

Handbook for Tivicay[®]

Guidance of the medication

 Tivicay[®]



Hospital:

Planning: ViiV Healthcare K.K., 1-8-1 Akasaka, Minato-ku, Tokyo, Japan

TVXT0402-P1802N
TV-C-0003 (V02)
Issued in February 2018(MK)
(Reprint in February 2020)

ViiV Healthcare K.K.

 SHIONOGI & CO., LTD.

Introduction

This **Handbook for Tivicay®** will tell you, especially as a first-time user of Tivicay®, about what Tivicay® is, how it should be taken, points that you need to know regarding Tivicay®, and other relevant information. If you have any questions regarding Tivicay® or your treatment, talk to your doctor, pharmacist, nurses or other healthcare providers.

Also, if you notice a change in your health or any other symptoms that cause concern on taking Tivicay®, you should consult your healthcare providers rather than depending on your own judgment to stop taking Tivicay® or reduce your dose.

Even if you feel that your concern is trivial, you should not hesitate to consult your healthcare providers. Your healthcare providers are ready to help you at all times.



What Tivicay[®] is and what it does

Product name

Tivicay[®] 50 mg tablet

Generic name (name of active ingredient)

Dolutegravir sodium

Type of medicine

Tivicay[®] belongs to a group of medicines called integrase inhibitors (INIs). It needs to be taken together with other medicines for treating HIV infection.

What Tivicay[®] looks like

Tivicay[®] tablets are yellow tablets (with a diameter of approx. 9.1 mm and a thickness of approx. 4.7 mm) marked with 'SV 572' on one side and '50' on the other side.



(actual size)

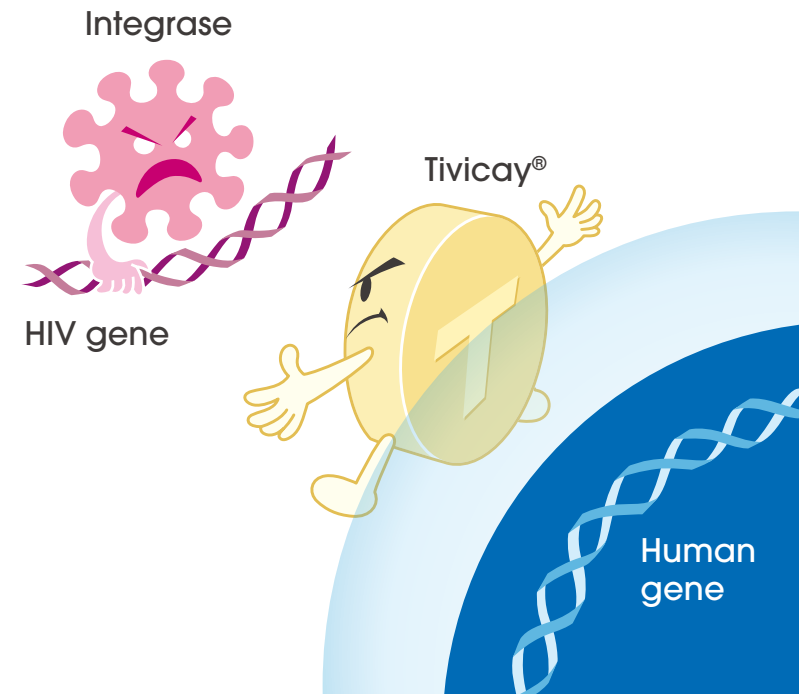
How to store Tivicay[®]

Keep this medicine out of the reach of children and away from direct sunlight at a temperature of less than 30°C.

What Tivicay[®] does

Tivicay[®] is used to treat HIV infection. It reduces the amount of HIV in your body by suppressing viral replication, and helps to maintain your immunological capacity. Tivicay[®] suppresses HIV by inhibiting integrase* that inserts HIV genes into human genes.

* An enzyme required to insert HIV genes into human genes



How to take Tivicay®

Dose and frequency

Your doctor decides the correct dose and frequency of Tivicay® for you according to your symptoms and other factors. Swallow the tablet with a cup of cold or warm water.

