

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?**”

Read this Patient Information before you start taking TYBOST and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

Also read the Patient Information for atazanavir (REYATAZ®) or darunavir (PREZISTA®) prescribed by your healthcare provider when taking TYBOST.

What is TYBOST?

TYBOST is a prescription medicine used in adults 1 time each day with the antiretroviral Human Immunodeficiency Virus-1 (HIV-1) medicines atazanavir (REYATAZ®) or darunavir (PREZISTA®) to increase the amount of those medicines in your blood.

- TYBOST is not an antiretroviral medicine and does not treat the HIV-1 virus. You must also take all the antiretroviral HIV-1 medicines prescribed by your healthcare provider even if you take TYBOST and atazanavir (REYATAZ®) or darunavir (PREZISTA®).
- TYBOST should not be used if you take darunavir (PREZISTA) 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 (LEXIVA®), saquinavir (INVIRASE®), or tipranavir (APTIVUS®).

It is not known if TYBOST is safe and effective in children under 18 years of age.

Do not take TYBOST combined with atazanavir or darunavir if you also take any of the following medicines:

- alfuzosin hydrochloride (UROXATRAL®)
- carbamazepine (CARBATROL®, EPITOL®, EQUETRO®, TEGRETOL®)
- cisapride (PROPULSID®, PROPULSID® QUICKSOLV)
- colchicine (COLCRYS, MITIGARE™), if you have liver or kidney problems
- dronedarone hydrochloride (MULTAQ®)
- ergot-containing medicines:
- dihydroergotamine mesylate (D.H.E. 45®, MIGRANAL®)
- ergotamine tartrate (CAFERGOT®, MIGERGOT®, ERGOSTAT®, MEDIHALER ERGOTAMINE®, WIGRAINE®, WIGRETTES®)
- methylergonovine maleate (ERGOTRATE®, METHERGINE®)
- lovastatin (ADVICOR®, ALTOPREV®, MEVACOR®)
- lurasidone (LATUDA®)
- midazolam (VERSED®), when taken by mouth
- phenobarbital (LUMINAL®)
- phenytoin (DILANTIN®, PHENYTEX®)
- pimozide (ORAP®)
- ranolazine (RANEXA®)
- rifampin (RIFADIN®, RIFAMATE®, RIFATER®, RIMACTANE®)
- sildenafil (REVATIO®), when used for treating the lung problem pulmonary arterial hypertension (PAH)
- simvastatin (SIMCOR®, VYTORIN®, ZOCOR®)
- St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort
- triazolam (HALCION®)

Do not take TYBOST with atazanavir if you also take any of the following medicines:

- drospirenone/ethinyl estradiol (BEYAZ®, SAFYRAL®, YASMIN®, YAZ®)
- indinavir (CRIXIVAN®)
- irinotecan (CAMPTOSAR®)

- nevirapine (VIRAMUNE[®], VIRAMUNE XR[®])

What should I tell my healthcare provider before taking TYBOST?

Before you take TYBOST, tell your healthcare provider if you:

- have kidney problems
- have liver problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if TYBOST can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking TYBOST.

Pregnancy Registry: There is a pregnancy registry for women 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. Do not breastfeed if you take TYBOST.
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - It is not known if TYBOST can pass to your baby in your breast milk.

Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, 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 while taking TYBOST.
- **Take TYBOST 1 time each day at the same time you take atazanavir (REYATAZ[®]) or darunavir (PREZISTA[®]). 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 (REYATAZ[®]) or darunavir (PREZISTA[®]) 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 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 TYBOST.

The most common side effects of TYBOST with atazanavir (REYATAZ[®]) include yellowing of the skin and rash.

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 TYBOST. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider 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).
- 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 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. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about TYBOST that is written for health professionals. For more information, call 1-800-445-3235 or go to www.GILEAD.com.

What are the ingredients in TYBOST?

Active ingredient: cobicistat

Inactive ingredients: silicon dioxide, microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. The 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.

Manufactured and distributed by: Gilead Sciences, Inc. Foster City, CA 94404

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203094-GS-005

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: 07/2018