

# Complera

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## WHAT IS COMPLERA?

Complera is a complete HIV regimen used as part of [antiretroviral therapy \(ART\)](#). Complera contains three [antiretroviral drugs \(ARVs\)](#) combined in one tablet:

- [emtricitabine \(FTC, Emtriva\)](#)
- [rilpivirine \(RPV, Edurant\)](#)
- [tenofovir disoproxil fumarate \(tenofovir DF, TDF, Viread\)](#)

The FDA approved Complera in 2011 as an ARV for people with HIV infection. Complera is manufactured by [Gilead Sciences](#).

One of the drugs in Complera, rilpivirine, is a type of drug called a [non-nucleoside reverse transcriptase inhibitor \(NNRTI\)](#). The other two drugs, emtricitabine and tenofovir DF, are [nucleoside reverse transcriptase inhibitors \(NRTIs\)](#). NNRTIs and NRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used alone as a complete regimen to treat HIV infection, Complera may help:

- Reduce the amount of HIV in your blood. This is called [viral load](#).
- Increase the number of [CD4 cells](#) in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting [opportunistic infections \(OIs\)](#) that can happen when your immune system is weak. [Read more about viral suppression](#).

Complera [does not cure](#) HIV infection or [AIDS](#). You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

## WHO SHOULD TAKE COMPLERA?

Complera is a prescription three-drug fixed-dose combination medication to treat HIV infection in adults and children at least 12 years of age who weigh at least 77 pounds (35 kg):

- who have never taken ARVs before and who have a viral load that is no more than 100,000 copies/mL

**OR**

- in certain people who have a viral load less than 50 copies/mL when they start taking Complera, to replace their current HIV medicines

The safety and effectiveness of Complera has not been established in children less than 12 years of age weighing less than 77 pounds (35 kg). Complera has not been carefully studied in the elderly (65 years of age and older).

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. [Read more about U.S. ART guidelines.](#)

Complera provides three drugs in one pill. It can be more convenient to use Complera than some other combinations of drugs that must be taken separately or at different times of the day. This could mean fewer missed doses and better control of HIV. **Complera is used as a complete regimen for the treatment of HIV infection.**

### ***WHO SHOULD NOT TAKE COMPLERA?***

Do not take Complera if you are allergic to emtricitabine, rilpivirine, tenofovir DF, or any of the other ingredients in this drug.

Do not take Complera if you are taking any of the following medicines. Taking Complera with these medicines may affect how Complera works. Complera may cause serious or life-threatening side effects or death when used with these medicines:

- Seizure medicines: carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- [Tuberculosis \(TB\)](#) medicines: rifampin, rifapentine
- Proton pump inhibitor (PPI) medicines for stomach/intestinal problems: dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, rabeprazole
- Steroid medicine: dexamethasone or dexamethasone sodium phosphate (more than 1 dose)
- Herbal product: John's Wort (*Hypericum perforatum*)

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past four weeks, talk to your healthcare provider or pharmacist before starting treatment with Complera.

Complera is not recommended in people with moderate or severe kidney disease.

### ***WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING COMPLERA?***

Before you take Complera, tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have liver problems, including [hepatitis B virus \(HBV\)](#) or [hepatitis C virus \(HCV\)](#) infection
- Have [kidney problems](#)
- Have a history of depression or suicidal thoughts
- Have [bone problems](#)

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with with Complera. It is not known if Complera can harm your unborn baby. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. [Read more about pregnancy and HIV.](#)

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with Complera. At least two of the medicines in Complera can pass to your baby in your breastmilk. It is not known if the other medicine in Complera can pass to your baby in your breastmilk. Do not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

### **WHAT ABOUT DRUG RESISTANCE?**

Many new copies of HIV are mutations. These new copies 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. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. [Read more about HIV drug 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 COMPLERA TAKEN?**

Complera is taken by mouth as a tablet. Each Complera tablet contains 200 mg of emtricitabine, 25 mg of rilpivirine, and 300 mg of tenofovir DF. The recommended dosage of Complera in adults and children at least 12 years of age who weigh at least 77 pounds (35 kg) is one tablet once daily.

