**FULL PRESCRIBING INFORMATION: CONTENTS***



*Sections or subsections omitted from the full prescribing information are not listed

.

## 6.2 Postmarketing Experience

The following events have been identified during postmarketing use of REYATAZ. Because these reactions are reported voluntarily from a population of unknown size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

*Body as a Whole:* edema

*Cardiovascular System:* second-degree AV block, third-degree AV block, left bundle branch block, QTc prolongation *[see Warnings and Precautions (5.1)]*

*Gastrointestinal System:* pancreatitis

*Hepatic System:* hepatic function abnormalities

*Hepatobiliary Disorders:* cholelithiasis *[see Warnings and Precautions (5.6)]*, cholecystitis, cholestasis

*Metabolic System and Nutrition Disorders:* diabetes mellitus, hyperglycemia *[see Warnings and Precautions (5.9)]*

*Musculoskeletal System:* arthralgia

*Renal System:* nephrolithiasis *[see Warnings and Precautions (5.6)]*, interstitial nephritis, granulomatous interstitial nephritis, chronic kidney disease *[see Warnings and Precautions (5.5)]*

*Skin and Appendages:* alopecia, maculopapular rash *[see Contraindications (4) and Warnings and Precautions (5.2)]*, pruritus, angioedema

# 7 DRUG INTERACTIONS

## 7.1 Potential for REYATAZ to Affect Other Drugs

Atazanavir is an inhibitor of CYP3A and UGT1A1. Coadministration of REYATAZ and drugs primarily metabolized by CYP3A or UGT1A1 may result in increased plasma concentrations of the other drug that could increase or prolong its therapeutic and adverse effects.

Atazanavir is a weak inhibitor of CYP2C8. Use of REYATAZ without ritonavir is not recommended when coadministered with drugs highly dependent on CYP2C8 with narrow therapeutic indices (eg, paclitaxel, repaglinide). When REYATAZ with ritonavir is coadministered with substrates of CYP2C8, clinically significant interactions are not expected *[see Clinical Pharmacology, Table 22 (12.3)]*.

The magnitude of CYP3A-mediated drug interactions on coadministered drug may change when REYATAZ is coadministered with ritonavir. See the complete prescribing information for ritonavir for information on drug interactions with ritonavir.

## 7.2 Potential for Other Drugs to Affect REYATAZ

Atazanavir is a CYP3A4 substrate; therefore, drugs that induce CYP3A4 may decrease atazanavir plasma concentrations and reduce REYATAZ's therapeutic effect.

Atazanavir solubility decreases as pH increases. Reduced plasma concentrations of atazanavir are expected if proton-pump inhibitors, antacids, buffered medications, or $H_2$-receptor antagonists are administered with REYATAZ *[see Dosage and Administration (2.3, 2.4, 2.5 and 2.6)]*.

## 7.3 Established and Other Potentially Significant Drug Interactions

Table 16 provides dosing recommendations in adults as a result of drug interactions with REYATAZ. These recommendations are based on either drug interaction studies or predicted interactions due to the expected magnitude of interaction and potential for serious events or loss of efficacy.

**Table 16: Established and Other Potentially Significant Drug Interactions: Alteration in Dose or Regimen May Be Recommended Based on Drug Interaction Studies[a] or Predicted Interactions (Information in the table applies to REYATAZ with or without ritonavir, unless otherwise indicated)**

