Patient Information TYBOST® (TYE-bost) (cobicistat) tablets

Important: Ask your healthcare provider or pharmacist about medicines that should not be taken with TYBOST. For more information, see the section "What should I tell my healthcare provider before taking TYBOST?"

Also read the Patient Information for atazanavir or darunavir prescribed by your healthcare provider when taking TYBOST.

What is TYBOST?

TYBOST is a prescription medicine used in adults and children who weigh at least 31 pounds (14 kg):

- 1 time each day with the Human Immunodeficiency Virus-1 (HIV-1) medicines atazanavir or darunavir, to increase the amount of those medicines in your blood.
- TYBOST is not an HIV-1 medicine and does not treat the HIV-1 virus. You must also take all the HIV-1 medicines prescribed by your healthcare provider even if you take TYBOST and atazanavir or darunavir.
- TYBOST should not be used if you take darunavir when prescribed by your healthcare provider to be taken 2 times each day, or if you take other HIV-1 protease inhibitor medicines, including fosamprenavir, saquinavir, or tipranavir.

It is not known if TYBOST when taken with atazanavir is safe and effective in children who weigh less than 31 pounds (14 kg) of if TYBOST when taken with darunavir is safe and effective in children who weigh less than 33 pounds (15 kg).

Do not take TYBOST combined with atazanavir or darunavir if you also take a medicine that contains:

- alfuzosin hydrochloride
- carbamazepine
- colchicine, if you have liver or kidney problems
- dronedarone hydrochloride
- ergot-containing medicines:
 - o dihydroergotamine mesylate
 - o ergotamine tartrate
 - o methylergonovine maleate
- lomitapide
- lovastatin
- lurasidone

- midazolam, when taken by mouth
- phenobarbital
- phenytoin
- pimozide
- ranolazine
- rifampin
- sildenafil, when used for treating the lung problem pulmonary arterial hypertension (PAH)
- simvastatin
- St. John's wort (Hypericum perforatum) or a product that contains St. John's wort
- triazolam

Do not take TYBOST with atazanavir if you also take a medicine that contains:

- drospirenone/ethinyl estradiol
- indinavir
- irinotecan
- nevirapine

Before you take TYBOST, tell your healthcare provider about all of your medical conditions, including if you:

- have kidney problems
- have liver problems
- are pregnant or plan to become pregnant. It is not known if TYBOST can harm your unborn baby.
 - TYBOST should not be used during pregnancy because you may not have enough TYBOST in your body during pregnancy.
 - TYBOST may reduce how well some hormonal birth control (contraceptives) works. You should consider using a different form of birth control or an additional barrier method of birth control during treatment with TYBOST.
 - Tell your healthcare provider if you become pregnant during treatment with TYBOST. Your healthcare provider may prescribe different medicines if you become pregnant during treatment with TYBOST.

Pregnancy Registry: There is a pregnancy registry for people who take TYBOST during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.

are breastfeeding or plan to breastfeed. It is not known if TYBOST can pass to your baby in your breast milk. Talk to your healthcare provider about the following risks to your baby from breastfeeding during treatment with TYBOST:

 \circ the HIV-1 virus may pass to your baby if your baby does not have HIV-1.

 $_{\odot}$ the HIV-1 virus may become harder to treat if your baby has HIV-1.

• your baby may get side effects from TYBOST.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, antacids, vitamins, and herbal supplements. TYBOST with atazanavir or darunavir may affect the way other medicines work, and other medicines may affect how TYBOST with atazanavir or darunavir works. Taking TYBOST with atazanavir or darunavir, along with certain other medicines can lead to severe or life-threatening side effects, or could lead to death. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact when taken with TYBOST with atazanavir or darunavir.
- **Do not start a new medicine without telling your healthcare provider**. Your healthcare provider can tell you if it is safe to take TYBOST with atazanavir or darunavir, along with other medicines.

How should I take TYBOST?

- Take TYBOST exactly as your healthcare provider tells you.
- Do not change your dose or stop taking TYBOST without first talking with your healthcare provider.
- Stay under the care of your healthcare provider during treatment with TYBOST. See your healthcare provider regularly during treatment with TYBOST.
- Take TYBOST 1 time each day at the same time you take atazanavir or darunavir. It is important to take these medicines on a regular dosing schedule.
- Take TYBOST with atazanavir or TYBOST with darunavir, along with food.
- If you take too much TYBOST, call your healthcare provider or go to the nearest hospital emergency room right away.
- Do not run out of TYBOST. The virus in your blood may become resistant to the HIV-1 medicine atazanavir or darunavir if TYBOST is stopped for even a short time. When your supply starts to run low, get more from your healthcare provider or pharmacy.

What are the possible side effects of TYBOST?

TYBOST may cause serious side effects, including:

• **Kidney problems.** TYBOST when taken with certain other medicines can cause new or worse kidney problems, including kidney failure. Your healthcare provider should do blood and urine tests to check your kidneys before you start and during treatment with TYBOST.

The most common side effects of TYBOST with atazanavir include: yellowing of the skin or the whites of your eyes and rash.

These are not all the possible side effects of TYBOST.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TYBOST?

- Store TYBOST at room temperature between 68°F to 77°F (20°C to 25°C).
- TYBOST comes in a child-resistant container.
- Do not use TYBOST if the seal over the bottle opening is broken or missing.
- Keep TYBOST in its original container.
- Keep the container tightly closed.

Keep TYBOST and all medicines out of reach of children.

General information about the safe and effective use of TYBOST.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TYBOST for a condition for which it was not prescribed. Do not give TYBOST to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TYBOST that is written for health professionals.

What are the ingredients in TYBOST?

Active ingredient: cobicistat

Inactive ingredients: silicon dioxide, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. The 150 mg tablets are film-coated with a coating material containing polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide, sunset yellow FCF (FD&C Yellow #6) aluminum lake, and iron oxide yellow. The 90 mg tablets are film-coated with a coating material containing polyethylene glycol, and talc.

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For more information, call 1-800-445-3235 or go to www.GILEAD.com This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: 06/2025