You should take Complera at the same time each day with food. Taking Complera with food is important to help get the right amount of medicine in your body. A protein drink does not replace food.

### **WHAT ARE THE SIDE EFFECTS?**

When you start any ARV, you may have temporary [side effects](#) such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of Complera are [depression](#), trouble sleeping or abnormal dreams, headaches, [diarrhea](#), nausea, [tiredness](#), dizziness, and rash.

Complera can cause serious side effects including:

**Worsening of HBV infection.** Your healthcare provider will test you for HBV before starting treatment with Complera. If you have HBV infection and take Complera, your HBV may get worse (flareup) if you stop taking Complera. A flare-up is when your HBV infection suddenly returns in a worse way than before. Do not stop taking Complera without first talking to your healthcare provider. Do not run out of Complera. Refill your

prescription or talk to your healthcare provider before your Complera is all gone. If you stop taking Complera, 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 Complera.

**Severe skin rash and allergic reactions.** Skin rash is a common side effect of Complera. Rash can be serious. Call your healthcare provider right away if you get a rash. In some cases, rash and allergic reaction may need to be treated in a hospital. If you get a rash with any of the following symptoms, stop taking Complera and call your healthcare provider or get medical help right away:

- Fever
- Skin blisters
- Mouth sores
- Redness or swelling of the eyes (conjunctivitis)
- Swelling of the face, lips, mouth, tongue or throat
- Trouble breathing or swallowing
- Pain on the right side of the stomach (abdominal) area
- Dark or “tea colored” urine

**Severe liver problems.** In rare cases, severe liver problems can happen that can lead to death. Tell your healthcare provider right away if you get these symptoms:

- Skin or the white part of your eyes turns yellow
- Dark or “tea-colored” urine
- Light-colored stools (bowel movements)
- Loss of appetite for several days or longer
- Nausea or vomiting
- Stomach-area pain

**Change in liver enzymes.** People with a history of HBV or HCV or who have certain liver enzyme changes may have an increased risk of developing new or worsening liver problems during treatment with Complera. Liver problems can also happen during treatment with Complera in people without a history of liver disease. Your healthcare provider may need to do tests to check your liver enzymes before and during treatment with Complera.

**Depression or mood changes.** Tell your healthcare provider right away if you have any of the following symptoms:

- Feel sad or hopeless
- Feel anxious or restless
- Have thoughts of hurting yourself (suicide) or have tried to hurt yourself

**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 during treatment with Complera. If you have had kidney problems in the past or need to take another medicine that can cause kidney problems, your healthcare provider may need to do blood tests to check your kidneys during your treatment with Complera.

**Bone problems.** Bone problems include bone pain or softening or thinning of bones (which may lead to fractures). Your healthcare provider may need to do additional tests to check your bones.

**Too much lactic acid in your blood (lactic acidosis).** [Lactic acidosis](#) is a serious but rare medical emergency that can cause death. Tell your healthcare provider right away if you develop any of these symptoms:

- Weakness or being more tired than usual
- Being short of breath or fast breathing
- Cold or blue hands and feet
- Fast or abnormal heartbeat
- Unusual muscle pain
- Stomach pain with nausea and vomiting
- Feel dizzy or lightheaded

**Immune Reconstitution Inflammatory Syndrome (IRIS).** [IRIS](#) is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting treatment with Complera.

These are not all the possible side effects of Complera. 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 DOES COMPLERA REACT WITH OTHER DRUGS?***

All ARVs 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. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take Complera with other medicines.

See above for a list of medications that should not be taken with Complera.

Complera is a complete regimen for the treatment of HIV infection; therefore, taking Complera with other ARVs for the treatment of HIV infection is not recommended.

### ***MORE INFORMATION***

Visit the [Complera website](#).

Download the full [Prescribing Information](#) with Patient Information leaflet.

Apply for the [Gilead Advancing Access Program](#).

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