

Kivexa

Summary

Kivexa is a combination of two anti-HIV drugs, both of which belong to the group commonly called nukes. Each Kivexa tablet contains 600 mg of abacavir (Ziagen) and 300 mg of 3TC (lamivudine). The most common side effects of Kivexa can include unexpected tiredness, diarrhea, nausea, and headache. Kivexa is usually taken at a dose of one tablet daily, with or without food.

Note: Some people who take Kivexa may have a serious allergic (“hypersensitivity”) reaction to the abacavir it contains: please see the “Warnings” section. There is a screening test to help predict whether you are likely to have an abacavir hypersensitivity reaction. See CATIE’s fact sheet *Abacavir hypersensitivity screening*.

What is Kivexa?

Kivexa is the brand name of two anti-HIV drugs—abacavir (Ziagen) and 3TC—that are combined together in one tablet. Both of these drugs belong to a group or class of anti-HIV drugs (antiretrovirals) called nucleoside analogues or “nukes”. Kivexa is used in combination with other anti-HIV drugs to treat HIV.

How does Kivexa work?

To explain how Kivexa works, we need to first tell you some information about HIV. When HIV infects a cell, it takes control of that cell. HIV then forces the cell to make many more copies of the virus. To make these copies, the cell uses proteins called enzymes. When the activity of these enzymes is reduced the production of HIV slows.

Kivexa contains abacavir and 3TC, two drugs that belong to a class of anti-HIV drugs called nucleoside analogues. Abacavir and 3TC interfere with an enzyme called reverse transcriptase (RT), which is used by HIV-infected cells to make new viruses. Since abacavir and 3TC both inhibit, or reduce the activity of this enzyme, Kivexa causes HIV-infected cells to produce fewer viruses.

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How do people with HIV use Kivexa?

Kivexa is taken with at least one other anti-HIV drug. Such combinations are called antiretroviral therapy, or ART. For more information on ART, see CATIE's *Your Guide to HIV Treatment*.

For many people with HIV, the use of ART has increased their CD4+ cell counts and decreased the amount of HIV in their blood (viral load). These beneficial effects help to greatly reduce the risk of developing a life-threatening infection. Neither Kivexa nor any other anti-HIV medication is a cure for HIV. It is therefore important that you see your doctor for checkups and lab tests on a regular basis.

Evidence shows that HIV-positive people who are on ART, engaged in care, and have an ongoing undetectable viral load are substantially less likely to transmit HIV to others, be it through sex, when sharing equipment to use drugs or during pregnancy and birth. In fact, the evidence for sexual transmission shows that people on ART who maintain an undetectable viral load do not pass HIV to their sexual partners. For further information see the CATIE fact sheet *HIV treatment and an undetectable viral load to prevent HIV transmission*. However, it is still a good idea to use condoms because they can reduce your risk of getting and passing on other sexually transmitted infections.

Warnings

1. Hypersensitivity reaction

Up to 8% of people with HIV who use Kivexa experience an exaggerated immune reaction against the abacavir component of the combination. This reaction, called abacavir hypersensitivity reaction, is very serious and can be fatal.

Although the hypersensitivity reaction can occur at any time while a person is taking Kivexa, on average it occurs within the first six weeks of use. The manufacturer, ViiV Healthcare, states that you should stop using Kivexa if you have signs or symptoms from two or more of the following groups:

1. Fever
2. Rash

3. Gastrointestinal symptoms (including nausea, vomiting, diarrhea or belly pain)
4. General symptoms (including fatigue, lack of energy, achiness)
5. Respiratory symptoms (sore throat, shortness of breath, cough, unusual findings on X-rays of the chest)

If you develop symptoms from two or more of these groups while you are taking Kivexa or any drug containing abacavir, you should stop taking this medicine and contact your doctor right away. If a hypersensitivity reaction to abacavir has indeed occurred, then Kivexa should **never** be restarted, as a fatal reaction could occur within hours. You should also never take any other drug that contains abacavir.

There is a screening test to help predict whether you are likely to have an abacavir hypersensitivity reaction. See CATIE's fact sheet *Abacavir hypersensitivity screening*.

2. Restarting treatment

Kivexa should never be restarted following a hypersensitivity reaction, as a fatal reaction could occur within hours. You should also never take any other drug that contains abacavir (this includes Ziagen, Triumeq and Trizivir).

This hypersensitivity reaction has even occurred among people who did not have any problems when they first took abacavir-containing drugs, but who then stopped and restarted.

3. Cardiovascular risk

Data from a well-designed trial (called Reprise) of 7,769 people with HIV have been analysed. This was a study that recruited people at low to moderate risk of cardiovascular disease. Participants were randomly assigned to receive the cholesterol-lowering medicine pitavastatin or placebo. After an average of five years of monitoring, researchers found that people who received pitavastatin had a 35% reduced risk of major symptoms of cardiovascular disease (heart attack, stroke and so on).

Although people in Reprieve were not randomly assigned to receive their HIV treatment (they were all on treatment), the randomization used in the study helps to reduce the possibility of drawing biased conclusions when analyzing the data. The researchers are able to further analyse the information captured from the Reprieve study to answer important research questions. One such question is the potential risk associated with the use of the drug abacavir.

Since 2008, some observational studies have reported that there has been an increased risk of a heart attack in some people with HIV who used abacavir. However, because these studies were observational in design, they could not prove that use of abacavir was linked to an increased risk of a heart attack. Furthermore, most of these analyses from observational studies appeared to have issues – missing data or not being able to take into account factors such as smoking and substance use.

Now that has changed. An analysis from the very well-designed Reprieve study has found that recent or past use of abacavir was linked to a 50% increased risk for heart attack and other major symptoms of severe cardiovascular disease.

