugs that may prolong the PR interval. (5.1, 7.3, 12.2, 17)
- *Severe Skin Reactions* Discontinue if severe rash develops. (5.2, 17)
- *Hyperbilirubinemia* Most patients experience asymptomatic increases in indirect bilirubin, which is reversible upon discontinuation. Do not dose reduce. If a concomitant transaminase increase occurs, evaluate for alternative etiologies. (5.8)
- *Phenylketonuria* REYATAZ oral powder contains phenylalanine which can be harmful to patients with phenylketonuria. (5.3)
- *Hepatotoxicity* Patients with hepatitis B or C infection are at risk of increased transaminases or hepatic decompensation. Monitor hepatic laboratory tests prior to therapy and during treatment. (2.8, 5.4, 8.8)
- *Chronic kidney disease* has been reported during postmarketing surveillance in HIV-infected patients treated with atazanavir, with or without ritonavir. Consider alternatives in patients at high risk for renal disease or with preexisting renal disease. Monitor renal laboratory tests prior to therapy and during treatment. Consider discontinuation of REYATAZ in patients with progressive renal disease. (5.5)
- *Nephrolithiasis and cholelithiasis* have been reported. Consider temporary interruption or discontinuation. (5.6)
- The concomitant use of REYATAZ/ritonavir and certain other medications may result in known or potentially significant drug interactions. Consult the full prescribing information prior to and during treatment for potential drug interactions. (5.7, 7.3)
- Patients receiving REYATAZ may develop new onset or exacerbations of diabetes mellitus/hyperglycemia (5.9), immune reconstitution syndrome (5.10), and redistribution/accumulation of body fat (5.11).
- *Hemophilia* Spontaneous bleeding may occur and additional factor VIII may be required. (5.12)

----------ADVERSE REACTIONS----------

Most common adverse reactions (≥2%) are nausea, jaundice/scleral icterus, rash, headache, abdominal pain, vomiting, insomnia, peripheral neurologic symptoms, dizziness, myalgia, diarrhea, depression, and fever. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Bristol-Myers Squibb at 1-800-721-5072 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------

Coadministration of REYATAZ can alter the concentration of other drugs and other drugs may alter the concentration of atazanavir. The potential drug-drug interactions must be considered prior to and during therapy. (4, 7, 12.3)

----------USE IN SPECIFIC POPULATIONS----------

- *Pregnancy* Available human and animal data suggest that atazanavir does not increase the risk of major birth defects overall compared to the background rate. (8 1)
- *Lactation* Breastfeeding is not recommended. (8.2)
- *Hepatitis B or C co-infection* Monitor liver enzymes. (5.4, 6.1)
- *Renal impairment* REYATAZ is not recommended for use in treatment-experienced patients with end-stage renal disease managed with hemodialysis. (2.7, 8.7)
- *Hepatic impairment* REYATAZ is not recommended in patients with severe hepatic impairment. REYATAZ/ritonavir is not recommended in patients with any degree of hepatic impairment. (2.8, 8.8)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 3/2018