

TIVICAY FILM-COATED TABLETS

Dolutegravir (50 mg)

What is in this leaflet

1. What Tivicay is used for
2. How Tivicay works
3. Before you use Tivicay
4. How to use Tivicay
5. While you are using it
6. Side Effects
7. Storage and Disposal of Tivicay
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Tivicay is used for

Tivicay contains the active ingredient dolutegravir 50 mg (as 52.6 mg dolutegravir sodium) which is an antiretroviral medicine known as an integrase inhibitor (which inhibit the reproduction of retroviruses such as HIV).

Tivicay is used for the treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents (inhibit the reproduction of retroviruses) in adults and children over 12 years of age.

How Tivicay works

Tivicay does not cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. As a result of that, it also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

Not everyone responds to treatment with Tivicay in the same way. Your doctor will monitor the effectiveness of your treatment.

Tivicay is always used in combination with other anti-retroviral medicines

(*combination therapy*). To control your HIV infection, and to stop your illness from getting worse, you must keep taking all your medicines, unless your doctor tells you to stop taking any.

Before you use Tivicay

When you must not use it

Don't use Tivicay

- If you are allergic to dolutegravir or any of the other ingredients of this medicine.
- In combination with the medicine dofetilide (to treat heart conditions).

If you think this applies to you, don't use Tivicay until you have checked with your doctor.

Tivicay should not be used in children and adolescents with HIV infection that is resistant to other medicines similar to Tivicay.

Before you start to use it

Do not give this medicine to children under 12 years of age, weighing less than 40 kg or with HIV infection that is resistant to other medicines similar to Tivicay. The use of Tivicay in children under 12 has not yet been studied.

Pregnancy

If you are pregnant, if you become pregnant, or if you are planning to have a baby, talk to your doctor about the risks and benefits of taking Tivicay.

Breast-feeding

Women who are HIV-positive must not breast feed because HIV infection can be passed on to the baby in breast milk. It is not known whether the

ingredients of Tivicay can pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding, talk to your doctor immediately.

Taking other medicines

Tell your doctor or pharmacist if you're taking any other medicines, if you have taken any recently or if you start taking new ones. This includes medicines bought without a prescription.

Some medicines may affect how Tivicay works, or make it more likely that you'll have side effects. These include:

- metformin, to treat diabetes
- medicines called antacids, to treat indigestion and heartburn.
- calcium supplements, iron supplements and multivitamins.
- etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir, to treat HIV infection
- rifampicin, to treat tuberculosis (TB) and other bacterial infections
- phenytoin and phenobarbital, to treat epilepsy
- oxcarbazepine and carbamazepine, to treat epilepsy or bipolar disorder
- St. John's wort (*Hypericum perforatum*), a herbal remedy to treat depression

Tell your doctor or pharmacist if you are taking any of these.

This is not a complete list of medications to be careful with, please ask your doctor or pharmacist for further information.

How to use Tivicay

How much to use

If you do not have resistance to integrase inhibitors, the usual dose is one tablet once daily (dolutegravir 50 mg).

If you are taking certain other medicines (e.g. efavirenz, nevirapine, tipranavir/ritonavir, or rifampicin), the dose is one tablet twice daily.

If you have resistance to integrase inhibitors, the dose is one tablet twice daily.

Use in children and adolescents
Children and adolescents aged between 12 and 17 years and weighing at least 40 kg can take the adult dose of one tablet (50 mg), once daily.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How to take

Swallow the tablet with some liquid. Tivicay can be taken with or without food. When Tivicay is taken twice a day, your doctor may advise you to take with food.

When to use it

Always use Tivicay exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

Antacid medicines

Antacids, to treat indigestion and heartburn, can stop Tivicay being absorbed into your body and make it less effective.

Do not take an antacid during the 6 hours before you take Tivicay, or for at least 2 hours after you take it. Talk to your doctor for further advice on taking acid-lowering medicines with Tivicay.

Calcium supplements, iron supplements or multivitamins
Calcium supplements, iron supplements or multivitamins can stop Tivicay being absorbed into your body and make it less effective. Do not take a calcium supplement, iron supplement or multivitamin during the 6 hours before you take Tivicay, or for at least 2 hours after you take it. Talk to your doctor for further advice on taking calcium supplements, iron supplements or multivitamins with Tivicay.