The analysis from Reprieve was able to consider factors such as sex, smoking, age, substance use, kidney health and so on. Even when the Reprieve researchers adjusted for these and other factors, abacavir was still linked to a significantly increased risk for heart attack and related issues.

These results from Reprieve have again heightened concern about the safety of abacavir-containing medicines.

Therefore, as a precaution, before starting Kivexa or any abacavir-containing medicine, let your doctor know if you have any of these or other risk factors for cardiovascular disease:

- your close family members (mother, father, brother, sister) have a history of problems such as heart attack or stroke
- you have high blood pressure, abnormal cholesterol or triglyceride levels in your blood, pre-diabetes or diabetes, or kidney injury/disease.

- you use tobacco or smoke drugs
- you inject drugs or use stimulants (e.g. cocaine, crystal meth, MDMA/ecstasy, amphetamine or speed)

Your doctor can help you find ways to reduce your risk factors for cardiovascular disease. Your doctor can also help you decide if abacavir is right for you.

4. Lactic acidosis and hepatic steatosis

In the current era, in very rare cases, two related conditions, lactic acidosis (a buildup of lactic acid in the blood) and hepatic steatosis (excess fat in the liver), have occurred in some people who have used nucleoside analogues. These conditions can be serious or fatal. They have mostly been seen in women and people who are overweight or who have been on nucleosides a long time, and can cause the following symptoms:

- unexpected tiredness or weakness
- nausea and/or vomiting
- persistent abdominal pain
- painful inflammation of the pancreas (pancreatitis)

If any of these symptoms occur without apparent reason, call your nurse or doctor right away.

Lactic acidosis is very rare. If you do develop any of these symptoms, it does not necessarily mean you have lactic acidosis, but you should still let your doctor know right away.

5. Hepatitis B

If someone with hepatitis B infection is taking 3TC—a component of Kivexa—the hepatitis can “flare up” (symptoms can develop) if the medication is stopped. People with hepatitis B who are taking Kivexa should be carefully monitored if they stop taking the drug. If you are co-infected with HBV, talk to your doctor about how best to treat this co-infection.

6. Pancreatitis

In very rare cases, some people taking the two medications found in Kivexa—abacavir and 3TC—have developed a painful inflammation of their pancreas gland. Talk to your doctor right away if these symptoms occur as they may be suggestive of pancreatitis:

- abdominal pain
- nausea
- vomiting
- fever
- anxiety
- unexpected sweating

Side effects

General

The general side effects that occur in people with HIV taking 3TC and abacavir separately may also occur in people taking Kivexa. These side effects include unexpected tiredness, diarrhea, nausea, sleeping problems and headache. Many people find that side effects caused by anti-HIV drugs improve or go away after the first several weeks of treatment.

Less common, but more serious, side effects may include peripheral neuropathy (a numbness, tingling or burning sensation in the hands or feet), neutropenia (a decrease in the number of white blood cells called neutrophils), and anemia (a decrease in hemoglobin or red blood cells).

Drug interactions

Always consult your doctor and pharmacist about taking any other prescription or non-prescription medication, including herbs, supplements, and street drugs.

Some drugs can interact with the abacavir in Kivexa, increasing or decreasing its levels in your body. Increased drug levels can cause you to experience side effects or make pre-existing side effects worse. On the other hand, if drug levels become too

low, HIV can develop resistance and your future treatment options may be reduced.

It may also be necessary to avoid drugs that do not affect abacavir drug levels, but cause similar side effects.

If you must take a drug that has the potential to interact with your existing medications, your doctor can do the following:

- adjust your dose of either your anti-HIV drugs or other medications
- prescribe different anti-HIV drugs for you

Drug interactions for Kivexa

No significant drug interactions have been reported with 3TC.

The following drugs interact or have the potential to interact with the abacavir in Kivexa. This list is not exhaustive.

- In men, the use of alcohol in combination with abacavir causes an increase of abacavir in the blood, which could cause an increase in toxicity. This has not been studied in women.
- Abacavir interacts with riociguat (used to treat pulmonary arterial hypertension) and can raise levels of riociguat in the blood about three times above its normal level. The manufacturer of abacavir, ViiV Healthcare recommends that both drugs should be used with caution. They note that the dose of riociguat may need to be reduced in people who use abacavir.

Resistance and cross-resistance

Over time, as new copies of HIV are made in the body, the virus changes its structure. These changes, called mutations, can cause HIV to resist the effects of anti-HIV drugs, which means those drugs will no longer work for you.

To reduce the risk of developing drug resistance, all anti-HIV drugs should be taken every day exactly as prescribed and directed. If doses are delayed, missed or not taken as prescribed, the level of medicines in the blood may fall too low. If this happens, the HIV in your body can become resistant

to the medication. If you find you are having problems taking your medications as directed, speak to your doctor, nurse or pharmacist about this. They can find ways to help you.

When HIV becomes resistant to one drug in a class, it sometimes becomes resistant to other drugs in that class. This is called cross-resistance. Feel free to talk with your doctor about your current and future treatment options. To help you decide what these future options might be, at some point your doctor can have a small sample of your blood analyzed to test for resistance. Should the HIV in your body become resistant to abacavir and/or 3TC, your doctor can recommend a new treatment combination for you.

Dosage and formulations

Kivexa is available as tablets, each containing 600 mg abacavir and 300 mg 3TC (lamivudine). The usual standard adult dose of Kivexa is one tablet daily, with or without food. All medications should always be taken as prescribed and directed.

Availability

Kivexa is licensed in Canada for the treatment of HIV infection in adults, in combination with other anti-HIV drugs. Your doctor can tell you more about the availability and coverage of Kivexa in your region. CATIE's online module *Federal, Provincial and Territorial Drug Access Programs* also contains information about Canadian drug coverage.

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