

Package leaflet: Information for the patient

Tybost 150 mg film-coated tablets cobicistat

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tybost is and what it is used for
2. What you need to know before you take Tybost
3. How to take Tybost
4. Possible side effects
5. How to store Tybost
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1. What Tybost is and what it is used for

Tybost contains the active substance cobicistat.

Tybost is used for the treatment of human immunodeficiency virus-1 (HIV-1) infection, the virus that causes acquired immune deficiency syndrome (AIDS). It is used in HIV-1 infected adults and adolescents aged 12 years and older:

- weighing at least 35 kg (when co-administered with atazanavir 300 mg) or
- weighing at least 40 kg (when co-administered with darunavir 800 mg).

Tybost acts as a **booster** (*enhancer*) of **atazanavir or darunavir** (both protease inhibitors) to improve their effect (see section 3 of this leaflet).

Tybost does not directly treat your HIV, but boosts the levels of atazanavir and darunavir in the blood. It does this by slowing down the breakdown of atazanavir and darunavir which will make them stay in the body for longer.

2. What you need to know before you take Tybost

Do not take Tybost

- **If you are allergic to cobicistat** or any of the other ingredients of this medicine (listed in section 6 of this leaflet).
- **If you are taking medicines containing any of the following:**
 - **alfuzosin**, used to treat an enlarged prostate gland
 - **amiodarone, quinidine**, used to correct irregular heartbeats
 - **dabigatran**, used to prevent and treat blood clots
 - **carbamazepine, phenobarbital, phenytoin**, used to prevent seizures
 - **rifampicin**, used to prevent and treat tuberculosis and other infections
 - **dihydroergotamine, ergometrine, ergotamine**, used to treat migraine headache

- **St. John's wort** (*Hypericum perforatum*), a herbal remedy used for depression and anxiety
- **lovastatin, simvastatin**, used to lower blood cholesterol
- **pimozide, lurasidone**, used to treat abnormal thoughts or feelings
- **sildenafil**, used to treat pulmonary arterial hypertension – a lung disease that makes breathing difficult
- orally administered **midazolam, triazolam**, used to help you sleep and/or relieve anxiety

→ If any of these applies to you, you should not take Tybost and you should tell your doctor immediately.

Warnings and precautions

You must remain under the care of your doctor while taking Tybost.

Talk to your doctor before taking Tybost:

- **If you are taking another protease inhibitor.** Tybost taken with atazanavir or darunavir should not be used with another antiviral medicine that requires boosting.
- **Talk to your doctor or pharmacist if you have or have had kidney disease, or if tests have shown problems with your kidneys.** Your doctor will carefully consider whether to treat you with Tybost.
- **Talk to your doctor or pharmacist if you have or have had severe liver disease, or if tests have shown problems with your liver.** Your doctor will carefully consider whether to treat you with Tybost.

→ If any of these applies to you, talk to your doctor before taking Tybost.

Children and adolescents

Do not give this medicine to children under 12 years of age, or who weigh less than 35 kg (or 40 kg) as explained in section 3 of this leaflet. The use of Tybost in children under 12 years of age or who weigh less than 35 kg has not yet been studied.

Other medicines and Tybost

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tybost may interact with other substances. As a result, the amounts of Tybost or other medicines in your blood may be affected. This may stop your medicines from working properly, or may make any side effects worse. In some cases, your doctor may need to adjust your dose or check the levels of medicine in your blood.

There are some medicines that should never be taken with Tybost.

These are mentioned above under the heading “Do not take Tybost-If you are taking medicines containing any one of the following”.

Medicines used in treating HIV infection:

You should not take Tybost with other medicines containing:

- **ritonavir**
- **cobicistat**

Talk to your doctor if you are taking

- **another protease inhibitor**
- **efavirenz**
- **etravirine**

- **nevirapine**
 - **maraviroc**
- **Tell your doctor** if you are taking any of these HIV medicines.

Other types of medicine:

- **ketoconazole, itraconazole, voriconazole, posaconazole and fluconazole**, medicines used to treat fungal infections
- **clarithromycin and rifabutin**, medicines used to treat bacterial infections including tuberculosis
- **dasatinib, nilotinib, vinblastine and vincristine**, medicines used to treat cancer
- **corticosteroids** including **betamethasone, budesonide, fluticasone, mometasone, prednisone, triamcinolone**. These medicines are used to treat allergies, asthma, inflammatory bowel diseases, inflammatory conditions of the skin, eyes, joints and muscles and other inflammatory conditions. These medicines are generally taken orally, inhaled, injected or applied to the skin or eye. If alternatives cannot be used, its use should only take place after medical evaluation and under close monitoring by your doctor for corticosteroid side effects.
- **metformin**, medicine used for the treatment of type 2 diabetes
- **oral or implanted hormonal contraceptives** used to prevent pregnancy
- **amlodipine, digoxin, diltiazem, disopyramide, felodipine, flecainide, lidocaine, metoprolol, mexiletine, nifedipine, nifedipine, propafenone, timolol and verapamil**, medicines used to treat heart problems
- **bosentan**, a medicine used to treat pulmonary arterial hypertension
- **apixaban, edoxaban, rivaroxaban and warfarin**, medicines used to prevent and treat blood clots
- **salmeterol**, a medicine used to treat asthma
- **atorvastatin, fluvastatin, pitavastatin, pravastatin and rosuvastatin**, medicines used to lower cholesterol
- **sildenafil and vardenafil**, medicines used to treat impotence, and **tadalafil**, a medicine used to treat impotence and pulmonary hypertension
- **trazodone**, a medicine used to treat depression
- **ciclosporin, sirolimus and tacrolimus**, medicines used to control your body's immune response after a transplant
- **bupirone, clorazepate, diazepam, estazolam, flurazepam, perphenazine, risperidone, thioridazine, zolpidem**, medicines used to treat nervous system disorders
- **colchicine**, a medicine used to treat gout
- **clopidogrel**, a medicine used to reduce the risk of blood clots

→ **Tell your doctor** if you are taking any of these medicines.

