

17.6 Fat Redistribution

Patients should be informed that redistribution or accumulation of body fat may occur in patients receiving antiretroviral therapy including protease inhibitors and that the cause and long-term health effects of these conditions are not known at this time. It is unknown whether long-term use of REYATAZ will result in a lower incidence of lipodystrophy than with other protease inhibitors.

17.7 FDA-Approved Patient Labeling

Patient Information

REYATAZ[®] (RAY-ah-taz)

(generic name = **atazanavir sulfate**)

Capsules

ALERT: Find out about medicines that should NOT be taken with REYATAZ. Read the section “What important information should I know about taking REYATAZ with other medicines?”

Read the Patient Information that comes with REYATAZ before you start using it and each time you get a refill. There may be new information. This leaflet provides a summary about REYATAZ and does not include everything there is to know about your medicine. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is REYATAZ?

REYATAZ is a prescription medicine used with other anti-HIV medicines to treat people who are infected with the human immunodeficiency virus (HIV). HIV is the virus that causes acquired immune deficiency syndrome (AIDS). REYATAZ is a type of anti-HIV medicine called a protease inhibitor. HIV infection destroys CD4+ (T) cells, which are important to the immune system. The immune system helps fight infection. After a large number of (T) cells are destroyed, AIDS develops. REYATAZ helps to block HIV protease, an enzyme that is needed for the HIV virus to multiply. REYATAZ may lower the amount of HIV in your blood, help your body keep its supply of CD4+ (T) cells, and reduce the risk of death and illness associated with HIV.

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Does REYATAZ cure HIV or AIDS?

REYATAZ does not cure HIV infection or AIDS. At present there is no cure for HIV infection. People taking REYATAZ may still get opportunistic infections or other conditions that happen with HIV infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium* complex (MAC) infections. **It is very important that you see your healthcare provider regularly while taking REYATAZ.**

REYATAZ does not lower your chance of passing HIV to other people through sexual contact, sharing needles, or being exposed to your blood. For your health and the health of others, it is important to always practice safer sex by using a latex or polyurethane condom or other barrier to lower the chance of sexual contact with semen, vaginal secretions, or blood. Never use or share dirty needles.

Who should not take REYATAZ?

Do not take REYATAZ if you:

- **are taking certain medicines.** (See “What important information should I know about taking REYATAZ with other medicines?”) Serious life-threatening side effects or death may happen. Before you take REYATAZ, tell your healthcare provider about all medicines you are taking or planning to take. These include other prescription and nonprescription medicines, vitamins, and herbal supplements.
- **are allergic to REYATAZ or to any of its ingredients.** The active ingredient is atazanavir sulfate. See the end of this leaflet for a complete list of ingredients in REYATAZ. Tell your healthcare provider if you think you have had an allergic reaction to any of these ingredients.

What should I tell my healthcare provider before I take REYATAZ?

Tell your healthcare provider:

- **If you are pregnant or planning to become pregnant.** It is not known if REYATAZ can harm your unborn baby. Pregnant women have experienced serious side effects when taking REYATAZ with other HIV medicines called nucleoside analogues. You and your healthcare provider will need to decide if REYATAZ is right for you. If you use REYATAZ while you are pregnant, talk to your healthcare provider about the Antiretroviral Pregnancy Registry.
- **If you are breast-feeding.** You should not breast-feed if you are HIV-positive because of the chance of passing HIV to your baby. Also, it is not known if REYATAZ can pass into

your breast milk and if it can harm your baby. If you are a woman who has or will have a baby, talk with your healthcare provider about the best way to feed your baby.