| ***Concomitant Drug Class:*** **Specific Drugs** | **Effect on Concentration of Atazanavir or Concomitant Drug** | **Clinical Comment** |
|---|---|---|
| ***HIV Antiviral Agents*** | | |
| *Nucleoside Reverse Transcriptase Inhibitors (NRTIs):*<br>didanosine buffered formulations<br>enteric-coated (EC) capsules | ↓ atazanavir<br>↓ didanosine | Coadministration of REYATAZ with didanosine buffered tablets resulted in a marked decrease in atazanavir exposure. It is recommended that REYATAZ be given (with food) 2 h before or 1 h after didanosine buffered formulations. Simultaneous administration of didanosine EC and REYATAZ with food results in a decrease in didanosine exposure. Thus, REYATAZ and didanosine EC should be administered at different times. |
| *Nucleotide Reverse Transcriptase Inhibitors:* tenofovir disoproxil fumarate (DF) | ↓ atazanavir<br>↑ tenofovir | Tenofovir DF may decrease the AUC and $C_{min}$ of atazanavir. When coadministered with tenofovir DF in adults, it is recommended that REYATAZ 300 mg be given with ritonavir 100 mg and tenofovir DF 300 mg (all as a single daily dose with food). REYATAZ increases tenofovir concentrations. The mechanism of this interaction is unknown. Higher tenofovir concentrations could potentiate tenofovir-associated adverse reactions, including renal disorders. Patients receiving REYATAZ and tenofovir DF should be monitored for tenofovir-associated adverse reactions. For pregnant patients taking REYATAZ with ritonavir *and* tenofovir DF, see *Dosage and Administration (2.6)*. |
| *Non-nucleoside Reverse Transcriptase Inhibitors (NNRTIs):* efavirenz | ↓ atazanavir | Efavirenz decreases atazanavir exposure.<br>***In treatment-naive adult patients:***<br>If REYATAZ is combined with efavirenz, REYATAZ 400 mg (two 200-mg capsules) should be administered with ritonavir 100 mg simultaneously once daily with food, and efavirenz 600 mg should be administered once daily on an empty stomach, preferably at bedtime.<br>***In treatment-experienced adult patients:***<br>Coadministration of REYATAZ with efavirenz in treatment-experienced patients is not recommended due to decreased atazanavir exposure. |
| nevirapine | ↓ atazanavir<br>↑ nevirapine | Coadministration of REYATAZ with nevirapine is contraindicated. This is due to substantial decreases in atazanavir exposure, which may result in loss of therapeutic effect and development of resistance. Potential risk for nevirapine-associated adverse reactions due to increased nevirapine exposures *[see Contraindications (4)]*. |

**Table 16: Established and Other Potentially Significant Drug Interactions: Alteration in Dose or Regimen May Be Recommended Based on Drug Interaction Studies[a] or Predicted Interactions (Information in the table applies to REYATAZ with or without ritonavir, unless otherwise indicated)**

| ***Concomitant Drug Class:*** **Specific Drugs** | **Effect on Concentration of Atazanavir or Concomitant Drug** | **Clinical Comment** |
|---|---|---|
| *Protease Inhibitors:* saquinavir (soft gelatin capsules) | ↑ saquinavir | Appropriate dosing recommendations for this combination, with or without ritonavir, with respect to efficacy and safety have not been established. In a clinical study, saquinavir 1200 mg coadministered with REYATAZ 400 mg and tenofovir DF 300 mg (all given once daily), and nucleoside analogue reverse transcriptase inhibitors did not provide adequate efficacy *[see Clinical Studies (14.2)]*. |
| indinavir | | Coadministration of REYATAZ with indinavir is contraindicated. Both REYATAZ and indinavir are associated with indirect (unconjugated) hyperbilirubinemia *[see Contraindications (4)]*. |
| ritonavir | ↑ atazanavir | If REYATAZ is coadministered with ritonavir, it is recommended that REYATAZ 300 mg once daily be given with ritonavir 100 mg once daily with food in adults. See the complete prescribing information for ritonavir for information on drug interactions with ritonavir. |
| Others | ↑ other protease inhibitor | Although not studied, the coadministration of REYATAZ with ritonavir and an additional protease inhibitor would be expected to increase exposure to the other protease inhibitor. Such coadministration is not recommended. |
| ***Hepatitis C Antiviral Agents*** | | |
| elbasvir/grazoprevir | ↑ grazoprevir | Coadministration of REYATAZ with grazoprevir is contraindicated. The resulting increase in grazoprevir plasma concentrations can lead to an increased risk of ALT elevations *[see Contraindications (4)]*. |
| glecaprevir/pibrentasvir | ↑ glecaprevir<br>↑ pibrentasvir | Coadministration of REYATAZ with glecaprevir/pibrentasvir is contraindicated. It may increase the risk of ALT elevations due to an increase in glecaprevir and pibrentasvir concentrations *[see Contraindications (4)]*. |
| voxilaprevir/sofosbuvir/ velpatasvir | ↑ voxilaprevir | Coadministration with REYATAZ is not recommended. |
| ***Other Agents*** | | |
| *Alpha 1-Adrenoreceptor Antagonist:* alfuzosin | ↑ alfuzosin | Coadministration of REYATAZ with alfuzosin is contraindicated. The resulting increase in alfuzosin plasma concentrations can lead to hypotension *[see Contraindications (4)]*. |
| *Antacids and buffered medications* | ↓ atazanavir | Reduced plasma concentrations of atazanavir are expected if antacids, including buffered medications, are administered with REYATAZ. REYATAZ should be administered 2 hours before or 1 hour after these medications. |
| *Antiarrhythmics:* amiodarone, quinidine<br><br>amiodarone, bepridil, lidocaine (systemic), quinidine | ↑ amiodarone, bepridil, lidocaine (systemic), quinidine | Concomitant use of REYATAZ with ritonavir and either quinidine or amiodarone is contraindicated. This is due to the potential for substantial increase in systemic exposure of either quinidine or amiodarone, which may result in serious or life-threatening reactions such as cardiac arrhythmias *[(see Contraindications (4)]*.<br><br>Coadministration with REYATAZ has the potential to produce serious and/or life-threatening adverse events but has not been studied. Caution is warranted and therapeutic concentration monitoring of these drugs is recommended if they are used concomitantly with REYATAZ. |

