

Patient Information
STRIBILD™ (STRY-bild)
(elvitegravir, cobicistat, emtricitabine,
and tenofovir disoproxil fumarate)
Tablets

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

Read this Patient Information before you start taking STRIBILD 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.

What is the most important information I should know about STRIBILD?

STRIBILD can cause serious side effects, including:

- 1. Build-up of lactic acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take STRIBILD or similar (nucleoside analogs) medicines. Lactic acidosis is a serious medical emergency that can lead to death.

Lactic acidosis can be hard to identify early, because the symptoms could seem like symptoms of other health problems. **Call your healthcare provider right away if you get any of the following symptoms which could be signs of lactic acidosis:**

- feel very weak or tired
- have unusual (not normal) muscle pain
- have trouble breathing
- have stomach pain with
 - nausea
 - vomiting
- feel cold, especially in your arms and legs
- feel dizzy or lightheaded
- have a fast or irregular heartbeat

- 2. Severe liver problems.** Severe liver problems can happen in people who take STRIBILD. In some cases, these liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (steatosis).

Call your healthcare provider right away if you get any of the following symptoms of liver problems:

- your skin or the white part of your eyes turns yellow (jaundice)
- dark “tea-colored” urine
- light-colored bowel movements (stools)
- loss of appetite for several days or longer
- nausea

- stomach pain

You may be more likely to get lactic acidosis or severe liver problems if you are female, very overweight (obese), or have been taking STRIBILD for a long time.

3. Worsening of Hepatitis B infection. If you have hepatitis B virus (HBV) infection and take STRIBILD, your HBV may get worse (flare-up) if you stop taking STRIBILD. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.

- Do not run out of STRIBILD. Refill your prescription or talk to your healthcare provider before your STRIBILD is all gone.
- Do not stop taking STRIBILD without first talking to your healthcare provider.
- If you stop taking STRIBILD, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking STRIBILD.

For more information about side effects, see the section **“What are the possible side effects of STRIBILD?”**

What is STRIBILD?

STRIBILD is a prescription medicine that is used without other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) in adults who have never taken HIV-1 medicines before. HIV-1 is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

STRIBILD contains the prescription medicines elvitegravir, cobicistat, emtricitabine (EMTRIVA[®]) and tenofovir disoproxil fumarate (VIREAD[®]).

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

When used to treat HIV-1 infection, STRIBILD may:

- Reduce the amount of HIV-1 in your blood. This is called “viral load”.
- Increase the number of CD4+ (T) cells in your blood that help fight off other infections.
- Reduce the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

STRIBILD does not cure HIV-1 infections or AIDS. You must stay on continuous HIV-1 therapy to control HIV-1 infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others.

- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.

- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions about how to prevent passing HIV-1 to other people.

Who should not take STRIBILD?

Do not take STRIBILD if you also take a medicine that contains:

- alfuzosin hydrochloride (UROXATRAL[®])
- cisapride (PROPULSID[®], PROPULSID QUICKSOLV[®])
- ergot-containing medicines, including:
 - dihydroergotamine mesylate (D.H.E. 45[®], MIGRANAL[®])
 - ergotamine tartrate (CAFERGOT[®], MIGERGOT[®], ERGOSTAT[®], MEDIHALER ERGOTAMINE[®], WIGRAINE[®], WIGRETTES[®])
 - methylergonovine maleate (ERGOTRATE[®], METHERGINE[®])
- lovastatin (ADVICOR[®], ALTOPREV[®], MEVACOR[®])
- oral midazolam
- pimozone (ORAP[®])
- rifampin (RIFADIN[®], RIFAMATE[®], RIFATER[®], RIMACTANE[®])
- sildenafil (REVATIO[®]), when used for treating the lung problem, pulmonary arterial hypertension (PAH)
- simvastatin (SIMCOR[®], VYTORIN[®], ZOCOR[®])
- triazolam (HALCION[®])
- St. John's wort (*Hypericum perforatum*) or a product that contains St. John's wort

What should I tell my healthcare provider before taking STRIBILD?

Before taking STRIBILD, tell your healthcare provider if you:

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

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

- are breastfeeding or plan to breastfeed. Do not breastfeed if you take STRIBILD.
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - Two of the medicines in STRIBILD can pass to your baby in your breast milk. It is not known if the other medicines in STRIBILD can pass into your breast milk.

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

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. STRIBILD may affect the way other medicines work, and other medicines may affect how STRIBILD works.