- **If you have liver problems or are infected with the hepatitis B or C virus.** See “What are the possible side effects of REYATAZ?”
- **If you have end stage kidney disease** managed with hemodialysis.
- **If you have diabetes.** See “What are the possible side effects of REYATAZ?”
- **If you have hemophilia.** See “What are the possible side effects of REYATAZ?”
- **About all the medicines you take** including prescription and nonprescription medicines, vitamins, and herbal supplements. Keep a list of your medicines with you to show your healthcare provider. For more information, see “What important information should I know about taking REYATAZ with other medicines?” and “Who should not take REYATAZ?” Some medicines can cause serious side effects if taken with REYATAZ.

How should I take REYATAZ?

- **Take REYATAZ once every day exactly as instructed by your healthcare provider.** Your healthcare provider will prescribe the amount of REYATAZ that is right for you.
 - For adults who have never taken anti-HIV medicines before, the usual dose is 400 mg (two 200-mg capsules) once daily taken with food.
 - For adults who have taken anti-HIV medicines in the past, the usual dose is 300 mg (two 150-mg capsules) plus 100 mg of NORVIR[®] (ritonavir) once daily taken with food.
- Your dose will depend on your liver function and on the other anti-HIV medicines that you are taking. REYATAZ is always used with other anti-HIV medicines. If you are taking REYATAZ with SUSTIVA[®] (efavirenz) or with VIREAD[®] (tenofovir disoproxil fumarate), you should also be taking NORVIR[®] (ritonavir).
- **Always take REYATAZ with food** (a meal or snack) to help it work better. Swallow the capsules whole. **Do not open the capsules.** Take REYATAZ at the same time each day.
- **If you are taking antacids or didanosine (VIDEX[®] or VIDEX[®] EC),** take REYATAZ 2 hours before or 1 hour after these medicines.
- **If you are taking medicines for indigestion, heartburn, or ulcers such as AXID[®] (nizatidine), PEPCID AC[®] (famotidine), TAGAMET[®] (cimetidine), ZANTAC[®] (ranitidine), AcipHex[®] (rabeprazole), NEXIUM[®] (esomeprazole), PREVACID[®]**

(lansoprazole), PRILOSEC[®] (omeprazole), or PROTONIX[®] (pantoprazole), talk to your healthcare provider.

- **Do not change your dose or stop taking REYATAZ without first talking with your healthcare provider.** It is important to stay under a healthcare provider's care while taking REYATAZ.
- **When your supply of REYATAZ starts to run low**, get more from your healthcare provider or pharmacy. It is important not to run out of REYATAZ. The amount of HIV in your blood may increase if the medicine is stopped for even a short time.
- **If you miss a dose of REYATAZ**, take it as soon as possible and then take your next scheduled dose at its regular time. If, however, it is within 6 hours of your next dose, do not take the missed dose. Wait and take the next dose at the regular time. Do not double the next dose. **It is important that you do not miss any doses of REYATAZ or your other anti-HIV medicines.**
- **If you take more than the prescribed dose of REYATAZ**, call your healthcare provider or poison control center right away.

Can children take REYATAZ?

Dosing recommendations are available for children 6 years of age and older for REYATAZ Capsules. Dosing recommendations are not available for children from 3 months to less than 6 years of age. REYATAZ should not be used in babies under the age of 3 months.

What are the possible side effects of REYATAZ?

The following list of side effects is **not** complete. Report any new or continuing symptoms to your healthcare provider. If you have questions about side effects, ask your healthcare provider. Your healthcare provider may be able to help you manage these side effects.

The following side effects have been reported with REYATAZ:

- **mild rash** (redness and itching) without other symptoms sometimes occurs in patients taking REYATAZ, most often in the first few weeks after the medicine is started. Rashes usually go away within 2 weeks with no change in treatment. Tell your healthcare provider if rash occurs.
- **severe rash:** In a small number of patients, a rash can develop that is associated with other symptoms which could be serious and potentially cause death.