How long to use it

Take Tivicay for as long as your doctor recommends. Don't stop unless your doctor advises you to. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you forget to use it

Don't take a double dose to make up for a missed dose. If you miss a dose, take it as soon as you remember. But if your next dose is due within 4 hours, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before.

If you use too much (overdose)

If you accidentally take a larger dose of Tivicay, contact your doctor or pharmacist for advice. If possible, show them the Tivicay tablet.

While you are using it

Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

Things you must not do

Tivicay can make you dizzy and have other side effects that make you less alert. Do not drive or operate machinery unless you are sure you're not affected.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Things to be careful of

Look out for important symptoms
Some people taking medicines for HIV infection develop other conditions, which can be serious. These include:

- symptoms of infections and inflammation
- joint pain, stiffness and bone problems

You need to know about important signs and symptoms to look out for while you're taking Tivicay.

Protect other people

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

Side Effects

Like all medicines, Tivicay can cause side effects, although not everybody gets them.

When you're being treated for HIV, it can be hard to tell whether a symptom is a side effect of Tivicay or other medicines you are taking, or an effect of the HIV disease itself. So it is very important to talk to your doctor about any changes in your health.

Allergic reactions

These are uncommon in people taking Tivicay. Signs include:

- skin rash
- a high temperature (*fever*)
- lack of energy (*fatigue*)
- swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in breathing
- muscle or joint aches.

See a doctor straight away. Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking Tivicay.

Very common side effects (may affect more than 1 in 10 people):

- headache
- diarrhea
- feeling sick (*nausea*)

Common side effects (may affect up to 1 in 10 people):

- rash
- itching (*pruritus*)
- being sick (*vomiting*)
- stomach pain (*abdominal pain*)
- upper abdominal pain
- stomach (*abdominal*) discomfort
- insomnia
- dizziness
- abnormal dreams
- depression (feelings of deep sadness and unworthiness)
- lack of energy (*fatigue*)
- wind (*flatulence*)
- increase in the level of liver enzymes

- increase in the level of enzymes produced in the muscles (*creatin phosphokinase*)

Uncommon side effects (may affect up to 1 in 100 people):

- inflammation of the liver (*hepatitis*)
- suicidal thoughts and behaviours (particularly in patients who have had depression or mental health problems before)

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

Other possible side effects

People taking combination therapy for HIV may get other side effects.

Symptoms of infection and inflammation

People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections (*opportunistic infections*). Such infections may have been "silent" and not detected by the weak immune system before treatment was started. After starting treatment, the immune system becomes stronger, and may attack the infections, which can cause symptoms of infection or inflammation. Symptoms usually include fever, plus some of the following:

- headache
- stomach ache
- difficulty breathing

In rare cases, as the immune system becomes stronger, it can also attack healthy body tissue (*autoimmune disorders*). The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV

infection. Symptoms may include:

- palpitations (rapid or irregular heartbeat) or tremor
- hyperactivity (excessive restlessness and movement)
- weakness beginning in the hands and feet and moving up towards the trunk of the body.

If you get any symptoms of infection and inflammation or if you notice any of the symptoms above, tell your doctor immediately. Don't take other medicines for the infection without your doctor's advice.

Joint pain, stiffness and bone problems

Some people taking combination therapy for HIV develop a condition called *osteonecrosis*. With this condition, parts of the bone tissue die because of reduced blood supply to the bone. People may be more likely to get this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight.

Signs of osteonecrosis include:

- stiffness in the joints
- aches and pains in the joints (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms, tell your doctor.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.
Ask your doctor or pharmacist if you do not understand anything in this list.

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Tivicay

Storage

- Keep this medicine out of the sight and reach of children.
- Store in the original package container in order to protect from moisture.
- Do not use this medicine after the expiry date shown on the pack.
- Do not store above 30°C

Disposal

Do not throw away any medicines via wastewater. Ask your pharmacist how to dispose of medicines no longer required. This will help protect the environment.

Product Description

What it looks like

Tivicay tablets are yellow, round, biconvex tablets debossed with 'SV 572' on one side and '50' on the other side.

Ingredients

- Active ingredient
Dolutegravir

- Inactive ingredients:
Tablet core:
Mannitol (E421)
Microcrystalline cellulose
Povidone K29/32
Sodium starch glycolate
Sodium stearyl fumarate

Tablet coating:
Polyvinyl alcohol-partially hydrolyzed
Titanium dioxide (E171)
Macrogol
Talc
Iron oxide yellow (E172)

MAL number

MAL14055050ARZ

Manufacturer

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Product Registration Holder

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