You should not take STRIBILD if you also take:

- any other medicines to treat HIV-1 infection
- other medicines that contain tenofovir (ATRIPLA[®], COMPLERA[®], VIREAD[®], TRUVADA[®])
- other medicines that contain emtricitabine or lamivudine (COMBIVIR[®], EMTRIVA[®], EPIVIR[®] or EPIVIR-HBV[®], EPZICOM[®], TRIZIVIR[®])
- adefovir (HEPSERA[®])

Especially tell your healthcare provider if you take:

- hormone-based contraceptives (birth control pills and patches)
- an antacid medicine that contains aluminum, magnesium hydroxide, or calcium carbonate. Take antacids at least 2 hours before or after you take STRIBILD.
- medicines to treat depression
- medicines to prevent organ transplant rejection
- medicines to treat high blood pressure
- any of the following medicines:
 - amiodarone (CORDARONE[®], PACERONE[®])
 - atorvastatin (LIPITOR[®], CADUET[®])
 - bepridil hydrochloric (VASCOR[®], BEPADIN[®])
 - bosentan (TRACLEER[®])
 - buspirone
 - carbamazepine (CARBATROL[®], EPITOL[®], EQUETRO[®], TEGRETO[®])
 - clarithromycin (BIAXIN[®], PREVPAC[®])
 - clonazepam (KLONOPIN[®])

- clorazepate (GEN-XENE[®], TRANXENE[®])
- colchicine (Colcrys[®])
- medicines that contain dexamethasone
- diazepam (VALIUM[®])
- digoxin (LANOXIN[®])
- disopyramide (NORPACE[®])
- estazolam
- ethosuximide (ZARONTIN[®])
- flecainide (TAMBOCOR[®])
- flurazepam
- fluticasone (FLOVENT[®], FLONASE[®], FLOVENT[®] DISKUS, FLOVENT[®] HFA, VERAMYST[®])
- itraconazole (SPORANOX[®])
- ketoconazole (NIZORAL[®])
- lidocaine (XYLOCAINE[®])
- mexiletine
- oxcarbazepine (TRILEPTAL[®])
- perphenazine
- phenobarbital (LUMINAL[®])
- phenytoin (DILANTIN[®], PHENYTEK[®])
- propafenone (RYTHMOL[®])
- quinidine (NEUDEXTA[®])
- rifabutin (MYCOBUTIN[®])
- rifapentine (PRIFTIN[®])
- risperidone (RISPERDAL[®], RISPERDAL CONSTA[®])
- salmeterol (SEREVENT[®]) or salmeterol when taken in combination with fluticasone (ADVAIR DISKUS[®], ADVAIR HFA[®])
- sildenafil (VIAGRA[®]), tadalafil (CIALIS[®]) or vardenafil (LEVITRA[®], STAXYN[®]), for the treatment of erectile dysfunction (ED). If you get dizzy or faint (low blood pressure), have vision changes or have an erection that last longer than 4 hours, call your healthcare provider or get medical help right away.
- tadalafil (ADCIRCA[®]), for the treatment of pulmonary arterial hypertension
- telithromycin (KETEK[®])
- thioridazine
- voriconazole (VFEND[®])
- warfarin (COUMADIN[®], JANTOVEN[®])
- zolpidem (AMBIEN[®], EDLULAR[®], INTERMEZZO[®], ZOLPIMIST[®])

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. Do not start any new medicines while you are taking STRIBILD without first talking with your healthcare provider or pharmacist.

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

How should I take STRIBILD?

- Take STRIBILD exactly as your healthcare provider tells you to take it.
STRIBILD is taken by itself (not with other antiretroviral medicines) to treat HIV-1 infection.

- STRIBILD is usually taken 1 time each day.
- Take STRIBILD with food.
- Do not change your dose or stop taking STRIBILD without first talking with your healthcare provider. Stay under a healthcare provider's care when taking STRIBILD.
- Do not miss a dose of STRIBILD. If you miss a dose of STRIBILD, take the missed dose as soon as you remember. If it is almost time for your next dose of STRIBILD, do not take the missed dose. Take the next dose of STRIBILD at your regular time. Do not take 2 doses at the same time to make up for a missed dose.
- If you take too much STRIBILD, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your STRIBILD supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to STRIBILD and become harder to treat.

What are the possible side effects of STRIBILD?

STRIBILD may cause the following serious side effects, including:

- **See "What is the most important information I should know about STRIBILD?"**
- **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 while you are taking STRIBILD. Your healthcare provider may tell you to stop taking STRIBILD if you develop new or worse kidney problems.
- **Bone problems** can happen in some people who take STRIBILD. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your healthcare provider may need to do tests to check your bones.
- **Changes in body fat can happen in people who take HIV-1 medicine.** These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.

The most common side effects of STRIBILD include:

- nausea
- diarrhea

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 STRIBILD. 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 STRIBILD?

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

Keep STRIBILD and all medicines out of reach of children.

General information about STRIBILD.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use STRIBILD for a condition for which it was not prescribed. Do not give STRIBILD to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about STRIBILD. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about STRIBILD that is written for health professionals.

For more information, call 1-800-445-3235 or go to www.STRIBILD.com.

What are the ingredients in STRIBILD?

Active ingredients: elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate

Inactive ingredients: lactose monohydrate, microcrystalline cellulose, silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, sodium lauryl sulfate, and magnesium stearate. The tablets are film-coated with a coating material containing indigo carmine (FD&C blue #2) aluminum lake, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide, and yellow iron oxide.

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

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