

TITLE - COBICISTAT + ELVITEGRAVIR + EMTRICITABINE+ TENOFOVIR / GENVOYA MEDICATION PATIENT INFORMATION IN ENGLISH

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Source : U.S. National Institutes of Health

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Drug information

Pronounce: Elvitegravir / Cobicistat / Emtricitabine / Tenofovir Disoproxil Fumarate

Brand Name: Stribild

Other Names: EVG / COBI / FTC / TDF, EVG / c / TDF / FTC

Drug Class: Combination Drugs

Integrase Strand Transfer Inhibitor (elvitegravir)

Nucleoside Reverse Transcriptase Inhibitor (emtricitabine, tenofovir DF)

Pharmacokinetic Enhancer (cobicistat)

Drug Image(s): (Click to enlarge)



What are the most important things to know about Stribild?

Stribild can cause serious, life-threatening side effects. These include a buildup of [lactic acid](#) in the blood ([lactic acidosis](#)), [liver](#) problems, new or worsening kidney problems, including kidney failure, and [drug interactions](#).

Contact your health care provider right away if you have any of the following symptoms that could be signs of lactic acidosis:

Weakness or tiredness

Unusual muscle pain

Shortness of breath or fast breathing

Stomach pain with nausea and vomiting

Cold or blue hands and feet

Dizziness or lightheadedness

Fast or abnormal heartbeat

Contact your health care provider right away if you have any of the following symptoms that could be signs of liver problems:

Yellowing of your skin or the whites of your eyes ([jaundice](#))

Dark-colored urine

Light-colored bowel movements

Loss of appetite for several days or longer

Nausea or vomiting

Pain, aching, or tenderness on the right side of your stomach/abdominal area

Itching

If you have both HIV and [hepatitis B virus infection](#) (HBV) and take Stribild, your HBV [infection](#) may get worse (flare up) if you stop taking Stribild. Do not stop taking Stribild without first talking to your health care provider.

Contact your health care provider right away if you have any of the following symptoms that could be signs of a worsening kidney problem (called [Fanconi Syndrome](#)), which may be related to tenofovir-containing drugs:

Bone pain that does not go away or gets worse

Pain in your arms, hands, legs or feet

Broken bones

Muscle pain or weakness

Taking Stribild with certain medicines may cause serious, life-threatening side effects. Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

While taking Stribild, it is important to keep all of your appointments with your health care provider.

What is Stribild?

Stribild is a prescription medicine approved by the U.S. [Food and Drug Administration](#) (FDA) for the treatment of HIV infection in adults and children 12 years of age and older who weigh at least 77 lbs (35 kg) and meet certain requirements, as determined by a health care provider.

Stribild is a complete HIV [treatment regimen](#) and should **not** be used with other HIV medicines

Stribild contains four different medicines: elvitegravir, [cobicistat](#), [emtricitabine](#), and [tenofovir disoproxil fumarate](#).

For more information on the use of Stribild in people with HIV, please refer to the [Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV](#) and the [Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection](#).

HIV medicines cannot cure HIV/AIDS, but taking HIV medicines every day helps people with HIV live longer, healthier lives. HIV medicines also reduce the risk of HIV [transmission](#). If you are taking HIV medicines, do not cut down on, skip, or stop taking them unless your health care provider tells you to.

What should I tell my health care provider before taking Stribild?

Before taking Stribild, tell your health care provider:

If you are allergic to any of the HIV medicines in Stribild (elvitegravir, [cobicistat](#), [emtricitabine](#), or [tenofovir disoproxil fumarate](#)) or any other medicines.

If you have liver problems, including hepatitis B virus infection (HBV).

If you have kidney problems.

If you have bone problems.

If you have any other medical conditions.

If you are pregnant or plan to become pregnant. Stribild should not be used during pregnancy because there may not be enough of the drug in the body during pregnancy. Talk to your health care provider about possible risks with taking Stribild during pregnancy. For more information on the use of Stribild during pregnancy, please refer to the [Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States](#).

