

**STRIBILD (elvitegravir + cobicistat + emtricitabine + tenofovir)****WHAT IS STRIBILD?**

Stribild is a tablet that contains three drugs used to fight HIV: emtricitabine (Emtriva, see fact sheet 420), tenofovir (Viread, see fact sheet 419), and elvitegravir (see fact sheet 466), plus cobicistat, which boosts blood levels of elvitegravir but does not directly work against HIV. Stribild is the third once-daily tablet that includes a complete antiretroviral regimen. The first two were Complera (see fact sheet 471) and Atripla (see fact sheet 472.)

The drugs in Stribild are an integrase inhibitor (elvitegravir, 150 mg) paired with a new booster, cobicistat (150 mg.) They are combined with two nucleoside analog reverse transcriptase inhibitors, or nukes (emtricitabine, 200 mg and tenofovir, 300 mg). These drugs block the reverse transcriptase enzyme. This enzyme changes HIV's genetic material (RNA) into the form of DNA. This has to occur before HIV's genetic code gets inserted into an infected cell's own genetic codes.

When HIV infects a cell, it combines its genetic code into the cell's own code. This is shown in fact sheet 400, step 5. Elvitegravir blocks this process. When elvitegravir blocks integration, HIV infects a cell but cannot make more copies of itself. Cobicistat is a booster. It increases the blood levels of elvitegravir. It does not directly work against HIV.

WHO SHOULD TAKE STRIBILD?

Stribild was approved in 2012 as an ARV for adults with HIV infection who have not yet taken any antiretroviral drugs. The FDA is requiring Gilead to study the drug's safety in women and children. People with liver or kidney problems may not be able to take Stribild.

While antiretroviral therapy (ART) is now recommended for all people living with HIV, there are no absolute rules about when to start antiretroviral therapy (ART). You and your health care provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your attitude about taking ART. Fact Sheet 404 has more information about guidelines for the use of ART. If you take Stribild, you can reduce your viral load to extremely low levels, and increase your CD4 cell counts. This should mean staying healthier longer. Stribild provides three drugs in one pill. It can be more convenient to use Stribild than

some other combinations of drugs. This could mean fewer missed doses and better control of HIV. Stribild can be an effective regimen of ARVs in one pill.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. They are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called "developing resistance" to the drug. See Fact Sheet 126 for more information on resistance. Sometimes, if your virus develops resistance to one drug, it will also have resistance to other ARVs. This is called "cross-resistance."

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS STRIBILD TAKEN?

Stribild is taken by mouth as a tablet, with food. The normal adult dose is one tablet, once a day with food. If you miss your dose, you can take Stribild up to 12 hours late. Otherwise, take your next dose at the regular time. Take Stribild and antacids at least 2 hours apart.

WHAT ARE THE SIDE EFFECTS?

When you start any ART, you may have temporary side effects such as headaches, high blood pressure, or a general sense of feeling ill. These side effects usually get better or disappear over time.

Tenofovir can cause kidney damage. Creatinine levels should be monitored in people taking tenofovir. Tenofovir can also damage the liver. People taking tenofovir should have their liver health monitored. Lactic acidosis (see fact sheet 556) swelling of the liver have been reported with the use of nucleoside analogs, including tenofovir, a component of Stribild.

Stribild is not approved for the treatment of chronic hepatitis B virus (HBV) infection. Severe acute exacerbations of hepatitis B have been reported in patients who are coinfecting with HBV and HIV-1 and have discontinued Emtriva or Viread, which are components of Stribild.

WARNINGS

Stribild should not be used with drugs that are processed through the same liver pathway, called CYP 3A4. This includes ritonavir, rifampin (used to treat tuberculosis, see fact sheet 508), lovastatin, simvastatin, pimozide, sildenafil for pulmonary arterial hypertension, triazolam, oral midazolam, and St. John's wort.

Tenofovir, a component of Stribild, can reduce bone mineral density (see fact sheet 557).

The most common side effects of Stribild are the same as with the drugs it contains: elvitegravir (see fact sheet 466), emtricitabine (see fact sheet 420), and tenofovir (see fact sheet 419). They include headache, diarrhea, nausea, vomiting, vivid dreams, anxiety, rash, dizziness, insomnia, and loss of appetite.

If you have had hepatitis B or C, your liver function tests may increase significantly. These should be monitored carefully.

HOW DOES STRIBILD REACT WITH OTHER DRUGS?

Stribild can interact with other drugs or supplements you are taking. **These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. Make sure that your health care provider knows about ALL drugs and supplements you are taking.**

As a condition of approval, Gilead will be required to conduct additional studies to help further characterize the drug's safety in women and children, how resistance develops to Stribild, and the possibility of interactions between Stribild and other drugs. Drugs to watch out for include other ARVs, drugs to treat tuberculosis (see fact sheet 518), for erectile dysfunction (such as Viagra), for heart rhythm (antiarrhythmics), and for migraine headaches. Interactions are also possible with several antihistamines (allergy medications), sedatives, drugs to lower cholesterol, and anti-fungal drugs.

The herb **St. John's Wort** (See Fact Sheet 729) lowers the blood levels of some non-nucleoside reverse transcriptase inhibitors. Do not take it with Stribild.

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