

STARTING ON TIVICAY

**INFORMATION
FOR USERS**

FOREWORD

You have received this folder because you will be taking Tivicay with other medication to inhibit your HIV. This folder and the package leaflet contain important information that you will need when starting your therapy.

The decision to take HIV inhibitors is an important one. HIV inhibitors can keep the virus under control in the long term, but this does require something from you: it is very important that you take your medication on time every day. Even if you don't feel ill at all. This is called therapy compliance. If you skip taking your pills or take them too late, your HIV inhibitors may no longer work one day because the virus has become resistant. If you are very therapy compliant, you will have the greatest chance of your HIV inhibitors continuing to work for a long time. This folder is intended to help you with this.

Your HIV doctor and HIV consultant will advise and assist you on all the topics addressed in this folder. If there is something you do not understand, you are unsure of what to do or you have difficulty with the treatment, you can ask the doctor and consultant for information, advice or support.

 **FOR MORE INFORMATION ABOUT HIV:**
www.livlife.com

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WHAT IS TIVICAY?

This medication contains the active substance dolutegravir which is used to treat an infection with human immunodeficiency virus (HIV):

Currently there are several groups of HIV medication. Each group suppresses the virus in a different manner. Dolutegravir is part of the group of integrase inhibitors (INIs) and is used in combination with one or more drugs from another group.

This medication is used to treat HIV in adults, adolescents and children over 6 years old.

WHAT DOES TIVICAY LOOK LIKE?

The tablets are yellow and round and contain: 50 mg dolutegravir for use in adults, adolescents and children weighing at least 40 kg. Lower doses are available for younger children.

Tablets are marked with the code 'SV 572' on one side and '50' on the other side.



Image not to size.

PURPOSE OF THE TREATMENT

The purpose of the treatment is to decrease the amount of HIV virus in your body. Treatment is successful if the amount of the virus (viral load) in your body is so low that it is barely measurable in the blood (**also called undetectable**). Hence, this medication does not cure the HIV infection.

If the viral load in the blood is low, this helps maintain the number of CD4 cells in your blood. CD4 cells are a type of white blood cells that are important because they help your body fight infections.

Your doctor will draw blood from you at regular intervals to see if the treatment is successful.

Large studies have been conducted amongst couples where one partner was living without HIV, and the other with HIV, but having suppressed viral load (<200 c/ml). After condomless sex without PrEP between the partners there was no transmission of the virus. This is referred to as U=U, undetectable = untransmittable.

WHEN SHOULD I BE EXTRA CAREFUL?

You must not use this medication if you use the medicine (dal)fampridine, or if you are allergic (hypersensitive) to dolutegravir or one of the ingredients in this tablet. You can find a complete overview in the package leaflet.

HOW SHOULD I TAKE THE TABLETS?

The recommended dose is one tablet once daily. Your doctor may have prescribed you one 50 mg tablet twice a day, for example if you are taking some other medicines, or if you have a virus that is resistant to medicines similar to Tivicay,

Take the tablet with some water. The tablet can be taken with or without food. When Tivicay is taken twice a day, your doctor or HIV consultant may advise you to take with food.

If you use antacids, to treat indigestion and heartburn, or supplements (calcium supplement, iron supplement or multivitamin), do not take these during the 6 hours before you take Tivicay, or for at least 2 hours after you take it.

FINDING A GOOD TIME TO TAKE YOUR MEDICATION

Usually you will choose the time to take Tivicay yourself, but your HIV consultant can advise you on what is the best time for your situation. You should choose a schedule that makes it as easy as possible to take your pills at the same time every day based on your daily routine.

You can use a pillbox. Then you only need to sort your pills once per week and you can easily check whether you've taken your pills already. There are also key chain pillboxes where you can place a small number of pills so that you always have a pill at hand.

Some people use an alarm (e.g. on a mobile phone) or an app to help them remember that it's time to take their pills.

TIVICAY AND OTHER MEDICATION

It is prudent to tell your doctor which other medication you are using or will be using in the near future. This also applies to over-the-counter medication and to alternative remedies.

Do not use Tivicay with the medicine fampridine (also called dalfampridine), used in multiple sclerosis.

Some medication can affect how Tivicay works or increase your chances of getting side effects.

Tivicay can also affect the way other medication work.

Tell your doctor or pharmacist if you are using one of the drugs on the list below:

- / Metformin (diabetes treatment)
- / Antacids with magnesium/aluminium (for heartburn)
- / Calcium supplements, iron supplements and multivitamins
- / Other medication for treating an HIV infection: etravirine, efavirenz, fosamprenavir/ritonavir, nevirapine or tipranavir/ritonavir
- / Rifampicin (treatment of tuberculosis or other bacterial infections)
- / Phenytoin and phenobarbital (treatment of epilepsy)
- / Oxcarbazepine and carbamazepine (for treating epilepsy or bipolar disorder)
- / St. John's wort (a herbal remedy for treating depression)

The package leaflet contains a more comprehensive explanation. Discuss this with your doctor; the dosage can be adjusted, if necessary.

