

Patient Information

VIREAD® (VEER ee ad) Tablets

Generic Name: tenofovir disoproxil fumarate (te NOE' fo veer dye soe PROX il FYOU-mar-ate)

Read this leaflet carefully before you start taking VIREAD. Also, read it each time you get your VIREAD prescription refilled, in case something has changed. This information does not take the place of talking with your healthcare provider when you start this medicine and at check ups. You should stay under a healthcare provider's care when taking VIREAD. Do not change or stop your medicine without first talking with your healthcare provider. Talk to your healthcare provider if you have any questions about VIREAD.

What is VIREAD and how does it work?

VIREAD is a type of medicine called an HIV-1 (human immunodeficiency virus) nucleotide analog reverse transcriptase inhibitor (NRTI). VIREAD is always used in combination with other anti-HIV medicines to treat people with HIV-1 infection. VIREAD is for adults age 18 and older.

HIV infection destroys CD4 (T) cells, which are important to the immune system. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) develops.

VIREAD helps to block HIV-1 reverse transcriptase, a chemical in your body (enzyme) that is needed for HIV-1 to multiply. VIREAD lowers the amount of HIV-1 in the blood (called viral load) and may help to increase the number of T cells (called CD4 cells). Lowering the amount of HIV-1 in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

Does VIREAD cure HIV-1 or AIDS?

VIREAD does not cure HIV-1 infection or AIDS. The long-term effects of VIREAD are not known at this time. People taking VIREAD may still get opportunistic infections or other conditions that happen with HIV-1 infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium* complex (MAC) infections.

Does VIREAD reduce the risk of passing HIV-1 to others?

VIREAD does not reduce the risk of passing HIV-1 to others through sexual contact or blood contamination. Continue to practice safe sex and do not use or share dirty needles.

Who should not take VIREAD?

Together with your healthcare provider, you need to decide whether VIREAD is right for you.

Do not take VIREAD if

- you are allergic to VIREAD or any of its ingredients

- you are already taking TRUVADA® or ATRIPLA™ because VIREAD is one of the active ingredients in TRUVADA and ATRIPLA

What should I tell my healthcare provider before taking VIREAD?

Tell your healthcare provider

- *If you are pregnant or planning to become pregnant:* The effects of VIREAD on pregnant women or their unborn babies are not known.
- *If you are breast-feeding:* Do not breast-feed if you are taking VIREAD. Do not breast-feed if you have HIV. If you are a woman who has or will have a baby, talk with your healthcare provider about the best way to feed your baby. If your baby does not already have HIV, there is a chance that the baby can get HIV through breast-feeding.
- **If you have kidney or bone problems**
- **If you have liver problems including Hepatitis B Virus infection**
- **Tell your healthcare provider about all your medical conditions**

TELL YOUR HEALTHCARE PROVIDER ABOUT ALL THE MEDICINES YOU TAKE, INCLUDING PRESCRIPTION AND NON-PRESCRIPTION MEDICINES AND DIETARY SUPPLEMENTS. ESPECIALLY TELL YOUR HEALTHCARE PROVIDER IF YOU TAKE:

- **VIDEX, VIDEX EC (DIDANOSINE).** VIREAD MAY INCREASE THE AMOUNT OF VIDEX IN YOUR BLOOD. YOU MAY NEED TO BE FOLLOWED MORE CAREFULLY IF YOU ARE TAKING **VIDEX AND VIREAD** TOGETHER. IF YOU ARE TAKING VIDEX AND VIREAD TOGETHER YOUR HEALTHCARE PROVIDER MAY NEED TO REDUCE YOUR DOSE OF VIDEX.
- **REYATAZ (ATAZANAVIR SULFATE) OR KALETRA (LOPINAVIR/RITONAVIR).** THESE MEDICINES MAY INCREASE THE AMOUNT OF VIREAD IN YOUR BLOOD, WHICH COULD RESULT IN MORE SIDE EFFECTS. YOU MAY NEED TO BE FOLLOWED MORE CAREFULLY IF YOU ARE TAKING **VIREAD AND REYATAZ OR KALETRA TOGETHER.** VIREAD MAY DECREASE THE AMOUNT OF REYATAZ IN YOUR BLOOD. IF YOU ARE TAKING VIREAD AND REYATAZ TOGETHER YOU SHOULD ALSO BE TAKING NORVIR (RITONAVIR).

IT IS A GOOD IDEA TO KEEP A COMPLETE LIST OF ALL THE MEDICINES THAT YOU TAKE. MAKE A NEW LIST WHEN MEDICINES ARE ADDED OR STOPPED. GIVE COPIES OF THIS LIST TO ALL OF YOUR HEALTHCARE PROVIDERS **EVERY** TIME YOU VISIT YOUR HEALTHCARE PROVIDER OR FILL A PRESCRIPTION.

How should I take VIREAD?

