

STARTING ON TRIUMEQ

**INFORMATION
FOR USERS**

FOREWORD

You have received this folder because you will be taking Triumeq 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 TRIUMEQ?

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

- / dolutegravir
- / lamivudine
- / abacavir

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 lamivudine and abacavir belong to a group called nucleoside analogue reverse-transcriptase inhibitors (NRTIs).

This medication is used to treat HIV in adults and adolescents 12 years and older who weigh at least 40 kg.

Before you are prescribed Triumeq your doctor will arrange a test to find out whether you carry the HLA-B*5701 gene. People who carry this gene should not use Triumeq because they are at a high risk of developing a serious hypersensitivity (allergic) reaction.

WHAT DOES TRIUMEQ LOOK LIKE?

The tablets are purple and oval and contain: 50 mg dolutegravir, 300 mg lamivudine, and 600 mg abacavir.



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 dolutegravir, lamivudine or one of the substances in this medication. You can find a complete overview in the package leaflet. You should never take abacavir-containing products again if you have a hypersensitivity reaction. Do not take Triumeq if you are taking (dal)fampridine.

You should consult your doctor before starting on Triumeq if you:

- / have a moderately serious or serious liver disease;
- / have ever had a liver disease, such as hepatitis B or C;
- / have a kidney problem.

HOW SHOULD I TAKE THE TABLETS?

The recommended dose is one tablet once daily. Take the tablet with some water. The tablet can be taken with or without food.

If you use supplements or multivitamins containing calcium, iron or magnesium, or if you take antacids, then do not take these during the 6 hours before you take Triumeq, or for at least 2 hours after you take it.

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

If you forget to take a dose, you should take it as soon as you remember. But not if you are set to take your next dose within the next 4 hours. Do not take a double dose to make up for the forgotten dose.

FINDING A GOOD TIME TO TAKE YOUR MEDICATION

Usually you will choose the time to take Triumeq 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.

TRIUMEQ 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 Triumeq if you are taking fampridine (also known as dalfampridine), used in multiple sclerosis.

Some medication can affect Triumeq's action or increase your chances of getting side effects. Triumeq 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)
- / antacid with magnesium/aluminium (for heartburn)
- / supplement or multi-vitamins containing calcium, iron or magnesium
- / other medication for treating an HIV infection
- / in the event of regular use: liquid medication with sorbitol, xylitol or mannitol, for example
- / cladribine (treatment of leukaemia or multiple sclerosis)
- / rifampicin (treatment of tuberculosis or other bacterial infections)
- / trimethoprim/sulfamethoxazole (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)
- / methadone (as a heroin substitute)

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

POSSIBLE SIDE EFFECTS

All medication can cause side effects, including Triumeq. 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 Triumeq – occurring in more than one in ten users – are: headache, diarrhoea, nausea, difficulty in sleeping and lack of energy.

Triumeq contains abacavir that can cause a hypersensitivity reaction (a serious allergic reaction), especially in people who carry a particular type of gene called HLA-B*5701.

Even people who don't have this gene may still develop a hypersensitivity reaction, with a chance of about 3 to 4%. Hypersensitivity reactions can start at any time during treatment but are more likely during the first 6 weeks of treatment.

You can find more information about hypersensitivity on the next page, or on the website: abacavirhsr.viivhealthcare.com/en-gb

NEVER STOP TAKING YOUR MEDICATION WITHOUT PRIOR CONSULTATION

Do not stop taking Triumeq 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).

CONTACT YOUR DOCTOR IMMEDIATELY IF YOU:

- / 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.

Some patients taking abacavir containing medication may develop a hypersensitivity reaction (serious allergic reaction). This reaction can be life-threatening if treatment with Triumeq is continued. CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking Triumeq if:

1. You get skin rash OR
2. You get symptoms from at least TWO of the following groups:
 - / fever
 - / shortness of breath, sore throat or cough
 - / nausea or vomiting or diarrhoea or abdominal pain
 - / severe tiredness or achiness or generally feeling ill

You can find more information about on the website: abacavirhsr.viivhealthcare.com/en-gb.

Talk to your doctor before you start again. Your doctor will check whether your symptoms were related to a hypersensitivity reaction.

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
- / More than 1 hour* after the dose: 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.

PREGNANCY AND BREASTFEEDING

If you are able to become pregnant while using Triumeq, 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.

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.

STORAGE AND RETURN

Store in the original package in order to protect from moisture. Do not remove the desiccant. Store this medication outside of the sight and reach of children and pets.

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

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

VIIV HEALTHCARE B.V.

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