

Tybost® Tablets (150 mg cobicistat)

Cobicistat

Consumer Medicine Information

What is in this leaflet

Read all of this leaflet carefully before you start taking this medicine.

This leaflet answers some of the common questions about TYBOST tablets.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist about your medical condition or treatment. If you have further questions, please ask your doctor or your pharmacist.

This medicine has been prescribed for you personally and you should not pass it on to others.

It may harm them, even if their symptoms are the same as yours.

Medicines are sometimes prescribed for conditions that are not mentioned in this leaflet.

Do not use TYBOST for a condition for which it was not prescribed.

Keep this leaflet with your TYBOST medicine.

You may need to read it again.

What is TYBOST

How TYBOST works

TYBOST contains the active substance cobicistat.

TYBOST is a type of medicine called a pharmacokinetic enhancer (or “booster”), which is used with

one of the two following medicines for the treatment of HIV:

- Reyataz (atazanavir) and
- Prezista (darunavir).
- TYBOST helps increase the levels of these HIV medicines in your body.

Use in children

TYBOST is for adults. TYBOST has not been studied in children under the age of 18 or adults aged 65 and over.

Does TYBOST cure HIV or AIDS

TYBOST does not treat HIV infection or AIDS; it helps improve the effect of the HIV medicines:

- Reyataz (atazanavir) and
- Prezista (darunavir).

The long-term effects of TYBOST are not known at this time. People taking TYBOST 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) infection.

This medicine is only available from a pharmacist after it has

been prescribed by a doctor who specialises in the treatment of HIV infection.

If you wish to continue receiving treatment with TYBOST it is important you remain under the care of a hospital or doctor who specialises in the treatment of HIV infection.

Does TYBOST reduce the risk of passing HIV to others

TYBOST 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 passing the infection through semen, vaginal secretions, or blood.

Never re-use or share needles.

Before you take TYBOST

When you must not take it

Together with your doctor, you need to decide whether TYBOST is right for you.

Do not take TYBOST if you are allergic to:

- cobicistat or

- any of the other ingredients of Tybost

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body

The ingredients of TYBOST are listed in the product description section of this leaflet.

Do not take TYBOST if you take other HIV medicines such as:

- Fosamprenavir (e.g.Telzir)
- Lopinavir (e.g. Kaletra).
- Saquinavir (e.g.Invirase)
- STRIBILD
- GENVOYA
- Ritonovir (e.g. Norvir)
- Tipranavir (e.g.Aptivus)

Do not take TYBOST if you take:

- alfuzosin hydrochloride (e.g. Xatral)
- carbamazepine (e.g. Tegretol)
- ergot-containing medicines like dihydroergotamine, ergotamine (e.g. Cafergot, Dihydergot, Migerot)
- lovastatin (e.g. Mevacor)
- midazolam (e.g.Hypnovel)
- phenobarbital
- phenytoin (e.g.Dilantin)
- rifabutin (e.g.Mycobutin)
- sildenafil (e.g. Revatio)
- simvastatin (e.g. Invast/Zimcol)
- St John's Wort or products containing St John's Wort.
- tadalafil (e.g.Cialis/Adcirca)
- triazolam (e.g.Halcion)

Medicines that may affect your kidneys unless you have discussed this with your doctor.

This is not a complete list of medicines that you should tell your doctor about.

Do not take TYBOST after the expiry or "use by" date (EXP) printed on the bottle.

If you take it after the expiry date has passed, it may not work as well.

Do not take TYBOST if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes. Tell your doctor if you have, or have had, any of the following medical conditions:

- kidney problems or are undergoing kidney dialysis treatment.
- liver problems, including hepatitis B or C virus infection.

Tell your doctor if you are taking any other HIV medicines (e.g. atazanavir or darunavir).

Tell your doctor if you are allergic to foods, dyes, preservatives or any other medicines.

Tell your doctor if you are pregnant, or likely to become pregnant during your course of medication.

We do not know if TYBOST can harm your unborn child. You and your doctor will need to decide if TYBOST is right for you.

Tell your doctor if you are breastfeeding, or likely to breastfeed during your course of medication.

You should not breast-feed if you are HIV-positive because of the chance of passing the HIV virus to your baby.

It is not known if TYBOST 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 doctor about the best way to feed your baby.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect the levels of TYBOST or TYBOST

may affect the levels of other medicines in the body when they are taken at the same time as TYBOST.

Your doctor may change your other medicines or change their doses. Other medicines, including herbal products may affect TYBOST.

