

Advise patients not to share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.

Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Female patients should be advised not to breastfeed because it is not known if TIVICAY can be passed to your baby in your breast milk and whether it could harm your baby. Mothers with HIV-1 should not breastfeed because HIV-1 can be passed to the baby in the breast milk.

Instruct patients to read the Patient Information before starting TIVICAY and to reread it each time the prescription is renewed. Instruct patients to inform their physician or pharmacist if they develop any unusual symptom, or if any known symptom persists or worsens.

Instruct patients that if they miss a dose, they should take it as soon as they remember. If they do not remember until it is within 4 hours of the time for the next dose, they should be instructed to skip the missed dose and go back to the regular schedule. Patients should not double their next dose or take more than the prescribed dose.

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Manufactured for:

ViiV Healthcare

Research Triangle Park, NC 27709

by:

GlaxoSmithKline

Research Triangle Park, NC 27709

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TVC:5PI

Patient Information

TIVICAY® (TIV-eh-kay)

(dolutegravir)

tablets

Read this Patient Information before you start taking TIVICAY and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is TIVICAY?

TIVICAY is a prescription HIV-1 medicine that is used with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

It is not known if TIVICAY is safe and effective in children under 12 years of age or who weigh less than 88 pounds.

When used with other HIV-1 medicines to treat HIV-1 infection, TIVICAY may help:

- reduce the amount of HIV-1 in your blood. This is called “viral load”.

- increase the number of white blood cells called CD4+ (T) cells in your blood, which help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may help improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

TIVICAY does not cure HIV-1 infection or AIDS. You must stay on continuous HIV-1 therapy to control HIV-1 infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others.

- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions about how to prevent passing HIV to other people.

Who should not take TIVICAY?

Do not take TIVICAY if you:

- have ever had an allergic reaction to a medicine that contains dolutegravir (TIVICAY, TRIUMEQ).
- take dofetilide (TIKOSYN®). Taking TIVICAY and dofetilide (TIKOSYN) can cause side effects that may be life-threatening.

What should I tell my healthcare provider before taking TIVICAY?

Before you take TIVICAY, tell your healthcare provider if you:

- have ever had an allergic reaction to TIVICAY.
- have or had liver problems, including hepatitis B or C infection.
- have any other medical condition.
- are pregnant or plan to become pregnant. It is not known if TIVICAY will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking TIVICAY.

Pregnancy Registry. There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take TIVICAY.**
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - It is not known if TIVICAY passes into your breast milk.
 - Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements.

TIVICAY and other medicines may affect each other causing side effects. TIVICAY may affect the way

other medicines work, and other medicines may affect how TIVICAY works.

Especially tell your healthcare provider if you take:

- other HIV-1 medicines including: efavirenz (SUSTIVA[®]), etravirine (INTELENCE[®]), fosamprenavir (LEXIVA[®])/ritonavir (NORVIR[®]), nevirapine (VIRAMUNE[®]), tipranavir (APTIVUS[®])/ritonavir (NORVIR).
- another medicine that contains dolutegravir (TRIUMEQ).
- antacids, laxatives or other medicines that contain aluminum, magnesium, sucralfate (CARAFATE[®]), or buffered medicines. TIVICAY should be taken at least 2 hours before or 6 hours after you take these medicines.
- iron or calcium supplements. Supplements including multivitamins containing calcium or iron may be taken at the same time with TIVICAY if taken with food. Otherwise, TIVICAY should be taken at least 2 hours before or 6 hours after you take these medicines.
- anti-seizure medicines:
 - oxcarbazepine (TRILEPTAL[®])
 - phenytoin (DILANTIN[®], DILANTIN[®]-125, PHENYTEK[®])
 - phenobarbital (LUMINAL[®])
 - carbamazepine (CARBATROL[®], EQUETRO[®], TEGRETOL[®], TEGRETOL[®]-XR, TERIL[®], EPITOL[®])
- St. John's wort (*Hypericum perforatum*)
- a medicine that contains metformin
- rifampin (RIFATER[®], RIFAMATE[®], RIMACTANE[®], RIFADIN[®])

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take TIVICAY?

- **Take TIVICAY exactly as your healthcare provider tells you.**
- Do not change your dose or stop taking TIVICAY without talking with your healthcare provider.
- Stay under the care of a healthcare provider while taking TIVICAY.
- You can take TIVICAY with or without food.
- If you miss a dose of TIVICAY, take it as soon as you remember. If it is within 4 hours of your next dose, skip the missed dose and take the next dose at your regular time. Do not take 2 doses at the same time. If you are not sure about your dosing, call your healthcare provider.
- Do not run out of TIVICAY. The virus in your blood may become resistant to other HIV-1 medicines if TIVICAY is stopped for even a short time. When your supply starts to run low, get more from your healthcare provider or pharmacy.
- If you take too much TIVICAY, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of TIVICAY?

TIVICAY may cause serious side effects, including:

- **Allergic reactions.** Call your healthcare provider right away if you develop a rash with

TIVICAY. Stop taking TIVICAY and get medical help right away if you:

- **develop a rash with any of the following signs or symptoms**
 - fever
 - generally ill feeling
 - extreme tiredness
 - muscle or joint aches
 - blisters or sores in mouth
 - blisters or peeling of the skin
 - redness or swelling of the eyes
 - swelling of the mouth, face, lips, or tongue
 - problems breathing
- **develop any of the following signs or symptoms of liver problems:**
 - yellowing of the skin or whites of the eyes
 - dark or tea-colored urine
 - pale-colored stools or bowel movements
 - nausea or vomiting
 - loss of appetite
 - pain, aching, or tenderness on the right side below the ribs
- **Changes in liver tests.** People with a history of hepatitis B or C virus may have an increased risk of developing new or worsening changes in certain liver tests during treatment with TIVICAY. Your healthcare provider may do tests to check your liver function before and during treatment with TIVICAY.
- **Changes in body fat** can happen in people who take HIV-1 medicines. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these problems are not known.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after starting your HIV-1 medicine.

The most common side effects of TIVICAY include:

- see “Allergic reactions” above
- trouble sleeping
- tiredness
- headache

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of TIVICAY. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TIVICAY?

- Store TIVICAY at room temperature between 68°F to 77°F (20°C to 25°C).

Keep TIVICAY and all medicines out of the reach of children.

General information about the safe and effective use of TIVICAY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TIVICAY for a condition for which it was not prescribed. Do not give TIVICAY to other people, even if they have the same symptoms you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about TIVICAY that is written for health professionals.

For more information, call 1-877-844-8872 or go to www.TIVICAY.com.

What are the ingredients in TIVICAY?

Active ingredient: dolutegravir sodium

Inactive ingredients: d-mannitol, microcrystalline cellulose, povidone K29/32, sodium starch glycolate, and sodium stearyl fumarate. The tablet film-coating contains the inactive ingredients iron oxide yellow, macrogol/PEG, polyvinyl alcohol-part hydrolyzed, talc, and titanium dioxide.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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PRINCIPAL DISPLAY PANEL

NDC 49702-228-13

Tivicay®

(dolutegravir)

Tablets

50 mg

30 Tablets

Rx Only

Each film-coated tablet contains dolutegravir sodium equivalent to 50 mg of dolutegravir.

Store at controlled room temperature of 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) (see USP).