If you develop a rash with any of the following symptoms stop using REYATAZ and call your healthcare provider right away:

- shortness of breath
 - general ill feeling or “flu-like” symptoms
 - fever
 - muscle or joint aches
 - conjunctivitis (red or inflamed eyes, like “pink eye”)
 - blisters
 - mouth sores
 - swelling of your face
- **yellowing of the skin or eyes.** These effects may be due to increases in bilirubin levels in the blood (bilirubin is made by the liver). Call your healthcare provider if your skin or the white part of your eyes turn yellow. Although these effects may not be damaging to your liver, skin, or eyes, it is important to tell your healthcare provider promptly if they occur.
 - **a change in the way your heart beats (heart rhythm change).** Call your healthcare provider right away if you get dizzy or lightheaded. These could be symptoms of a heart problem.
 - **diabetes and high blood sugar (hyperglycemia)** sometimes happen in patients taking protease inhibitor medicines like REYATAZ. Some patients had diabetes before taking protease inhibitors while others did not. Some patients may need changes in their diabetes medicine.
 - **if you have liver disease** including hepatitis B or C, your liver disease may get worse when you take anti-HIV medicines like REYATAZ.
 - **kidney stones** have been reported in patients taking REYATAZ. If you develop signs or symptoms of kidney stones (pain in your side, blood in your urine, pain when you urinate) tell your healthcare provider promptly.
 - **some patients with hemophilia** have increased bleeding problems with protease inhibitors like REYATAZ.
 - **changes in body fat.** These changes may include an increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these conditions are not known at this time.

Other common side effects of REYATAZ taken with other anti-HIV medicines include nausea; headache; stomach pain; vomiting; diarrhea; depression; fever; dizziness; trouble sleeping; numbness, tingling, or burning of hands or feet; and muscle pain.

Gallbladder disorders (which may include gallstones and gallbladder inflammation) have been reported in patients taking REYATAZ.

What important information should I know about taking REYATAZ with other medicines?

Do not take REYATAZ if you take the following medicines (not all brands may be listed; tell your healthcare provider about all the medicines you take). REYATAZ may cause serious, life-threatening side effects or death when used with these medicines.

- Ergot medicines: dihydroergotamine, ergonovine, ergotamine, and methylergonovine such as CAFERGOT[®], MIGRANAL[®], D.H.E. 45[®], ergotrate maleate, METHERGINE[®], and others (used for migraine headaches).
- ORAP[®] (pimozide, used for Tourette's disorder).
- PROPULSID[®] (cisapride, used for certain stomach problems).
- Triazolam, also known as HALCION[®] (used for insomnia).
- Midazolam, also known as VERSED[®] (used for sedation), when taken by mouth.

Do not take the following medicines with REYATAZ because of possible serious side effects:

- CAMPTOSAR[®] (irinotecan, used for cancer).
- CRIXIVAN[®] (indinavir, used for HIV infection). Both REYATAZ and CRIXIVAN sometimes cause increased levels of bilirubin in the blood.
- Cholesterol-lowering medicines MEVACOR[®] (lovastatin) or ZOCOR[®] (simvastatin).

Do not take the following medicines with REYATAZ because they may lower the amount of REYATAZ in your blood. This may lead to an increased HIV viral load. Resistance to REYATAZ or cross-resistance to other HIV medicines may develop:

- Rifampin (also known as RIMACTANE[®], RIFADIN[®], RIFATER[®], or RIFAMATE[®], used for tuberculosis).

- St. John's wort (*Hypericum perforatum*), an herbal product sold as a dietary supplement, or products containing St. John's wort.
- **VIRAMUNE[®]** (nevirapine, used for HIV infection).

Do not take the following medicine if you are taking REYATAZ and NORVIR[®] together:

- VFEND[®] (voriconazole).