TRAVELLING TO ANOTHER TIME ZONE

Talk to your HIV consultant about how to take your medication when you travel to a different time zone.

Ask for advice on how you can best take your medication with you when travelling. If you will be travelling for a longer period of time, it is important to have additional medication with you so that you don't run out, for example if there is a delay.

NEVER STOP TAKING YOUR MEDICATION WITHOUT PRIOR CONSULTATION

Do not stop taking Tivicay without consulting your doctor!

By taking your HIV medication on time every day, you increase your chances of long-term successful treatment against HIV. If you stop without consultation or guidance, you run the risk of viral resistance and of a less successful treatment in the future because some medication will no longer work (well).

FORGOT TO TAKE YOUR MEDICATION?

If you forget to take a dose, you should take it as soon as you remember. But if you are set to take your next dose within the next 4 hours, you should skip the forgotten dose and take your next dose at the usual time. Then continue your treatment as usual.

Do not take a double dose to make up for the forgotten dose. If you have any doubts, contact your doctor or HIV consultant.

DID YOU TAKE MORE THAN 1 TABLET OF TIVICAY

If you've taken too many tablets, contact your doctor or pharmacist for advice. Show them the packaging, if possible.

ADVICE IF YOU THROW UP

Advice on taking HIV inhibitors after throwing up. If you took the medication on an empty stomach:

- / Within 1 hour* after taking the medication: take another dose of the medication
- / More than 1 hour* after taking the medication: do not take another dose
- / If there are remnants of the medication in the vomit: always take another dose of the medication

* Or 3 hours if you took the medication with food.

Source: The above advice on taking HIV medication after vomiting is taken from chapter 9.1 of the NVHB (Dutch Association of HIV Practitioners) guideline, consulted in April 2020.

POSSIBLE SIDE EFFECTS

All medication can cause side effects, including Tivicay. Your chance of experiencing side effects cannot be predicted. You can find a complete overview of the possible side effects in the package leaflet. If you believe you are experiencing a side effect, contact your doctor or HIV consultant.

Very common side effects of Tivicay – occurring in more than one in ten users – are: headache, diarrhoea and nausea.

CONTACT YOUR DOCTOR IMMEDIATELY IF YOU:

- / Experience an allergic reaction: high temperature, skin rash, lack of energy, swelling (sometimes of face or mouth with difficulty in breathing) or muscle or joint aches.
- / Experience symptoms of infection or inflammation (usually fever and one of the following symptoms: headache, stomach ache or difficulty breathing).
- / Have heart palpitations, trembling, excessive activity or weakness starting in the hands and feet that moves upwards towards the torso.

PREGNANCY AND BREASTFEEDING

If you are able to become pregnant while using Tivicay, you must use reliable means of preventing pregnancy.

Contact your doctor immediately if you become pregnant or want to become pregnant. Your doctor will then investigate what the best treatment is for you.

Do not stop using HIV medication without first consulting with your doctor, as this could be harmful to you and your unborn child.

According to Dutch HIV guidelines, it is recommended to feed your baby with bottle feeding (formula feeding), since this will add no risk of passing the virus to your baby via feeding. If you still choose to breastfeed, kindly contact your doctor or HIV consultant first.

Source: Advise was taken from NVHB guideline, Chapter 7.8, referring to national protocol PHON. Accessed April 2020.

WHEN SHOULD I ASK FOR A NEW PRESCRIPTION??

Sometimes the pharmacy needs a little time to dispense the medication. The following tips can help make sure that you always have sufficient quantities of the medication at home.

- / Ask your doctor for a new prescription on time.
- / Ask for a prescription for a period of time that is longer than up to the exact day of your next appointment.
- / Remember any vacations or imminent travel plans.
- / Take your prescription to the pharmacy on time.

STORAGE AND RETURN

Store this medication outside of the sight and reach of children and pets. There are no special instructions for storing this medication.

Do not use medication after the expiry date, which can be found on the box and the bottle after the letters 'EXP'.

Do not flush medication down the drain or the toilet and do not throw them away in the waste bin. Return any medication you no longer need to the pharmacy or ask the pharmacist what you should do with them. They will then be destroyed in a responsible manner and will not end up in the environment.

Colophon

The contents of this folder were compiled with the greatest possible care. No rights can be derived from any errors that were made despite the care taken.

We also recommend that you always read the package leaflet before using Tivicay and other medication. If you lose a package leaflet, ask your pharmacist for advice. You can also find the package leaflet on the Internet at: ema.europa.eu (search for Tivicay and filter for documents) or request it from ViiV Healthcare B.V.

Tivicay is the property of or licensed to the ViiV Healthcare group of companies.

**FOR THE 37 MILLION UNTIL IT IS ZERO.
WE ARE HERE UNTIL HIV AND AIDS AREN'T.**

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