

For patients taking Triumeq

Drug treatment guide



Hospital/Clinic name

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

TRMQ00099-P1811N (V3.0)
TRI-C-0001 (V02)
改訂年月2018年11月

ViiV Healthcare K.K.  SHIONOGI & CO., LTD.

Introduction

This booklet is designed for patients taking Triumeq combination tablets to explain about the drug, how to take it, and various points to remember when taking this medication.

With HIV infection, it is important to diagnose the infection at an early stage, begin treatment before the HIV virus reduces the functioning of the immune system, and suppress the amount of HIV in the body as far as possible.

Please consult with your doctor or other healthcare staff, such as a pharmacist or nurse, if there is anything you do not understand about this medication or you have any uncertainties.

You should not stop taking Triumeq or reduce the dose taken, even if you experience any changes in your health when you start the medication or have some other concerns, without consulting your doctor or other healthcare staff.



Contents

1. What is Triumeq?	3
2. How do I take Triumeq?	4
3. How does Triumeq work?	5
4. Precautions when taking Triumeq	7
• Hypersensitivity reaction — precautions	8
5. Side effects	9
6. Using Triumeq in combination with other drugs	11
7. Important points to remember when taking Triumeq	13
8. If you forget to take Triumeq	14



1. What is Triumeq?

● Tablet shape and color

Triumeq is a purple tablet.



Triumeq tablet (actual size)



Bottle

Active ingredients :

Triumeq contains a combination of dolutegravir sodium, abacavir sulfate, and lamivudine.

● Storage

Avoid direct sunlight and store in a dry place at room temperature (1–30°C). Keep out of the reach of children.

● What is Triumeq prescribed for?

Triumeq is a drug taken by patients with **HIV infection**.

HIV : Human immunodeficiency virus



2. How do I take Triumeq?*

● You should take one Triumeq tablet once a day

Triumeq tablet



(actual size)

1 tablet



once a day

You should take one Triumeq tablet once a day with or without food.

Triumeq should be taken at roughly the same time of day each day, to ensure the doses are evenly spaced out.

★ It may be helpful to take the tablet at the same time as part of your daily routine, for example when you get up or before going to bed.

