

RILPIVIRINE/ EMTRICITABINE/ TENOFIVIR

Other NAMES: Complera®

WHY is this drug prescribed?

Complera is an antiretroviral (anti-HIV) drug made up of rilpivirine (*Edurant*), emtricitabine (*Emtriva*), and tenofovir (*Viread*). *Edurant* is a non-nucleoside reverse transcriptase inhibitor (NNRTIs or Non Nukes) and *Emtriva* and *Viread* are nucleoside reverse transcriptase inhibitors (NRTIs). *Complera* may be used alone to delay the progression of HIV infection. By doing this, your immune system should improve (increase in CD4⁺ count) and you will be better protected against infections.

Complera does not cure AIDS or completely kill the HIV virus, but helps to prevent further damage by slowing down the production of new viruses. Treatment with *Complera* does not reduce the risk of passing infection on to others. You will still be able to pass HIV by sexual contact, by blood transfer or by sharing needles. You should always use appropriate precautions to prevent passing HIV on to others.

HOW should this drug be taken?

The dose of *Complera* is one tablet (consisting of 25 mg rilpivirine, 200 mg of emtricitabine, and 300 mg of tenofovir) once a day, with a meal.

Your dosage is:

____ tablet once daily

What should you do if you FORGET a dose?

If you miss a dose of *Complera*, and it is less than **12 hours** since the appointed time take it as soon as possible, with a meal; then take your next dose at the scheduled time. However, if it is more than **12 hours** since you missed your dose, do not take a dose until your next regularly scheduled dose.

Why should you not forget to take this drug?

If you miss doses of *Complera*, the amount of HIV virus in your blood (known as the viral load) will start increasing again and your immune system will be further damaged. A few missed doses can be enough for *Complera* to stop being active. This is a phenomenon known as **resistance. Therefore, missing doses of *Complera* can decrease treatment options for the future.** Please do not stop *Complera* without talking to your doctor first.

What ADVERSE EFFECTS can this drug cause? What should you do about them?

Some people taking rilpivirine may experience depression or mood changes. Contact your doctor if you feel symptoms of sadness or hopelessness, thoughts of hurting yourself, anxiety or restlessness, or

have had previous struggles with depression.

Other side effects people experience include headache, trouble sleeping, and changes in body fat distribution.

If you develop a severe rash, or a rash with symptoms such as fever, blistering, mouth sores, red eyes, swelling, muscle or joint aches and a general feeling of being unwell, **STOP taking *Complera*. Speak with your doctor immediately.**

Your doctor will do blood tests regularly to see if there are any changes in your liver function, kidney function, cholesterol and triglyceride levels.

It is important that you keep your doctor appointments and come for your laboratory tests so that your progress can be followed.

What other PRECAUTIONS should you follow while using this drug?

You must make sure that you are taking the right dose. If you take higher doses of *Complera* than what is prescribed, you may increase the chance of having adverse effects. If you take lower doses of *Complera* than what is prescribed, the HIV virus may become resistant to the drug.

Inform your doctor and pharmacist of all prescribed and non-prescribed drugs you are taking. As well, you should inform them of natural products or recreational (street drugs) you are taking. The effect of combining alcohol and *Complera* has not been studied. If you wish to start a new

drug or natural product, please consult with your pharmacist before doing so.

Certain drugs can increase or decrease the effect of *Complera*. Also, *Complera* might influence the effect of other drugs you are taking. The doses of certain drugs may need to be increased if you are taking *Complera*.

The following drugs should not be taken with Complera:

- Anticonvulsants (carbamazepine, oxcarbazepine, phenobarbital, phenytoin)
- Rifamycins (rifampin, rifabutin, rifapentine)
- Proton pump inhibitors (e.g. esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole)
- St. John's Wort (*Hypericum perforatum*)

Do not take *Complera* with Emtriva, Viread, Truvada, Edurant, Combivir, 3TC, Heptovir, Kivexa or Trizivir since these drugs contain ingredients which duplicate or are similar to ingredients in *Complera*.

***Complera* should NOT be taken if you are pregnant or planning on becoming pregnant.** Please inform your doctor if you believe you are pregnant or if you wish to become pregnant in the near future. A registry has been established to monitor patients on *Complera* while pregnant. Please inform your doctor if you are pregnant, as he/she is able to register your exposure at 1-800-258-4263. Your doctor can recommend an appropriate treatment to help reduce the risk of passing the HIV virus on to your baby. Breastfeeding is NOT

recommended if you have HIV as you can transmit the virus to your baby through your breast milk.

How should this drug be STORED?

Complera should be stored in a cool (15-30°C) dry place, protected from light and well out of the reach of children. Ensure that the drug has not expired by checking the expiry date ("EXP") shown on the outside of the package.

Do not store in your bathroom or kitchen, as heat and moisture may cause the drug to be less active.

If you have any questions or concerns about this drug or if you are experiencing adverse effects, please discuss them with your pharmacist, doctor or nurse.

Write questions or concerns down to ensure they are addressed.

The following pharmacist is available to answer questions:

Pharmacist: _____
Telephone: _____

Reference: Product Monograph *Complera*® (rilpivirine/emtricitabine/tenofovir). Gilead Sciences Canada Inc: Mississauga, ON, 2012. Prepared by the Ontario HIV Pharmacy Professional Specialty Group, 2012.

Additional medication fact sheets and updates may be found at: www.hivclinic.ca

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MEDICATION

FACT SHEET