

STARTING ON JULUCA

**INFORMATION
FOR USERS**

FOREWORD

You have received this brochure because you will be taking Juluca to inhibit your HIV, after your virus has been virally suppressed by your previous treatment. This folder and the package leaflet contain important information that you will need when starting this 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 JULUCA?

This medication contains two active substances that are used to treat an infection with human immunodeficiency virus (HIV):

- / dolutegravir
- / rilpivirine

Currently there are several groups of HIV medication. Each group suppresses the virus in a different manner. Dolutegravir is part of a group called integrase inhibitors (INIs) and rilpivirine belongs to a group called non-nucleoside analogue reverse-transcriptase inhibitors (NNRTIs).

This medication is used to treat HIV in adults.

WHAT DOES JULUCA LOOK LIKE?

The tablets are pink and oval and contain: 50 mg dolutegravir and 25 mg rilpivirine.

Tablets are marked with the code 'SV J3T'.



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 are allergic (hypersensitive) to one of the ingredients in this tablet. Juluca tablets contain lactose. You can find a complete overview in the package leaflet.

Do not take Juluca if you are taking any of the following medicines: (dal)fampridine, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampicin, rifapentine, omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole, dexamethasone (except single dose) and products that contain St John's wort.

Also discuss with your doctor if you have or have had problems with your liver, including hepatitis B and/or C.

HOW SHOULD I TAKE THE TABLETS?

The recommended dose is one tablet once daily.

Take the tablet with a meal. A meal is important to get the right levels of medicine in your body. A protein-rich nutritional drink alone does not replace a meal.

If you use supplements (calcium supplement, iron supplement or multivitamins), these can be taken together with Juluca and a meal. If you can't take these supplements at the same time, then do not take these during the 6 hours before you take Juluca, or for at least 4 hours after you take it.

Medicines to treat indigestion or heartburn:

- / antacids: not 6 hours before or at least 4 hours after Juluca
- / H2-receptorantagonists: not during the 12 hours before or at least 4 hours after you take Juluca

FINDING A GOOD TIME TO TAKE YOUR MEDICATION

Usually you will choose the time to take Juluca 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.

JULUCA 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 take Juluca if you are taking any of the following medicines:

- / (dal)fampridine (used in multiple sclerosis)
- / carbamazepine, oxcarbazepine, phenytoin or phenobarbital (to treat epilepsy and prevention of fits)
- / rifampicin, rifapentine (treatment of tuberculosis (TB) or other bacterial infections)
- / omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole (treatment of e.g. heartburn or acid reflux disease)
- / dexamethasone (treatment inflammation and allergic reactions), except as a single dose treatment
- / products that contain St John's wort (herbal product used for depression)

Some medication can affect how Juluca works or increase your chances of getting side effects. Tell your doctor or pharmacist if you are using one of the drugs on the list below:

- / metformin (diabetes treatment)
- / antacids (to treat indigestion or heartburn)
- / multivitamins, calcium or iron supplements
- / cimetidine, famotidine, nizatidine, ranitidine (H2-receptor-antagonists e.g. to treat heartburn and acid reflux)
- / other medication to treat HIV infection
- / rifabutin (treatment of TB or other bacterial infections)
- / artemether/lumefantrine (prevention of malaria)
- / clarithromycin and erythromycin (to treat bacterial infections)
- / methadone (treatment of opioid dependence)
- / dabigatran etexilate (to prevent blood clots)

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

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 Juluca 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 JULUCA

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 Juluca. 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 Juluca – occurring in more than one in ten users – are: headache, dizziness, diarrhoea, feeling sick (nausea) and difficulty in sleeping (insomnia).

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 plus 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 Juluca, 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.

▼ This medication is subject to additional monitoring. Due to this, new safety information can be quickly determined. You can contribute to this by reporting all side effects you may experience.

We also recommend that you always read the package leaflet before using Juluca 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 Juluca and filter for documents) or request it from ViiV Healthcare B.V.

Juluca 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.**

VIIV HEALTHCARE B.V.

Van Asch van Wijkstraat 55H, 3811 LP Amersfoort

T +31 (0)33 208 11 99

W www.viivhealthcare.com