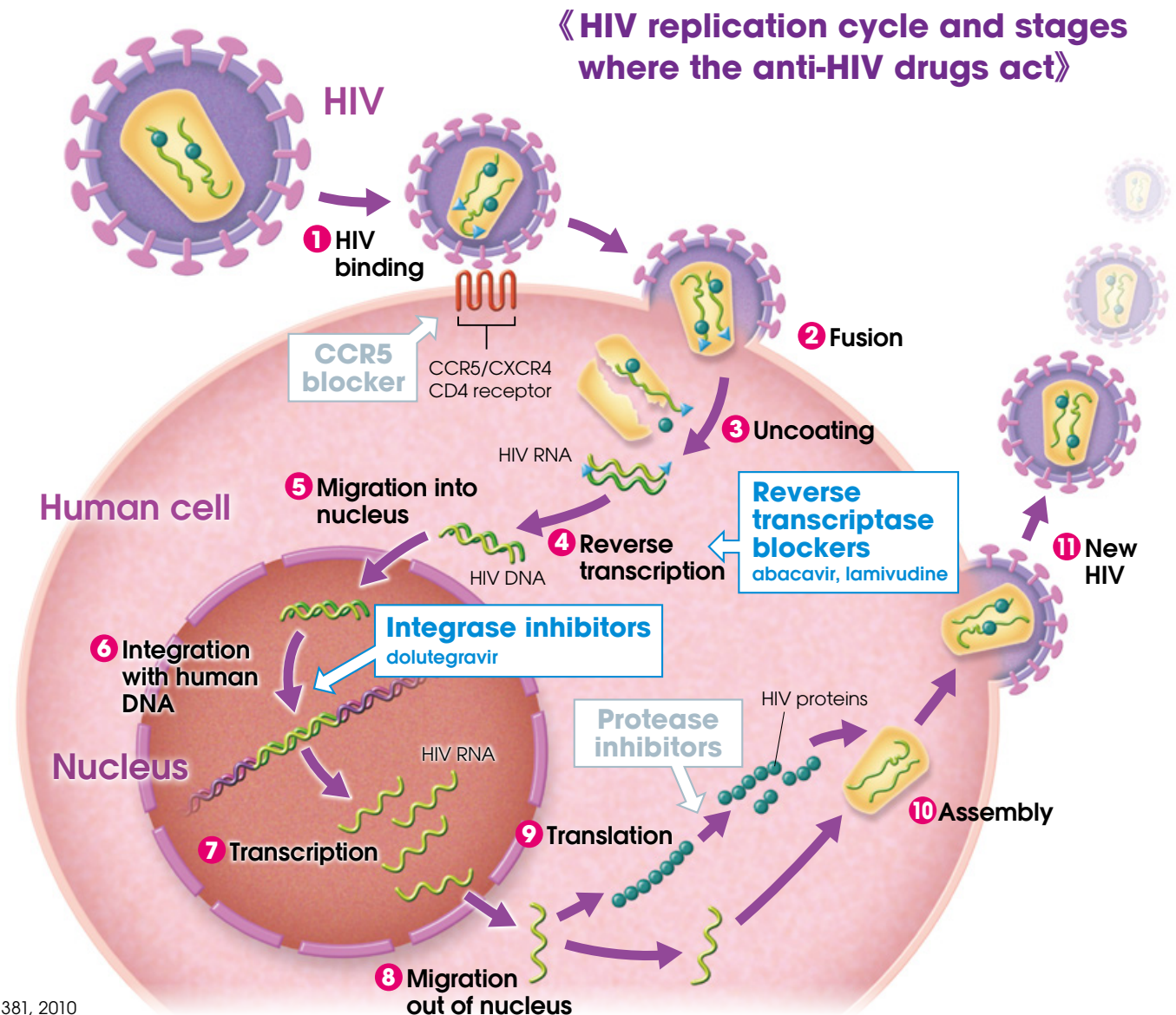


* Follow your doctor's instructions when taking Triumeq

3. How does Triumeq work?

● Triumeq treats HIV

Triumeq contains three different types of anti-HIV drugs (dolutegravir, abacavir, lamivudine) that have different mechanisms of action. Triumeq suppresses the replication of HIV in the body and prevents the reduction in the immune system caused by the HIV virus.



Reference :
Diagram based on Yoshio Koyanagi, et al. Nippon Rinsho 68 (3) : 378-381, 2010

4. Precautions when taking Triumeq

● People who must not take Triumeq (contraindications)

- 1) Patients with a history of **hypersensitivity** to the active ingredients in Triumeq (dolutegravir, abacavir, lamivudine) must not take Triumeq.
- 2) Patients with severe liver dysfunction must not take Triumeq.

● People who must be cautious about taking Triumeq

- 1) Patients who may develop pancreatitis (patients with a history of pancreatitis, patients receiving combination therapy with a drug known to cause pancreatitis)
- 2) Patients with mild or moderate liver dysfunction
- 3) Patients infected with the hepatitis B or C virus
- 4) Elderly patients
- 5) Patients who are or could be pregnant



☆If any of the above apply to you, please consult with your doctor or pharmacist.

Hypersensitivity reaction — precautions

Abacavir is one of the active ingredients in Triumeq.

Hypersensitivity reactions (allergic reactions) are known to occur in around 5% of patients treated with drugs containing abacavir. Serious, life-threatening reactions can occur if patients who are hypersensitive to abacavir continue to receive treatment with drugs containing abacavir.

The following symptoms could be a sign of a hypersensitivity reaction:

- ① **Rash**
- ② Symptoms from two or more of the following groups

- **Fever**
- **Nausea, vomiting, abdominal pain, diarrhea**
- **Severe tiredness, generally feeling unwell, muscle or joint pain, headache**
- **Shortness of breath, sore throat, cough**



Contact your doctor immediately if you experience these symptoms to discuss whether you should stop taking Triumeq. If your doctor indicates you should stop taking your medication because of these symptoms, **you must not take any medicine containing abacavir (Triumeq, Epzicom, Ziagen) ever again.**

If you have experienced a hypersensitivity reaction once and subsequently take a drug containing abacavir, a more severe hypersensitivity reaction can occur within a few hours, resulting in life-threatening hypotension that can be fatal.

If your Triumeq treatment was suspended or discontinued for a reason other than a hypersensitivity reaction, do not start taking Triumeq again, even after a few days, without consulting your doctor. If your doctor tells you to start taking Triumeq again, only do so if you are in a position to make immediate contact with your doctor.

☆An alert card on hypersensitivity is available for patients being treated with Ziagen Tablets 300 mg, Epzicom Combination Tablets, Triumeq Combination Tablets

5. Side effects

Serious side effects can sometimes occur in some people taking medication. Please contact your doctor quickly if you feel different from normal when taking Triumeq.

● Contact your doctor quickly if you experience the following symptoms

Rash, fever, fatigue, stomach symptoms (nausea, vomiting, diarrhea, etc.), breathing difficulties, sore throat, cough, etc.

These could be signs of hypersensitivity/allergic reaction to the medicine.
You must stop taking Triumeq immediately.

Skin symptoms (blisters, reddening, itching, soreness, bloodshot eyes, sore lips, fever, etc.)

These could be signs of toxic epidermal necrolysis (TEN) or mucocutaneous ocular syndrome (Stevens-Johnson syndrome).
You must stop taking Triumeq immediately.