- Stay under a healthcare provider's care when taking VIREAD. Do not change your treatment or stop treatment without first talking with your healthcare provider.

- Take VIREAD exactly as your healthcare provider prescribed it. Follow the directions from your healthcare provider, exactly as written on the label. Set up a dosing schedule and follow it carefully.
- The usual dose of VIREAD is 1 tablet once a day, in combination with other anti-HIV medicines. If you have kidney problems, your healthcare provider may recommend that you take VIREAD less frequently.
- VIREAD may be taken with or without a meal.
- When your VIREAD supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to VIREAD and become harder to treat.
- Only take medicine that has been prescribed specifically for you. Do not give VIREAD to others or take medicine prescribed for someone else.

What should I do if I miss a dose of VIREAD?

It is important that you do not miss any doses. If you miss a dose of VIREAD, take it as soon as possible and then take your next scheduled dose at its regular time. If it is almost time for your next dose, do not take the missed dose. Wait and take the next dose at the regular time. Do not double the next dose.

What happens if I take too much VIREAD?

If you suspect that you took more than the prescribed dose of VIREAD, contact your local poison control center or emergency room right away.

As with all medicines, VIREAD should be kept out of reach of children.

What should I avoid while taking VIREAD?

- Do not breast-feed. See “What should I tell my healthcare provider before taking VIREAD?”

What are the possible side effects of VIREAD?

- Clinical studies: The most common side effects of VIREAD are: diarrhea, nausea, vomiting, and flatulence (intestinal gas).
- Marketing experience: Other side effects reported since VIREAD has been marketed include: weakness, inflammation of the pancreas, low blood phosphate, dizziness, shortness of breath, and rash.
- Some patients treated with VIREAD have had kidney problems. If you have had kidney problems in the past or need to take another drug that can cause kidney problems, your healthcare provider may need to perform additional blood tests.
- Laboratory tests show changes in the bones of patients treated with VIREAD. It is not known whether long-term use of VIREAD will cause damage to your bones. If you have had bone problems in the past, your healthcare provider may need to perform additional tests or may suggest additional medication.
- Some patients taking antiviral drugs like VIREAD have developed a condition called lactic acidosis (a buildup in the blood of lactic acid, the same substance that causes your muscles to burn during heavy exercise). Symptoms of lactic acidosis include nausea, vomiting, unusual or unexpected stomach discomfort,

and weakness. If you notice these symptoms or if your medical condition changes suddenly, call your healthcare provider right away.

- Changes in body fat have been seen in some patients taking anti-HIV medicine. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen. The cause and long term health effects of these conditions are not known at this time.
- If you have hepatitis B virus (HBV) infection, you may have a “flare-up” of hepatitis B, in which the disease suddenly returns in a worse way than before if you stop taking VIREAD. VIREAD is not **approved** for the treatment of Hepatitis B Virus infection.
- There have been other side effects in patients taking VIREAD. However, these side effects may have been due to other medicines that patients were taking or to the illness itself. Some of these side effects can be serious.
- This list of side effects is **not** complete. If you have questions about side effects, ask your healthcare provider. You should report any new or continuing symptoms to your healthcare provider right away. Your healthcare provider may be able to help you manage these side effects.

How do I store VIREAD?

- Keep VIREAD and all other medications out of reach of children.
- Store VIREAD at room temperature 77 °F (25 °C). It should remain stable until the expiration date printed on the label.
- Do not keep your medicine in places that are too hot or cold.
- Do not keep medicine that is out of date or that you no longer need. If you throw any medicines away make sure that children will not find them.

General advice about prescription medicines:

TALK TO YOUR HEALTHCARE PROVIDER IF YOU HAVE ANY QUESTIONS ABOUT THIS MEDICINE OR YOUR CONDITION. MEDICINES ARE SOMETIMES PRESCRIBED FOR PURPOSES OTHER THAN THOSE LISTED IN A PATIENT INFORMATION LEAFLET. IF YOU HAVE ANY CONCERNS ABOUT THIS MEDICINE, ASK YOUR HEALTHCARE PROVIDER. YOUR HEALTHCARE PROVIDER OR PHARMACIST CAN GIVE YOU INFORMATION ABOUT THIS MEDICINE THAT WAS WRITTEN FOR HEALTH CARE PROFESSIONALS. DO NOT USE THIS MEDICINE FOR A CONDITION FOR WHICH IT WAS NOT PRESCRIBED. DO NOT SHARE THIS MEDICINE WITH OTHER PEOPLE. DO NOT USE IF SEAL OVER BOTTLE OPENING IS BROKEN OR MISSING.

What are the ingredients of VIREAD?

Active Ingredient: tenofovir disoproxil fumarate

Inactive Ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and pregelatinized starch. The tablets are coated with Opadry II Y-30-10671-A, which contains FD&C blue #2 aluminum lake, hydroxypropyl methylcellulose 2910, lactose monohydrate, titanium dioxide, and triacetin.

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