Genvoya (elvitegravir + cobicistat + emtricitabine + tenofovir alafenamide)

WHAT IS GENVOYA?

Genvoya is the fifth once-daily tablet that includes a complete antiretroviral regimen; it was approved by the FDA in 2015. The drug is one of six regimens recommended by the U.S. guidelines for initial treatment of HIV. Genvoya is a tablet that contains three drugs used to fight HIV: reverse transcriptase inhibitors emtricitabine (200 mg; Emtriva, see Fact Sheet 420) and tenofovir alafenamide (10 mg; TAF, similar to Viread, see Fact Sheet 419), integrase inhibitor elvitegravir (150 mg; Vitekta, see Fact Sheet 466), plus cobicistat (150 mg; Tybost, see Fact Sheet 455) which boosts blood levels of elvitegravir but does not directly work against HIV.

Genvoya is the first medication to use TAF. TAF is less likely to cause kidney or bone problems than Viread. Reverse transcriptase inhibitors 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 with the cell's own code. This is shown in Fact Sheet 106, step 5. Elvitegravir blocks this process. When that happens, 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 GENVOYA?

Genvoya was approved in 2015 as an antiretroviral (ARV) for people 12 years or older living with HIV who have not yet taken any antiretroviral drugs. It is also approved as a replacement for current medications in people who have never had a treatment failure, have been on the same medications for at least 6 months and have a viral load of less than 50 copies and no resistance to the medications in Genvoya. People with severe liver or kidney problems may not be able to take Genvoya.

While antiretroviral therapy (ART) is now recommended for all people living with HIV, there are no absolute rules about when to start 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 U.S. guidelines for the use of ART. If you take Genvoya, you can reduce your viral load to extremely low levels, and increase your CD4 cell counts. This should mean staying healthier longer and eliminating your risk of transmitting HIV to others.

Genvoya provides four drugs in one pill. It can be more convenient to use it than some other combinations of drugs. This could mean fewer missed doses and better control of HIV.

WHAT ABOUT DRUG RESISTANCE?

Many copies of HIV have mutations in their genes. These copies are slightly different from the original virus. Some mutant strains can keep multiplying even when you are taking an ARV. When this happens, the drug could stop working. This is called "developing resistance" to the drug (see Fact Sheet 126). 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 GENVOYA TAKEN?

Genvoya is taken by mouth with food. The normal adult dose is one tablet, once a day with food. If you miss your dose, you can take Genvoya up to 12 hours late. Otherwise, take your next dose at the regular time. Take Genvoya and antacids that contain aluminum or magnesium, such as milk of magnesia, 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.

Genvoya is usually very well tolerated. The most common reported side effect was nausea. Tenofovir can cause kidney or bone problems. Your health care provider should monitor your creatinine levels while you take Genvoya. Tenofovir can also damage the liver. Your health care provider should also monitor your liver health while you take this drug.

Lactic acidosis (see Fact Sheet 556), a type of serious liver injury, has been reported with the use of nucleoside analogs, including tenofovir, a component of Genvoya.

TAF works against the hepatitis B virus (HBV), but Genvoya has not been approved for the treatment of chronic HBV infection. HBV has been reported to become much worse in people living with both HBV and HIV who stopped taking emtricitabine or tenofovir, both of which are components of Genvoya.

WARNINGS

Genvoya should not be used with drugs or herbs that are processed through the same liver pathway, called CYP3A or CYP2A6. These include ritonavir, rifampin (used to treat tuberculosis; see Fact Sheet 518), lovastatin, simvastatin, pimozide, sildenafil, triazolam, oral midazolam, and St. John's wort.

Tenofovir, a component of Genvoya, can reduce bone mineral density (see Fact Sheet 557).

The most common side effects of Genvoya are the same as those for 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 results may change significantly. They should be monitored carefully.

HOW DOES GENVOYA REACT WITH OTHER DRUGS?

Genvoya 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.**

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