The following medicines may require your healthcare provider to monitor your therapy more closely:

- CIALIS[®] (tadalafil), LEVITRA[®] (vardenafil), or VIAGRA[®] (sildenafil). REYATAZ may increase the chances of serious side effects that can happen with CIALIS, LEVITRA, or VIAGRA. Do not use CIALIS, LEVITRA, or VIAGRA while you are taking REYATAZ unless your healthcare provider tells you it is okay.
- LIPITOR[®] (atorvastatin) or CRESTOR[®] (rosuvastatin). There is an increased chance of serious side effects if you take REYATAZ with this cholesterol-lowering medicine.
- Medicines for abnormal heart rhythm: CORDARONE[®] (amiodarone), lidocaine, quinidine (also known as CARDIOQUIN[®], QUINIDEX[®], and others).
- VASCOR[®] (bepridil, used for chest pain).
- COUMADIN[®] (warfarin).
- Tricyclic antidepressants such as ELAVIL[®] (amitriptyline), NORPRAMIN[®] (desipramine), SINEQUAN[®] (doxepin), SURMONTIL[®] (trimipramine), TOFRANIL[®] (imipramine), or VIVACTIL[®] (protriptyline).
- Medicines to prevent organ transplant rejection: SANDIMMUNE[®] or NEORAL[®] (cyclosporin), RAPAMUNE[®] (sirolimus), or PROGRAF[®] (tacrolimus).
- The antidepressant trazodone (DESYREL[®] and others).
- Fluticasone propionate (ADVAIR[®], FLONASE[®], FLOVENT[®]), given by nose or inhaled to treat allergic symptoms or asthma. Your doctor may choose not to keep you on fluticasone, especially if you are also taking NORVIR[®].

The following medicines may require a change in the dose or dose schedule of either REYATAZ or the other medicine:

- FORTOVASE[®], INVIRASE[®] (saquinavir).
- NORVIR[®] (ritonavir).
- SUSTIVA[®] (efavirenz).
- Antacids or buffered medicines.
- VIDEX[®] (didanosine).
- VIREAD[®] (tenofovir disoproxil fumarate).
- MYCOBUTIN[®] (rifabutin).
- Calcium channel blockers such as CARDIZEM[®] or TIAZAC[®] (diltiazem), COVERA-HS[®] or ISOPTIN SR[®] (verapamil) and others.
- BIAXIN[®] (clarithromycin).
- Medicines for indigestion, heartburn, or ulcers such as AXID[®] (nizatidine), PEPCID AC[®] (famotidine), TAGAMET[®] (cimetidine), or ZANTAC[®] (ranitidine).

Talk to your healthcare provider about choosing an effective method of contraception. REYATAZ may affect the safety and effectiveness of hormonal contraceptives such as birth control pills or the contraceptive patch. Hormonal contraceptives do not prevent the spread of HIV to others.

Remember:

- 1. Know all the medicines you take.**
- 2. Tell your healthcare provider about all the medicines you take.**
- 3. Do not start a new medicine without talking to your healthcare provider.**

How should I store REYATAZ?

- Store REYATAZ Capsules at room temperature, 59° to 86° F (15° to 30° C). Do **not** store this medicine in a damp place such as a bathroom medicine cabinet or near the kitchen sink.
- Keep your medicine in a tightly closed container.

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- Keep all medicines out of the reach of children and pets at all times. Do not keep medicine that is out of date or that you no longer need. Dispose of unused medicines through community take-back disposal programs when available or place REYATAZ in an unrecognizable, closed container in the household trash.

General information about REYATAZ

This medicine was prescribed for your particular condition. Do not use REYATAZ for another condition. Do not give REYATAZ to other people, even if they have the same symptoms you have. It may harm them. **Keep REYATAZ and all medicines out of the reach of children and pets.**

This summary does not include everything there is to know about REYATAZ. Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Remember no written summary can replace careful discussion with your healthcare provider. If you would like more information, talk with your healthcare provider or you can call 1-800-321-1335.

What are the ingredients in REYATAZ?

Active Ingredient: atazanavir sulfate

Inactive Ingredients: Crospovidone, lactose monohydrate (milk sugar), magnesium stearate, gelatin, FD&C Blue #2, and titanium dioxide.

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