**Table 16: Established and Other Potentially Significant Drug Interactions: Alteration in Dose or Regimen May Be Recommended Based on Drug Interaction Studies[a] or Predicted Interactions (Information in the table applies to REYATAZ with or without ritonavir, unless otherwise indicated)**

| ***Concomitant Drug Class:*** **Specific Drugs** | **Effect on Concentration of Atazanavir or Concomitant Drug** | **Clinical Comment** |
|---|---|---|
| *Anticoagulants:* warfarin | ↑ warfarin | Coadministration with REYATAZ has the potential to produce serious and/or life-threatening bleeding and has not been studied. It is recommended that International Normalized Ratio (INR) be monitored. |
| *Direct-Acting Oral Anticoagulants:* betrixaban, dabigatran, edoxaban | ↑ betrixaban<br>↑ dabigatran<br>↑ edoxaban | Concomitant use of REYATAZ with ritonavir, a strong CYP3A4/P-gp inhibitor, with either betrixaban, dabigatran, or edoxaban may result in increased exposure of the respective DOAC that could lead to an increased risk of bleeding. Refer to the respective DOAC prescribing information regarding dosing instructions for coadministration with P-gp inhibitors. |
| rivaroxaban | ***REYATAZ with ritonavir***<br>↑ rivaroxaban | Coadministration of REYATAZ with ritonavir and rivaroxaban is not recommended. Concomitant treatment with agents that are combined P-glycoprotein (P-gp) strong CYP3A4 inhibitors, such as ritonavir, increase exposure to rivaroxaban and may increase risk of bleeding. |
| | ***REYATAZ***<br>↑ rivaroxaban | Coadministration of REYATAZ, a CYP3A4 inhibitor, and rivaroxaban may result in increased increase exposure to rivaroxaban and may increase risk of bleeding. Close monitoring is recommended when REYATAZ is coadministered with rivaroxaban. |
| apixaban | ***REYATAZ with ritonavir***<br>↑ apixaban | Concomitant use of REYATAZ with ritonavir, a strong CYP3A4/P-gp inhibitor, with apixaban may result in increased exposure of apixaban, which could lead to an increased risk of bleeding. Refer to apixaban dosing instructions for coadministration with strong CYP3A4 and P-gp inhibitors in the apixaban prescribing information. |
| | ***REYATAZ***<br>↑ apixaban | Concomitant use of REYATAZ, a CYP3A4 inhibitor, and apixaban may result in increased exposure of apixaban, which could lead to an increased risk of bleeding. Close monitoring is recommended when apixaban is coadministered with REYATAZ. |
| *Antidepressants:* tricyclic antidepressants | ↑ tricyclic antidepressants | Coadministration with REYATAZ has the potential to produce serious and/or life-threatening adverse events and has not been studied. Concentration monitoring of these drugs is recommended if they are used concomitantly with REYATAZ. |
| trazodone | ↑ trazodone | Concomitant use of trazodone and REYATAZ with or without ritonavir may increase plasma concentrations of trazodone. Nausea, dizziness, hypotension, and syncope have been observed following coadministration of trazodone with ritonavir. If trazodone is used with a CYP3A4 inhibitor such as REYATAZ, the combination should be used with caution and a lower dose of trazodone should be considered. |
| *Antiepileptics:* carbamazepine | ↓ atazanavir<br>↑ carbamazepine | Plasma concentrations of atazanavir may be decreased when carbamazepine is administered with REYATAZ without ritonavir. Coadministration of carbamazepine and REYATAZ without ritonavir is not recommended. Ritonavir may increase plasma levels of carbamazepine. If patients beginning REYATAZ with ritonavir have been titrated to a stable dose of carbamazepine, a dose reduction for carbamazepine may be necessary. |

