cobicistat (Tybost)

WHAT IS COBICISTAT?

Cobicistat, also known as COBI (brand name Tybost), is a drug used as part of antiretroviral therapy (ART). The FDA approved cobicistat in 2012 for people with HIV infection. Cobicistat is manufactured by Gilead Sciences.

Cobicistat is a type of drug called a pharmacokinetic enhancer (PK enhancer) or CYP3A inhibitor. PK enhancers are used to boost the effectiveness of other drugs. When the two drugs are given together, the PK enhancer interferes with the liver metabolism and breakdown of the other drug, which allows the other drug to remain in the body longer at a higher concentration. PK enhancers are included in some HIV treatment regimens. Cobicistat itself is not an antiretroviral medicine (ARV) and does not treat HIV.

Cobicistat is used to increase the levels of the following protease inhibitors (PIs):

- atazanavir (Reyataz)
- darunavir (Prezista)

When used in combination with ARVs to treat HIV infection, cobicistat may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

Cobicistat does not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE COBICISTAT?

Cobicistat is a prescription medicine used with atazanavir (Reyataz) or darunavir (Prezista) to treat HIV infection in adults and children, in combination with other ARVs.

When used in combination with atazanavir, cobicistat can be given to children who weigh at least 77 pounds (35 kg). It is not known if cobicistat when taken with atazanavir is safe and effective in children who weigh less than 77 pounds (35 kg).

When used in combination with darunavir, cobicistat can be given to children who weigh at least 88 pounds (40 kg). It is not known if cobicistat when taken with darunavir is safe and effective in children who weigh less than 88 pounds (40 kg).

Cobicistat has not been carefully studied in the elderly (65 years of age and older).

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

WHO SHOULD NOT TAKE COBICISTAT?

Do not take cobicistat if you are allergic to cobicistat or any of the ingredients in this drug.

Do not take cobicistat if you take darunavir 2 times each day or if you take other HIV protease inhibitors.

Do not take cobicistat combined with atazanavir or darunavir if you take the following medications:

- Alpha 1-adrenoreceptor antagonist: alfuzosin
- Gout medicine: colchicine (if you have liver or kidney problems)
- Antipsychotic medicines: lurasidone, pimozide
- Seizure medicines: carbamazepine, phenobarbital, phenytoin
- Tuberculosis (TB) medicine: rifampin
- Benzodiazepines: midazolam (when taken by mouth), triazolam
- Cholesterol medicines: lomitapide, lovastatin, simvastatin
- Ergot-containing medicines: dihydroergotamine mesylate, ergotamine tartrate, methylergonovine maleate

- Heart medicines: dronedarone, ranolazine
- Heartburn and reflux medicine: cisapride
- Herbal product: St. John's Wort (*Hypericum perforatum*)
- PDE-5 inhibitor: sildenafil (when used for the treatment of pulmonary arterial hypertension [PAH])

Do not take cobicistat combined with atazanavir if you take the following medications:

- Cancer medicine: irinotecan
- Hormonal birth control: drospirenone/ethinyl estradiol
- Other ARVs: indinavir, nevirapine

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past 4 weeks, talk to your healthcare provider or pharmacist before starting treatment with cobicistat.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING COBICISTAT?

Before you take cobicistat tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have kidney problems
- Have liver problems

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with cobicistat. Cobicistat should not be used during pregnancy because you may not have enough cobicistat in your body during pregnancy. Your healthcare provider may prescribe different medicines if you become pregnant while taking cobicistat.

There is a pregnancy registry for people who take cobicistat during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to cobicistat during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with cobicistat. It is not known if cobicistat can pass to your baby in your breastmilk. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS COBICISTAT TAKEN?

Cobicistat is taken by mouth as a tablet. The recommended dosage of cobicistat for adults and children is one 150 mg tablet once daily, in combination with ARVs. The coadministered oral dosage of atazanavir is 300 mg once daily. The coadministered oral dosage of darunavir is 800 mg once daily.

Take cobicistat at the same time each day with food. Take cobicistat at the same time that you take atazanavir or darunavir.

A small amount of cobicistat is included in several combination medications as a booster. Combination HIV medicines contain 2 or more HIV medicines from 1 or more drug classes.

- atazanavir / cobicistat (Evotaz)
- darunavir / cobicistat (Prezcobix)
- darunavir / cobicistat / emtricitabine / tenofovir AF (Symtuza)
- elvitegravir / cobicistat / emtricitabine / tenofovir AF (Genvoya)
- elvitegravir / cobicistat / emtricitabine / tenofovir DF (Stribild)

WHAT ARE THE SIDE EFFECTS?

When you start any medicine, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of cobicistat with atazanavir include yellowing of the skin and rash.

Cobicistat when taken with certain other medicines can cause new or worse kidney problems, including kidney failure. Your

healthcare provider should check your kidneys before you start and while you are taking cobicistat

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of cobicistat. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES COBICISTAT REACT WITH OTHER DRUGS?

All medications can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take cobicistat with other medicines.

Cobicistat can change the blood levels of oral birth control medications. Alternative methods of birth control are recommended.

See above for a list of medicines that should not be taken with cobicistat.

MORE INFORMATION

Download the full Prescribing Information.

Download the Patient Information leaflet.

Apply for the Gilead Advancing Access Program.

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