→ **Tell your doctor if you are taking these or any other medicines.** Do not stop your treatment without contacting your doctor.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- **Tell your doctor immediately if you are pregnant, think you may be pregnant or are planning to have a baby.** Pregnant women should not take Tybost with atazanavir or darunavir. The amounts of these medicines in your blood may decrease during pregnancy, which may stop them from working properly.
- **Do not breast-feed during treatment with Tybost.** It is not known if the active substance in this medicine can pass into human breast milk.

- Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk.
- If you are breast-feeding, or thinking about breast-feeding, you should **discuss it with your doctor as soon as possible**.

Driving and using machines

Some patients have reported dizziness when Tybost was taken with atazanavir or darunavir. If you are affected while taking Tybost, do not drive and do not use any tools or machines.

Tybost contains sunset yellow FCF (E110)

Tell your doctor if you have an allergy to sunset yellow FCF (E110). Tybost contains sunset yellow FCF which may cause allergic reactions.

Tybost contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Tybost

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose for adults:

- **One tablet each day by mouth, with food.** Do not chew, crush or split the tablet.
- **Tybost must be taken with atazanavir (300 mg) or darunavir (800 mg).**

Recommended dose for adolescents 12 to less than 18 years of age:

- **One tablet each day by mouth, with food.** Do not chew, crush or split the tablet.
- When taking Tybost with **atazanavir (300 mg)**, adolescents **must weigh at least 35 kg**.
- When taking Tybost with **darunavir (800 mg)**, adolescents **must weigh at least 40 kg**.

Always take the dose recommended by your doctor. This is to make sure that your medicine is fully effective. Do not change the dose unless your doctor tells you to.

If you take more Tybost than you should

If you accidentally take more than the recommended dose of Tybost you may be at increased risk of experiencing side effects with this medicine (see section 4 of this leaflet).

Contact your doctor or nearest emergency department immediately for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

If you forget to take Tybost

It is important not to miss a dose of Tybost.

If you do miss a dose and notice:

- **within 12 hours** of the time you usually take Tybost, you must take the tablet as soon as possible. Always take the tablet with food. Then take the next dose as usual in combination with atazanavir or darunavir.
- **12 hours or more** after the time you usually take Tybost, then do not take the missed dose. Wait and take the next dose, with food, at your usual time.

Do not stop taking Tybost

Do not stop taking Tybost without talking to your doctor. Stopping Tybost and atazanavir or darunavir may reduce the success of future treatments prescribed by your doctor.

Always keep enough Tybost so you don't run out. When your supply of Tybost starts to run low, get more from your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. When treating HIV infection, it is not always possible to tell whether some of the unwanted effects are caused by Tybost or by other medicines that you are taking at the same time, or by the HIV disease itself. The following side effects may occur when taking Tybost with atazanavir.

Very common side effects

(may affect more than 1 in 10 people)

- feeling sick (*nausea*)
- yellowing of the skin and/or eyes (*jaundice*)

Common side effects

(may affect up to 1 in 10 people)

- high sugar levels in the blood (*hyperglycaemia*)
- increased appetite, disturbed sense of taste, dry mouth
- headache, dizziness
- vomiting, diarrhoea, stomach pain, problems with digestion resulting in pain after meals (*dyspepsia*), feeling bloated, wind (*flatulence*)
- increased levels of bilirubin in the blood (*hyperbilirubinaemia*)
- rash
- difficulty sleeping, abnormal dreams, drowsiness, tiredness (*fatigue*)

Uncommon side effects

(may affect up to 1 in 100 people)

- blood in the urine (*haematuria*)
- protein in the urine (*proteinuria*)
- feeling depressed
- itchiness
- aching muscles, weakness
- kidney stones
- fever
- sleep disorder

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the *Yellow Card Scheme*,

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

For more information on the side effects of atazanavir or darunavir see the package leaflets for these medicines.

5. How to store Tybost

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and carton after {EXP}. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tybost contains

The active substance is cobicistat. Each film-coated tablet contains 150 mg cobicistat.

The other ingredients are

Tablet core

Croscarmellose sodium, magnesium stearate, microcrystalline cellulose (E460), silicon dioxide (E551).

Film-coating

Sunset yellow FCF (E110), macrogol 3350 (E1521), polyvinyl alcohol (partially hydrolysed) (E1203), talc (E553b), titanium dioxide (E171), iron oxide yellow (E172) (see section 2 of this leaflet).

What Tybost looks like and contents of the pack

Tybost film-coated tablets are orange, round, biconvex tablets, debossed on one side with “GSI” and plain-faced on the other side of the tablet.

Tybost comes in bottles of 30 tablets (with a silica gel sachet or canister that must be kept in the bottle to help protect your tablets). The silica gel desiccant is contained in a separate sachet or canister and should not be swallowed.

The following pack sizes are available: outer cartons containing 1 bottle of 30 film-coated tablets and 90 (3 bottles of 30) film-coated tablets. Not all pack sizes may be marketed.

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