**Table 16: Established and Other Potentially Significant Drug Interactions: Alteration in Dose or Regimen May Be Recommended Based on Drug Interaction Studies[a] or Predicted Interactions (Information in the table applies to REYATAZ with or without ritonavir, unless otherwise indicated)**

| ***Concomitant Drug Class:*** **Specific Drugs** | **Effect on Concentration of Atazanavir or Concomitant Drug** | **Clinical Comment** |
|---|---|---|
| phenytoin, phenobarbital | ↓ atazanavir<br>↓ phenytoin<br>↓ phenobarbital | Plasma concentrations of atazanavir may be decreased when phenytoin or phenobarbital is administered with REYATAZ without ritonavir. Coadministration of phenytoin or phenobarbital and REYATAZ without ritonavir is not recommended. Ritonavir may decrease plasma levels of phenytoin and phenobarbital. When REYATAZ with ritonavir is coadministered with either phenytoin or phenobarbital, a dose adjustment of phenytoin or phenobarbital may be required. |
| lamotrigine | ↓ lamotrigine | Coadministration of lamotrigine and REYATAZ ***with*** ritonavir may decrease lamotrigine plasma concentrations, and may require dosage adjustment of lamotrigine. Coadministration of lamotrigine and REYATAZ ***without*** ritonavir is not expected to decrease lamotrigine plasma concentrations. No dose adjustment of lamotrigine is required when coadministered with REYATAZ without ritonavir. |
| *Antifungals:*<br>ketoconazole, itraconazole | ***REYATAZ with ritonavir:***<br>↑ ketoconazole<br>↑ itraconazole | Coadministration of ketoconazole has only been studied with REYATAZ without ritonavir (negligible increase in atazanavir AUC and $C_{max}$). Due to the effect of ritonavir on ketoconazole, high doses of ketoconazole and itraconazole (>200 mg/day) should be used cautiously when administering REYATAZ with ritonavir. |
| voriconazole | ***REYATAZ with ritonavir in subjects with a functional CYP2C19 allele:***<br>↓ voriconazole<br>↓ atazanavir<br><br>***REYATAZ with ritonavir in subjects without a functional CYP2C19 allele:***<br>↑ voriconazole<br>↓ atazanavir | The use of voriconazole in patients receiving REYATAZ with ritonavir is not recommended unless an assessment of the benefit/risk to the patient justifies the use of voriconazole. Patients should be carefully monitored for voriconazole-associated adverse reactions and loss of either voriconazole or atazanavir efficacy during the coadministration of voriconazole and REYATAZ with ritonavir. Coadministration of voriconazole with REYATAZ (without ritonavir) may affect atazanavir concentrations; however, no data are available. |
| *Antigout:* colchicine | ↑ colchicine | The coadministration of REYATAZ with colchicine in patients with renal or hepatic impairment is not recommended.<br>***Recommended adult dosage of colchicine when administered with REYATAZ:***<br>***Treatment of gout flares:***<br>0.6 mg (1 tablet) for 1 dose, followed by 0.3 mg (half tablet) 1 hour later. Not to be repeated before 3 days.<br>***Prophylaxis of gout flares:***<br>If the original regimen was 0.6 mg *twice* a day, the regimen should be adjusted to 0.3 mg *once a day*.<br>If the original regimen was 0.6 mg *once* a day, the regimen should be adjusted to 0.3 mg *once every other day*.<br>***Treatment of familial Mediterranean fever (FMF):***<br>Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day). |