Severe stomach pain, nausea, vomiting, abnormal pancreas test results

These could be signs of pancreatitis.

Sluggishness, loss of appetite, weight loss, stomach and respiratory symptoms

These could be signs of lactic acidosis*.

*When lactic acid rises to excessive levels in the blood, increasing acidity. Onset is sudden.

Numbness or pain in the hands or feet, confusion, convulsions, heart problems, etc.

In some people, the following symptoms may occur

- Disturbed sleep (insomnia, abnormal drowsiness, etc.)
- Headache, dizziness
- Feeling of depression
- Hair loss



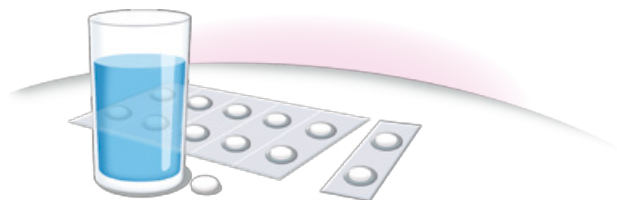
6. Using Triumeq in combination with other drugs

Please consult with your doctor or pharmacist if you are taking other drugs at the same time.

● Interactions of Triumeq with other drugs

Taking other drugs or supplements (iron supplements, agents containing calcium) and health foods (products containing St. John's wort) etc. when you are also taking Triumeq can make the medication less effective or cause resistance. Therefore, you should tell your doctor or pharmacist about all the drugs, supplements, and other products, including over-the-counter medicines bought at pharmacies or drugstores, that you are taking and check whether you can take them with Triumeq.

In some cases, you may need to stop taking other medications, reduce your dose, or switch to a different medication.



● Precautions for combination use of Triumeq with other anti-HIV drugs

Triumeq contains three types of anti-HIV drug (dolutegravir, abacavir, and lamivudine), so you should take care that you are not also taking other drugs with the same or similar mechanism of action. It is also important to note that some anti-HIV drugs can affect the concentration of other drugs in the blood.* Please take care if you take any of the main anti-HIV drugs listed below in combination with Triumeq. (Drug names shown in bold contain the same active ingredient as Triumeq)

*However, Tivicay Tablets (dolutegravir) can be administered additionally at 12 hours after a dose of Triumeq®—in this case, take these medicines in accordance with your doctor's instructions.

● HIV integrase inhibitors

Dolutegravir

● Nucleotide reverse transcriptase inhibitors

Abacavir
Lamivudine
Lamivudine + Zidovudine
Lamivudine + Abacavir
Emtricitabine
Emtricitabine + Tenofovir
Emtricitabine + Tenofovir Alafenamide
Other Combination Tablets containing Emtricitabine

● Non-nucleotide acid reverse transcriptase inhibitors

Nevirapine
Efavirenz
Etravirine

● Protease inhibitors

Fosamprenavir
Ritonavir

7. Important points to remember when taking Triumeq

Take medications properly

When treating HIV infection, it is extremely important to carefully follow the instructions on how much drug you take, how many times a day you take it, and how much time you leave between doses. If you do not follow these instructions carefully, you may not have enough drug in your blood, which could result in the development of viruses that are resistant to the drug such that the drug no longer works.

You should not decide on your own to stop taking the drug, even if your lab test results and symptoms improve. Please follow your doctor's instructions and continue taking the prescribed drug(s) in order to maintain the therapeutic effects.



Side effects

Please consult with your doctor quickly if you experience troubling symptoms while taking Triumeq.

If you take too much (overdose)

Consult with your doctor or pharmacist if you feel abnormal.

8. If you forget to take Triumeq

Missed dose

If you forget to take a dose of Triumeq, do not take two doses at one time. Take just one dose as soon as you realize you have forgotten a dose. However, if it is nearly time to take your next tablet, simply skip the missed dose and take your next tablet at the normal time.

☆Before you start taking Triumeq, think about your lifestyle and when is the best time in your daily life to take your tablet. It may also be helpful to get advice in advance from your doctor and other healthcare staff (pharmacists or nurses) on what to do if you forget to take a dose or you experience any side effects.

Helping you to take your medicine

Disruptions to your daily routine, for example when work gets busy or you change jobs or move house, can cause changes in the time you take your pill or the interval between doses. Please consult with your doctor or other healthcare staff (pharmacists or nurses) if you have any difficulties with taking your medicine.

The following websites on HIV infection may also provide helpful information.

- AIDS Clinical Center, National Center for Global Health and Medicine, National Research and Development Corporation
<http://www.acc.go.jp/accmenu.htm>
- AIDS Medical Center, National Hospital Organization Osaka National Hospital
<http://www.onh.go.jp/khac/>
- AIDS Prevention Information Network (API-NET)
<http://api-net.jfap.or.jp/>