For this reason, it is very important to let your doctor or pharmacist know what medications, herbal supplements, or vitamins you are taking.

Know the medicines you take. Keep a list of medicines and show it to your doctor and pharmacist when you get a new medicine.

Your doctor and your pharmacist can tell you if you can take these medicines with TYBOST.

Do not start any new medicines while you are taking TYBOST without first talking with your doctor or pharmacist.

How to take TYBOST

Take the exact amount of TYBOST your doctor has prescribed for you.

Never change the dose on your own.

Do not stop this medicine unless your healthcare provider tells you to stop.

How much to take

The usual dose is one TYBOST tablet orally, once daily.

How to take it

Always take TYBOST with Reyataz® (atazanavir) or Prezista® (darunavir).

Always take TYBOST with food. Taking TYBOST with food is important to get the right drug levels in your body.

If you forget to take TYBOST

Do not miss a dose of TYBOST.

If you forget to take TYBOST, take your missed dose right away

then take your next dose as usual with Reyataz (atazanavir) or Prezista (darunavir).

Do not take a double dose to make up for a forgotten dose.

Continue with your regular dosing schedule.

When your TYBOST supply starts to run low, get more from your doctor or pharmacy.

This is very important because the virus in your blood may become resistant to the HIV medicine Reyataz (atazanavir) or Prezista (darunavir) if TYBOST is stopped for even a short time and become harder to treat.

Do not change your dose or stop taking TYBOST without first talking to your doctor.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre: 131126 (Australia) and 0800 764 766 (New Zealand) or go to the accident and emergency department at your nearest hospital if you think you or anyone else may have taken too many TYBOST tablets. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

While you are taking TYBOST

Things you must not do

Do not breast-feed. See “Before you start to take it”

Avoid doing things that can spread HIV infection since TYBOST does not stop you from passing the HIV Infection to others:

- **Do not share needles or other injection equipment.**

- **Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.**
- **Do not have any kind of sex without protection.**

Always practice safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of passing the infection through semen, vaginal secretions, or blood.

Things to be careful of

Be careful driving or operating machinery until you know how TYBOST affects you.

If you are dizzy, have trouble concentrating, or are drowsy, avoid activities that may be dangerous, such as driving or operating machinery.

Side Effects

Like all medicines, TYBOST can have side effects, although not everybody gets them. Some may be serious and need medical attention.

Your doctor will monitor your kidney function prior to, and during your treatment with TYBOST. Your doctor may switch you to an alternative treatment if your kidney function changes.

Check with your doctor as soon as possible if you have any problems while taking TYBOST, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

TYBOST and REYATAZ (atazanavir) may cause the following common side effects:

- presence of jaundice seen in the white part of the eyes and yellowing of the skin and/or eyes.

Additional side effects may include:

- headache
- nausea
- diarrhea

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Talk to your doctor or pharmacist if you don't understand anything in this list.

Ask your doctor or pharmacist for a more complete list of side effects of TYBOST and all the medicines you will take.

This is not a complete list of side effects possible with TYBOST.

After taking TYBOST

Storage

Keep TYBOST tablets where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store them.

Keep TYBOST tablets in a cool, dry place where it stays below 25 °C.

Do not store TYBOST or any other medicine in a bathroom or near a sink.

Do not leave TYBOST in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep your TYBOST tablets in the bottle with the cap tightly closed until you take them.

If you take TYBOST tablets out of their pack they may not keep well.

Product description

What the tablets look like

TYBOST is the brand name of your medicine.

TYBOST tablets are round, film-coated and orange in colour.

Each tablet is debossed with “GSI” on one side and plain faced on the other side.

TYBOST tablets are supplied in bottles containing 30 tablets.

Ingredients

Each TYBOST tablet contains 150 mg of the active ingredient cobicistat.

Each TYBOST tablet also contains the following ingredients:

- cellulose-microcrystalline (E460)
- silicon dioxide
- croscarmellose sodium
- magnesium stearate (E572).

Film-coating:

- Sunset yellow FCF (FD&C yellow #6)
- aluminum lake (E110)
- polyethylene glycol
- polyvinyl alcohol
- talc (E553B)
- titanium dioxide (E171)
- yellow iron oxide (E172).

SPONSOR

TYBOST tablets are supplied in

Australia by:

Gilead Sciences Pty Ltd
Level 6, 417 St Kilda Road
Melbourne, Victoria 3004

In New Zealand:

Gilead Sciences (NZ)
c/- PricewaterhouseCoopers
Level 8 Pricewaterhousecoopers
Tower
188 Quay Street
Auckland 1010

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