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| ***Concomitant Drug Class:*** **Specific Drugs** | **Effect on Concentration of Atazanavir or Concomitant Drug** | **Clinical Comment** |
|---|---|---|
| *Antimycobacterials:* rifampin | ↓ atazanavir | Coadministration of REYATAZ with rifampin is contraindicated. Rifampin substantially decreases plasma concentrations of atazanavir, which may result in loss of therapeutic effect and development of resistance *[see Contraindications (4)]*. |
| rifabutin | ↑ rifabutin | A rifabutin dose reduction of up to 75% (eg, 150 mg every other day or 3 times per week) is recommended. Increased monitoring for rifabutin-associated adverse reactions including neutropenia is warranted. |
| *Antineoplastics:* *irinotecan* | ↑ irinotecan | Coadministration of REYATAZ with irinotecan is contraindicated. Atazanavir inhibits UGT1A1 and may interfere with the metabolism of irinotecan, resulting in increased irinotecan toxicities *[see Contraindications (4)]*. |
| *Antipsychotics:* pimozide | ↑ pimozide | Coadministration of REYATAZ with pimozide is contraindicated. This is due to the potential for serious and/or life-threatening reactions such as cardiac arrhythmias *[see Contraindications (4)]* |
| lurasidone | ***REYATAZ with ritonavir*** ↑ lurasidone | ***REYATAZ with ritonavir*** Coadministration of lurasidone with REYATAZ with ritonavir is contraindicated. This is due to the potential for serious and/or life-threatening reactions *[see Contraindications (4)]*. |
| | ***REYATAZ*** ↑ lurasidone | ***REYATAZ without ritonavir*** If coadministration is necessary, reduce the lurasidone dose. Refer to the lurasidone prescribing information for concomitant use with moderate CYP3A4 inhibitors. |
| quetiapine | ↑ quetiapine | ***Initiation of REYATAZ with ritonavir in patients taking quetiapine:*** Consider alternative antiretroviral therapy to avoid increases in quetiapine exposures. If coadministration is necessary, reduce the quetiapine dose to 1/6 of the current dose and monitor for quetiapine-associated adverse reactions. Refer to the quetiapine prescribing information for recommendations on adverse reaction monitoring. ***Initiation of quetiapine in patients taking REYATAZ with ritonavir:*** Refer to the quetiapine prescribing information for initial dosing and titration of quetiapine. |
| *Benzodiazepines:* midazolam (oral) triazolam | ↑ midazolam ↑ triazolam | Coadministration of REYATAZ with either orally administered midazolam or triazolam is contraindicated. Triazolam and orally administered midazolam are extensively metabolized by CYP3A4. REYATAZ may cause large increases in the concentration of these benzodiazepines that can lead to the potential for serious and/or life-threatening events such as prolonged or increased sedation or respiratory depression *[see Contraindications (4)]*. |
| parenterally administered midazolam[b] | ↑ midazolam | Concomitant use of parenteral midazolam with REYATAZ may increase plasma concentrations of midazolam. Coadministration should be done in a setting which ensures close clinical monitoring and appropriate medical management in case of respiratory depression and/or prolonged sedation. Dosage reduction for midazolam should be considered, especially if more than a single dose of midazolam is administered. |
| *Calcium channel blockers:* diltiazem | ↑ diltiazem and desacetyl-diltiazem | Caution is warranted. A dose reduction of diltiazem by 50% should be considered. ECG monitoring is recommended. Coadministration of diltiazem and REYATAZ with ritonavir has not been studied. |

**Table 16: Established and Other Potentially Significant Drug Interactions: Alteration in Dose or Regimen May Be Recommended Based on Drug Interaction Studies[a] or Predicted Interactions (Information in the table applies to REYATAZ with or without ritonavir, unless otherwise indicated)**

