



DOLUTEGRAVIR (TIVICAY®)

50 mg tablet

How does this medication work?

Dolutegravir (Tivicay) is an antiretroviral that prevents human immunodeficiency virus (HIV) from replicating. Dolutegravir belongs to a group of medicines called integrase inhibitors. The enzyme integrase is essential for integration of the viral DNA into the CD4+ T cells (immune system cells). Tivicay is prescribed in combination with other antiretrovirals to prevent the virus from attacking the immune system.

Tivicay does not cure AIDS and does not eradicate the virus. There will always remain a risk of HIV transmission by means of sexual activity or by contact with blood. Therefore, always take safe precautions (latex condoms, clean syringes, etc.).

Women of child-bearing age must use adequate means of contraception.

How do I take this medication?

Tivicay

- 1 x 50-mg tablet once daily
- 1 x 50-mg tablet twice daily

Tivicay may be taken **with or without food**.

Adhering to your antiretroviral therapy is a must. This means not forgetting doses, taking your medication as prescribed and not stopping your treatment. It is crucial to take your medication regularly, at the same time every day, and to follow your dosing schedule as closely as possible.

Adherence to treatment will prevent the onset of resistance (the ability of the virus to recognize the medication and render it ineffective) and avoid treatment failure (the loss in effectiveness of the antiretroviral treatment), which would translate into a higher viral load and a lower number of CD4 cells (cells that allow your system to fight infection).

At one time or another, anyone can have a lower compliance with the treatment. The key to success is motivation.



Do not hesitate to contact your health care team so they can explain the benefits of the therapy. They can also provide you with tips to help you adhere to your treatment.

Never stop or modify your treatment without first talking to your doctor.

Can I take Tivicay® with my other medication?

Dofetilide (Tikosyn): Tivicay should not be coadministered with dofetilide due to the risk of severe adverse effects.

Oxcarbazepine (Trileptal), phenytoin (Dilantin), phenobarbital, carbamazepine, nevirapine (Viramune), St. John's wort, etravirine (Intelence) and metformin (Glucophage) are all medications that interact with Tivicay. First talk to your doctor before taking these medications. He may modify the dosage and schedule follow up appointments.

Polyvalent cation-containing medications like antacids, laxatives and sucralfate can reduce Tivicay absorption.

Take Tivicay 2 hours before or 6 hours after these medications.

Calcium and iron

Tivicay with food: Tivicay can be taken with iron or calcium without needing to space the doses out.

Tivicay on an empty stomach: take Tivicay 2 hours before or 6 hours after taking calcium or iron.

First talk to your doctor or pharmacist before taking any new **prescription or nonprescription medicine**.



What are the adverse effects of this medication?

Normal reactions which will disappear or can be treated
Continue the medication



- Difficulty falling asleep
- Fatigue
- Diarrhea, nausea
- Headache

Contact your doctor
Continue the medication



- Rash alone (skin redness)
- Muscle pain or muscle weakness

See your doctor **IMMEDIATELY**

Rash WITH :

- Fever, oral ulcers (lesions)
- Swelling, blisters (bubbles on skin)
- Eye redness
- Nausea, vomiting, diarrhea
- Muscle pain or muscle weakness
- Extreme fatigue



Medical follow up: through regular blood testing, your doctor will monitor the effect of these medications on your liver, especially if you have hepatitis B or C. At the beginning of the treatment, your doctor will also measure the effect of Tivicay on your creatinine clearance. Tivicay can alter the parameters of creatinine clearance without however affecting your liver. Tell your doctor and pharmacist if you experience any adverse effect that bothers you so they can help you better cope with it.

I forgot a dose!

WITH TIVICAY 50 MG ONCE DAILY

You realize that you forgot a dose the same day the dose was scheduled: take the missed dose as soon as you remember and continue with your regular dosing schedule.

You realize that you forgot a dose the next day the dose was scheduled: do not take the missed dose. Continue with your regular dosing schedule.

WITH TIVICAY 50 MG TWICE DAILY

You realize that you forgot a dose and there's more than 6 hours before your next dose: take the missed dose as soon as you remember and continue with your regular dosing schedule.

You realize that you forgot a dose and there's less than 6 hours before your next dose: skip the missed dose and continue with your regular dosing schedule.



Can I drink alcohol with Tivicay ?

Avoid excessive or regular alcohol consumption (beer, wine and spirits), which can increase the risk of hepatitis (liver inflammation) or interact with some of your medications.



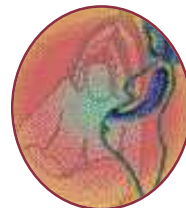
However, avoid "skipping" a dose only because you wish to have a drink. Unless contraindicated by your doctor, a reasonable alcohol consumption (in social settings) shouldn't harm you.

Pregnancy and breastfeeding

We do not know the effects of Tivicay in pregnant women.

First talk to your doctor if you are pregnant or plan to become pregnant and wish to take dolutegravir.

The virus can be passed through the breast milk. Breastfeeding is therefore not recommended in women infected with HIV.



General advice

Keep all of your appointments with your doctor and health care team so they can closely monitor your health.

For more information on your medication, or for tips on how to better manage your treatment, do not hesitate to ask your doctor or pharmacist for advice as they know your medication well.

Contact person: _____

Telephone number: _____

Storage

Store Tivicay in a dry place at room temperature (between 15°C to 30°C or 59°F to 86°F); avoid moist places like bathrooms.

Keep in a sealed container, out of sight and out of reach of children.