If you are breastfeeding or plan to breastfeed. For women with HIV in the United States, the [Guideline](#) does not recommend breastfeeding. Before your baby is born, or if you are already breastfeeding, talk to your health care provider to discuss alternative options for feeding your baby.

If you are using [hormone](#)-based birth control (such as pills, implants, or vaginal rings). Your health care provider may recommend that you use additional or alternative forms of birth control while taking Stribild. For more information about using birth control and HIV medicines at the same time, view the HIVinfo [HIV and Birth Control infographic](#).

About other prescription and nonprescription medicines, vitamins, nutritional supplements, and herbal products (including St. John's wort) you are taking or plan to take. Stribild may affect the way other medicines or products work, and other medicines or products may affect how

Stribild works. **Taking Stribild together with certain medicines or products may cause serious, life-threatening side effects.**

How should I take Stribild?

Stribild comes in tablet form. Each tablet contains:

150 mg elvitegravir

150 mg [cobicistat](#)

200 mg [emtricitabine](#)

300 mg [tenofovir disoproxil fumarate](#)

Take Stribild according to your health care provider's instructions.

Take Stribild by mouth and with food. Do not take Stribild with other HIV medicines.

If you need to take a medicine for indigestion (antacid) that contains aluminum and magnesium hydroxide or calcium carbonate during treatment with Stribild, take it at least 2 hours before or after you take Stribild.

If you have taken too much Stribild, contact your health care provider or local poison control center (1-800-222-1222) right away, or go to the nearest hospital emergency room.

For more information on how to take Stribild, see the [FDA drug label](#).

What should I do if I forget a dose?

If you miss a [dose](#) of Stribild, take the missed dose as soon as you remember it. But if it is almost time for your next dose, skip the missed dose and just take your next dose at the regular time. Do not take two doses at the same time to make up for a missed dose.

What side effects can Stribild cause?

Stribild may cause side effects. Some side effects can be serious as noted above. Many side effects from HIV medicines, such as nausea or occasional dizziness, are manageable. See the HIVinfo fact sheet on [HIV Medicines and Side Effects](#) for more information.

Other possible side effects of Stribild include:

Bone problems, including bone pain, softening, or thinning ([osteopenia](#)), which may lead to fractures.

Changes in your [immune system](#) (called [immune reconstitution inflammatory syndrome](#) or IRIS). IRIS is a condition that sometimes occurs when the immune system begins to recover after

treatment with an HIV medicine. As the immune system gets stronger, it may have an increased response to a previously hidden infection.

Tell your health care 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. To learn more about possible side effects of Stribild, read the [drug label](#) or [package insert](#) or talk to your health care provider or pharmacist.

You can report side effects to FDA at 1-800-FDA-1088 (1-800-332-1088) or [online](#).

How should Stribild be stored?

Store Stribild at room temperature, 68°F to 77°F (20°C to 25°C).

Keep Stribild in the container that it came in and keep the container tightly closed. If the container has a small packet of drying agent (called a desiccant), do not remove it. The desiccant protects the medicine from moisture.

Do not use Stribild if the original seal over the container opening is broken or missing.

Throw away Stribild that is no longer needed or expired (out of date). Follow [FDA guidelines](#) on how to safely dispose of unused medicine.

Keep Stribild and all medicines out of reach of children.

Where can I find more information about Stribild?

For more information on the use of Stribild in people with HIV, please refer to the [Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV](#) and the [Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection](#).

This Patient Version drug summary is based on the following FDA label(s): [Tablet](#). The Patient Counseling Information section of the label includes information for people taking Stribild.

Stribild-related research studies, from [ClinicalTrials.gov](#).

A list of [FDA-approved HIV medicines](#), from HIVinfo.

Manufacturer Information

Gilead Sciences, Inc.

Main number: 800-445-3235

Patient assistance: 800-226-2056

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[FDA Label: Tablet PDF](#)