| ***Concomitant Drug Class:*** **Specific Drugs** | **Effect on Concentration of Atazanavir or Concomitant Drug** | **Clinical Comment** |
|---|---|---|
| felodipine, nifedipine, nicardipine, and verapamil | ↑ calcium channel blocker | Caution is warranted. Dose titration of the calcium channel blocker should be considered. ECG monitoring is recommended. |
| *Endothelin receptor antagonists:* bosentan | ↓ atazanavir<br>↑ bosentan | Plasma concentrations of atazanavir may be decreased when bosentan is administered with REYATAZ without ritonavir. Coadministration of bosentan and REYATAZ without ritonavir is not recommended.<br>***Coadministration of bosentan in adult patients on REYATAZ with ritonavir:***<br>For patients who have been receiving REYATAZ with ritonavir for at least 10 days, start bosentan at 62.5 mg once daily or every other day based on individual tolerability.<br>***Coadministration of REYATAZ with ritonavir in adult patients on bosentan:***<br>Discontinue bosentan at least 36 hours before starting REYATAZ with ritonavir. At least 10 days after starting REYATAZ with ritonavir, resume bosentan at 62.5 mg once daily or every other day based on individual tolerability. |
| *Ergot derivatives:* dihydroergotamine, ergotamine, ergonovine, methylergonovine | ↑ ergot derivatives | Coadministration of REYATAZ with ergot derivatives is contraindicated. This is due to the potential for serious and/or life-threatening events such as acute ergot toxicity characterized by peripheral vasospasm and ischemia of the extremities and other tissues *[see Contraindications (4)]*. |
| *GI Motility Agents:* cisapride | ↑ cisapride | Coadministration of REYATAZ with cisapride is contraindicated. This is due to the potential for serious and/or life-threatening reactions such as cardiac arrhythmias *[see Contraindications (4)]*. |
| *Herbal Products:* St. John's wort *(Hypericum perforatum)* | ↓ atazanavir | Coadministration of products containing St. John's wort with REYATAZ is contraindicated. This may result in loss of therapeutic effect of REYATAZ and the development of resistance *[see Contraindications (4)]*. |
| *Lipid-modifying agents*<br>*HMG-CoA reductase inhibitors:* lovastatin, simvastatin | ↑ lovastatin<br>↑ simvastatin | Coadministration of REYATAZ with lovastatin or simvastatin is contraindicated. This is due to the potential for serious reactions such as myopathy, including rhabdomyolysis *[see Contraindications (4)]*. |
| atorvastatin, rosuvastatin | ↑ atorvastatin<br>↑ rosuvastatin | Titrate atorvastatin dose carefully and use the lowest necessary dose. Rosuvastatin dose should not exceed 10 mg/day. The risk of myopathy, including rhabdomyolysis, may be increased when HIV protease inhibitors, including REYATAZ, are used in combination with these drugs. |
| *Other Lipid Modifying Agents: lomitapide* | ↑ lomitapide | Coadministration of REYATAZ with lomitapide is contraindicated. This is due to the potential for risk of markedly increased transaminase levels and hepatotoxicity associated with increased plasma concentrations of lomitapide. The mechanism of interaction is CYP3A4 inhibition by atazanavir and/or ritonavir *[see Contraindications (4)]*. |

**Table 16: Established and Other Potentially Significant Drug Interactions: Alteration in Dose or Regimen May Be Recommended Based on Drug Interaction Studies[a] or Predicted Interactions (Information in the table applies to REYATAZ with or without ritonavir, unless otherwise indicated)**

| ***Concomitant Drug Class:*** **Specific Drugs** | **Effect on Concentration of Atazanavir or Concomitant Drug** | **Clinical Comment** |
|---|---|---|
| *$H_2$-Receptor antagonists* | ↓ atazanavir | Plasma concentrations of atazanavir were substantially decreased when REYATAZ 400 mg once daily was administered simultaneously with famotidine 40 mg twice daily in adults, which may result in loss of therapeutic effect and development of resistance.<br>***In treatment-naive adult patients:***<br>REYATAZ 300 mg with ritonavir 100 mg once daily with food should be administered simultaneously with, and/or at least 10 hours after, a dose of the $H_2$-receptor antagonist (H2RA). An H2RA dose comparable to famotidine 20 mg once daily up to a dose comparable to famotidine 40 mg twice daily can be used with REYATAZ 300 mg with ritonavir 100 mg in treatment-naive patients.<br>OR<br>For patients unable to tolerate ritonavir, REYATAZ 400 mg once daily with food should be administered at least 2 hours before and at least 10 hours after a dose of the H2RA. No single dose of the H2RA should exceed a dose comparable to famotidine 20 mg, and the total daily dose should not exceed a dose comparable to famotidine 40 mg. The use of REYATAZ without ritonavir in pregnant patients is not recommended.<br>***In treatment-experienced adult patients:***<br>Whenever an H2RA is given to a patient receiving REYATAZ with ritonavir, the H2RA dose should not exceed a dose comparable to famotidine 20 mg twice daily, and the REYATAZ with ritonavir doses should be administered simultaneously with, and/or at least 10 hours after, the dose of the H2RA.<br>• REYATAZ 300 mg with ritonavir 100 mg once daily (all as a single dose with food) if taken with an H2RA.<br>• REYATAZ 400 mg with ritonavir 100 mg once daily (all as a single dose with food) if taken with both tenofovir DF and an H2RA.<br>• REYATAZ 400 mg with ritonavir 100 mg once daily (all as a single dose with food) if taken with either tenofovir DF or an H2RA for pregnant patients during the second and third trimester. REYATAZ is not recommended for pregnant patients during the second and third trimester taking REYATAZ with both tenofovir DF and an H2RA. |