

- VIREAD should not be administered in combination with HEPSERA [See Warnings and Precautions (5.4)].
- Decreases in bone mineral density have been observed with the use of VIREAD in patients with HIV. Bone mineral density monitoring should be considered in patients who have a history of pathologic bone fracture or at risk for osteopenia [See Warnings and Precautions (5.6)].
- In the treatment of chronic hepatitis B, the optimal duration of treatment is unknown. The relationship between response and long-term prevention of outcomes such as hepatocellular carcinoma is not known.

17.2 FDA-Approved Patient Labeling

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 a nucleotide analog reverse transcriptase and HBV polymerase inhibitor (NRTI).

Use in the Treatment of HIV-1 Infection:

VIREAD is a treatment for Human Immunodeficiency Virus (HIV) infection in adults age 18 years and older. VIREAD is always used in combination with other anti-HIV-1 medicines to treat people with HIV-1 infection.

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).

Use in the Treatment of Chronic Hepatitis B:

VIREAD is also used to treat chronic hepatitis B (an infection with hepatitis B virus [HBV]) in adults age 18 years and older. VIREAD works by interfering with the normal working of enzymes (HBV DNA polymerase) that are essential for the HBV virus to

reproduce itself. VIREAD may help lower the amount of hepatitis B virus in your body by lowering the ability of the virus to multiply and infect new liver cells.

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.

We do not know how long VIREAD may help your hepatitis. Sometimes viruses change in your body and medicines no longer work. This is called drug resistance.

We do not know if VIREAD will reduce your chances of getting liver cancer from chronic hepatitis B.

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

VIREAD does not reduce the risk of passing HIV-1 or HBV 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
- you have not already discontinued treatment with HEPSERA

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**
- **If you have HIV-1 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.
- **If you are taking VIREAD to treat your HIV or if you have HIV and HBV co-infection and are taking VIREAD, always take VIREAD in combination with other anti-HIV medicines. VIREAD and other products like VIREAD may be less likely to work in the future if you are not taking VIREAD with other anti-HIV medicines because you may develop resistance to those medicines.**
- **Talk to your doctor about taking an HIV test before you start treatment with VIREAD for chronic hepatitis B.**
- The usual dose of VIREAD is 1 tablet once a day. 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 in patients with HIV-1:** The most common side effects of VIREAD are: rash, diarrhea, headache, pain, depression, weakness, and nausea. Less common side effects include vomiting, dizziness, and intestinal gas.

Clinical studies in patients with chronic hepatitis B: The most common side effect of VIREAD is nausea. Less common side effects include abdominal pain, diarrhea, headache, dizziness, fatigue, nasopharyngitis, back pain, and skin rash.

- **Marketing experience:** Other side effects reported since VIREAD has been marketed include: allergic reaction, low blood phosphate, shortness of breath, increased liver enzymes, increased amylase, inflammation of the liver, stomach pain, inflammation of the pancreas, rash, and weakness.
- 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. **Kidney problems may be associated with muscle problems and softening of the bones.**
- 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-1 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 HBV infection or HIV and HBV infection together, 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. Do not stop taking VIREAD without your doctor’s advice. After stopping VIREAD, tell your doctor immediately about any new, unusual, or worsening symptoms that you notice after stopping treatment. After you stop taking VIREAD, your doctor will still need to check your health and take blood tests to check your liver for several months.
- 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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