The usual dose and frequency for an adult is shown below.

Always use Tivicay® with other medicines for treating HIV infection.

	Dose	Frequency
People taking medicine for treating HIV infection for the first time / people who have taken medicines other than integrase inhibitors for treating HIV infection (including adolescents aged 12 or older and weighting at least 40 kg)	One tablet	Once a day
People who are resistant to integrase inhibitors	One tablet	Twice a day

What to do if you forget to take Tivicay®

Take a single dose when you remember, but if your next dose is due shortly, skip the dose you missed and take the next one at the usual time.

Do not take a double dose under any circumstances.

What to do if you take more Tivicay® than you should

Contact your healthcare providers when you remember.



Taking Tivicay[®] with other medicines or with food

Food

Tivicay[®] may be taken with or without meal. You do not need to worry particularly about what you eat, but you should consider your health and eat a balanced diet.

Other medicines

If you are taking other medicines (including herbal medicines) on a regular basis, or want to take another medicine for a cold or some other reason, consult your healthcare providers first. Do so not only for medicines prescribed by a doctor, but also for over-the-counter medicines bought in a pharmacy.

Health foods and supplements

Tell your healthcare providers about any health foods or supplements that you use. If you are taking Tivicay[®], you should also consult your healthcare providers before starting to take a health food or supplement, or before giving up the use of a health food or supplement.

Information that you should supply to your healthcare providers

- Always tell your healthcare providers if you have ever suffered a skin rash, fever or other allergic reaction to medicine (including Tivicay[®]).
- Always tell your healthcare providers if you are pregnant, breast feeding or planning to have a baby.
- Always tell your healthcare providers if you have any other health problems—particularly allergies, liver disease (history of hepatitis B or C), heart disease, or kidney disease.
- Always tell your healthcare providers about any medicines, health foods or supplements that you use on a regular basis.



Side effects

Tivicay® may cause side effects in some people. If you notice any changes in your health or feel different from usual, contact your healthcare providers immediately.

Common side effects include **feeling sick (nausea), diarrhea and headache.**

Other side effects may also occur, so you should contact your healthcare providers if you notice any changes in your health. Since some side effects (e.g. abnormal laboratory test results) may have no obvious symptoms, you should get regular health checkups.

Symptoms that you should pay particular attention to

Drug-induced hypersensitivity (skin rash, systemic symptoms) may occur after taking Tivicay®. Stop taking Tivicay® and contact your healthcare providers immediately if you experience any of the following symptoms: **skin rash, fever, chill, lightheadedness, excessive sweating, fainting, inability to think clearly, breathing problems, itchiness, numbness, impaired judgment.**



Your dose

Once your dose has been decided, write details in the space below in case you forget.

Taking Tivicay® with other medicines

Tivicay® and

and

Schedule

Time	Medicine	Dose
:		
:		
:		
:		
:		
:		

Dosing Check Sheet

* Mark any symptoms that occur with a ○.

Date	Dosing check (Mark with a ○ for a correctly taken dose, and with a x for a missed or incorrectly taken dose.)			Skin rash	Fever	Nausea, vomiting, diarrhea	Headache or dizziness	Tired, listless	Note any other changes in your condition or concerns that you have.
	Tivicay®	Other medicine A	Other medicine B						
Example: ○ / ○	○	○	○			○		○	
/									
/									
/									
/									
/									
/									
/									
/									
/									
/									
/									
/									
/									
/									
/									
/									
/									
/									
/									
/									

Try to fill in the above check sheet every day until you get used to taking Tivicay®. Also, side effects occur more commonly during the period after you first start taking Tivicay®. You should note any changes in your condition and show your check sheet to your healthcare providers at your next examination.

If you suffer any symptoms that you think are caused by hypersensitivity to Tivicay®, contact your healthcare providers immediately rather than waiting for your next examination. If you suffer from any other side effects and are having trouble coping, do not hesitate to contact your healthcare providers.

